

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
BNT162b2 (30 µg)	12-15	C4591001 1006 10061272	Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive 2 vaccinations. Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071409	Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071622	Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071642	Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441359	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571396	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571413	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive at least 1 vaccination. Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661407	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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		C4591001 1091 10911414	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911451	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1139 11391261	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1140 11401346	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421363	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1147 11471327	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521641	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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	16-55	C4591001 1001 10011125	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1003 10031143	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051381	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051411	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1008 10081492	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081529	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111039	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1012 10121001	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1012 10121103	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1012 10121163	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131544	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131670†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131834	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151199	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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		C4591001 1016 10161087	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1016 10161341	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1018 10181025	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1018 10181028	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181054	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1018 10181142	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1018 10181165	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181186	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181266	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.

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		C4591001 1018 10181310	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1018 10181311	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1019 10191166	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1019 10191254	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1024 10241002	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1024 10241004	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241006	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241014	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241023	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241032	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241033	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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		C4591001 1024 10241039	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241040	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241042	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241044	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241046	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241054	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241055	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241061	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241066	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241067	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241071	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241072	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241074	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241078	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241084	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1024 10241085	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241091	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241094	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241100	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241102	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241104	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241108	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1028 10281072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281267	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361050	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361127	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361135	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371078	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1038 10381061	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1042 10421069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1042 10421251	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441001	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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		C4591001 1044 10441015	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441028	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441029	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441031	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441034	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441037	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441045	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441048	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441050	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441052	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441054	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441060	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441063	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441068	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441071	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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		C4591001 1044 10441076	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441079	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441088	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441089	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441272	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1046 10461285	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461348	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521139	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521143	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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		C4591001 1054 10541022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561013	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561097	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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		C4591001 1056 10561146	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561193	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561195	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561271	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561300	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561316	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561317	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561352	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561361	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561402	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561452	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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		C4591001 1056 10561516	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561550	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561569	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561576	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561579	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561643	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571129	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571212	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571279	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571331	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1066 10661198	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661203	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661321	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661332	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661335	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661406	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1068 10681002	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681006	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681011	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681016	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681021	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1068 10681024	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681027	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681034	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681035	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681042	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681046	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681053	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681058	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681060	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681061	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681072	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681073	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681077	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681081	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1071 10711008	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1071 10711095	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711235	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1073 10731038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791004	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791058	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791079	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791135	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791252	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811071	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811105	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1082 10821078	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1083 10831141	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1083 10831152	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1083 10831197	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841118	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841272	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1085 10851245	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1085 10851332	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1087 10871209	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1087 10871336	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1087 10871557	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1087 10871562	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1088 10881045	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1088 10881077	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1089 10891158	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1089 10891182	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891311	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891346	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891351	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901136	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901510	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911005	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1091 10911008	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1091 10911015	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1091 10911039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1091 10911077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911130	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911358	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911387	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921128	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921249	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931055	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951110	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951124	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951141	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951168	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1095 10951173	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951208	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961141	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961197	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1096 10961287	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961288	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961344	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981169†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1098 10981189	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981200	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1101 11011021	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1107 11071018	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1107 11071162	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091234	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091349	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091391	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091406	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091414	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1109 11091417	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091422	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091522	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101154	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101333	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111064	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111105	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121192	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121229	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121270†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1114 11141037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161015	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161143	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161172	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161226	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1117 11171070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1121 11211025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1122 11221026	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1123 11231027	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231144	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231154	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231168	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231208	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231263	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231301	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1123 11231386	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1124 11241049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1124 11241100	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251148	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251159	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251243	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261053	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1127 11271022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281126	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1129 11291061	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291238	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291249	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331122	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331295	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331316	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331341	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331346	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331509	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341153	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341174	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341177	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341228	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351199	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1135 11351389	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351428	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351430	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351523	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361108	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361111	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401301	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411011	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1141 11411014	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1141 11411023	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1141 11411065	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1141 11411096	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411127	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411164	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411166	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411179	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411249	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461010	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1147 11471212	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1149 11491005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491067	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491088	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491209	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521477	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571070	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1157 11571169	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611001	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611002	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations; data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611006	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations; data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611009	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611011	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Randomized but did not meet all eligibility criteria; data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611014	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Randomized but did not meet all eligibility criteria; data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611017	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611019	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611020	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611026	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611032	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611034	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611041	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1162 11621005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621118	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621128	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1162 11621374	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621381	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621391	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621477	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1162 11621524	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621566	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631117	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631121	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631124	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631127	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631136	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631142	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631145	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1167 11671111	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681030	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1169 11691049	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1170 11701023	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701112	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701205	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701300	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701316	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701365	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1170 11701422†	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701435	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701441	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1170 11701450	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701451	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701452	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701457†	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1171 11711042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711151	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711153	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711214	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711219	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711225	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711229	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711236	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1171 11711242	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711249	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771491	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1178 11781061	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1178 11781107	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1194 11941061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1195 11951055	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1195 11951061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971042	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1197 11971045	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051028	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121023	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131012	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1214 12141016	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181045	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1218 12181046	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1218 12181051	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1218 12181055	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1218 12181059	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1219 12191047	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1219 12191054	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1220 12201020	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1220 12201036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201059	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1220 12201063	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); unblinded prior to 7 days post Dose 2.
		C4591001 1221 12211024	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1221 12211079	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1223 12231200	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1223 12231234	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241176	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261114	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261409	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1226 12261797	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262136	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262229	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262255†	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1226 12262262	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262313	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1229 12291204	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301045†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301099	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301113	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301148	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311027	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311125	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311189	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311200	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311409	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311443	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311499	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12311532	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12311641	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12311801	Evaluable efficacy (7 days) Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311825	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311894	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1231 12311911	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12311991	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12312052	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312077	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312284	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12312339	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312361	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312365	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312372	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312375	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312403	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312435	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312451	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312559	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12312577	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313006	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313175	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313207	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313225	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313289	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313357	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313428	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313429	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313449	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
		C4591001 1231 12313456	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313459	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
		C4591001 1231 12313467	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313469	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313479	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313483	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313486	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313487	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313492	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313497	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313498	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313501	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313505	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313506	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
		C4591001 1231 12313508	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313509	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
		C4591001 1231 12313512	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313514	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313515	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313517	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313518	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313519	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313528	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313533	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313534	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313537	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313541	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313542	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313546	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
		C4591001 1231 12313551	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313553	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313554	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
		C4591001 1231 12313556	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313564	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313567	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313592	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313622	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313662	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313709	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313869	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313892	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313967	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314179	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12314205	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314290	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314314	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314385	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314416	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314502	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314525	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314580	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314590	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314700	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314713	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315189	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315204	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315223	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315269	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315308	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315429	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315441	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12315518	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315600	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321033	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321037	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321101	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321175	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321219	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321233	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1232 12321250	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321299	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321305	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321354	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1232 12321361	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321373	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1232 12321382	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1232 12321385	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1232 12321394	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1232 12321395	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1232 12321396	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1232 12321412	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1232 12321419	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1232 12321425	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1235 12351188	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1241 12411132	Evaluable efficacy (7 days) Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411144	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411482	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1241 12411766	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1241 12411993	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412382	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1246 12461025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471054	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471149	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471151	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481025	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481169	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1248 12481175	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511095	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511204	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541142	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541154	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601049	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601126	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1261 12611054	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1265 12651164†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 4444 44441043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441134	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441135	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441273	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441569	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44441572	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 4444 44441818	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 4444 44441951	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 4444 44442058	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442062	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442065	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442080	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442084	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442085	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442087	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442088	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442113	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442114	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442131	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442135	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442157	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442159	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442174	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442188	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442190	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442194	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442197	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442199	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442216	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442217	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442219	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442226	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442236	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442241	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442245	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442250	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442255	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442262	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442268	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442269	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442270	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442277	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442278	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442283	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442287	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442288	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442298	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442306	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442313	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442314	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442319	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	>55	C4591001 1003 10031120	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1005 10051214	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051403	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071105	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1007 10071213	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111028	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111181	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111201	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1012 10121139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1012 10121149	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131176	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131186	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131714	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161026	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1016 10161162	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191201	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191299	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191308	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1019 10191314	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1021 10211221	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1022 10221150	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1024 10241003	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241031	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241037	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1024 10241041	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241049	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241057	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241059	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241065	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241068	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1024 10241081	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241083	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241087	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241096	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1024 10241097	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1027 10271206†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1037 10371057	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371275	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371356	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1039 10391019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441002	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441004	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441007	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441010	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441016	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441018	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441032	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1044 10441036	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441041	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441047	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441049	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441055	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441062	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441067	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441073	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441075	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441080	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441083	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441085	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441090	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441092	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441093	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1044 10441094	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441113	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461084	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461245	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471122	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1047 10471228	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1047 10471300	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521062	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521142	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541071	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1054 10541175	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561034	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561078	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561095	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561120	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561123	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561229	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561298	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561301	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561303	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561306	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561353	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561399	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561404	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561409	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561625	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661128	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1068 10681004	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681005	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681008	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681009	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1068 10681019	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681023	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681029	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681030	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681039	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681041	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681044	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681050	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681056	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681057	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681059	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681062	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681068	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681078	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681079	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1068 10681084	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1071 10711023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711169	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711178	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1072 10721065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791234	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791264	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791271	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791283	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1080 10801064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1080 10801217	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1081 10811053	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1081 10811061	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811150	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821062	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821126	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1083 10831173	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841403	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1084 10841446	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1087 10871080	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1087 10871121	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1087 10871224	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871418	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871434	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1087 10871512	Evaluable efficacy (7 days) Dose 1 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1088 10881122	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1088 10881139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901237	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911001	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1091 10911004	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1091 10911010	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1091 10911012	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1091 10911092	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911159	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911195	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921015	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921180	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921268	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931005	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941046	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941071	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941159	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951102	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971003	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971023	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1097 10971024	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971097	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971107	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1098 10981030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981092	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981109	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981162	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1101 11011027	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091259	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091345	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1109 11091374	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091475	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091503	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101309	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121118	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121134	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121255	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161117	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1116 11161227	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1117 11171047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1118 11181072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201350	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); unblinded prior to 7 days post Dose 2.
		C4591001 1121 11211071	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1122 11221034†	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1125 11251222	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1127 11271002	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1127 11271034	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281313	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1128 11281325	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291091	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1129 11291115	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1129 11291117	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291149	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291166	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1130 11301039	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1133 11331197	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331472	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341052	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341099	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341353	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351131	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361096	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361107	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411066	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1142 11421111	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421304	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491126	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491224	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491239	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491296	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521359	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521476	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521497	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571144	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611012	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611013	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611022	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611030	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611035	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611036	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611037	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611042	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1162 11621006	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621007	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621212	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621327	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621349	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621407	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621433	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631011	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1163 11631013	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631126	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631131	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631132	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631133	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631144	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631149	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1167 11671122	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1167 11671123	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1169 11691070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701067	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701354	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1171 11711160	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711217	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711218	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711227	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711233	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711243	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851006	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971036	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971037	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141046	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181056	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1219 12191036	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1220 12201060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211051	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1221 12211052	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1221 12211058	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1221 12211061	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1223 12231215	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1223 12231250	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241012	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); unblinded prior to 7 days post Dose 2.
		C4591001 1229 12291041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311709	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311815	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312098	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312222	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312496	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313003	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313359	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313391	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313446	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313461	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313468	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313478	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313480	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313496	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313503	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313511	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313524	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313530	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313536	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313538	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
		C4591001 1231 12313549	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313562	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Unblinded prior to 7 days post Dose 2.
		C4591001 1231 12313651	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2; had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
		C4591001 1231 12314060	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12314216	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12314301	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314488	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315018	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315246	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321105	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321144	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321326	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321367	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321383	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1232 12321389†	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1232 12321390	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1232 12321398	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1232 12321432	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481044	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481182	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481214	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1251 12511087	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511236	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1252 12521003	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541200	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601095	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441495	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441792	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442012	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442076	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442078	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442092	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442098	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442110	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442112	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442130	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442176	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442183	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442187	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442204	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442208	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442239	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442266	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442271	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442295	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442316	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
Placebo	12-15	C4591001 1006 10061219	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071415	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1007 10071593	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081871	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081884	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091229	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091320	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1009 10091338	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091363	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091366	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1016 10161316	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161379	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441360	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1077 10771293	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231501	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261254	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1126 11261287	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311292	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1147 11471280	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701237	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	16-55	C4591001 1003 10031140	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051308	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051341	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061099	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1006 10061215	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061246	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1007 10071095	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071407	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081682	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081721	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091257	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111175	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131017	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1013 10131034	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131040	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131216	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131426	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131740	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131746	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131832	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151134	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161126	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161167	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161348	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181313	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191098	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1027 10271105	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281026	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1028 10281241	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1028 10281285	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281294	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361128	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1038 10381057	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391244	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1042 10421250	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441152†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1044 10441287	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461140	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461318	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471176	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471221	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1047 10471314	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541150	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1055 10551145	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561098	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561129	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561152	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561192	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561194	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561226	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561320	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561354	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561372	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561384	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561395	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561396	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561400	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561403	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561414	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561554	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561591	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561636	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571031	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571211	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1057 10571215	Evaluable efficacy (7 days) Dose 1 all-available efficacy Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive at least 1 vaccination. Did not receive 2 vaccinations.
		C4591001 1057 10571248	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1057 10571268	Evaluable efficacy (7 days) Dose 1 all-available efficacy Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive at least 1 vaccination. Did not receive 2 vaccinations.
		C4591001 1066 10661396	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1068 10681010	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1071 10711162	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive at least 1 vaccination. Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1071 10711185	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711237	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1072 10721051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791082	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791130	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791143	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791162	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791253	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1079 10791267	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821013	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821221	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1083 10831029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1083 10831060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1085 10851286	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871089	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871186	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871354	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871356	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1088 10881080	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891076	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901245	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901334	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1090 10901379	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901507	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901516	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911014	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1091 10911083	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911291	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911352	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1092 10921158	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1092 10921175	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931094	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941155	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951056	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951144	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951197	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961081	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1096 10961195	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1096 10961276	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961321	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961345	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961388	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971085	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981001	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981155	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1098 10981168†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1098 10981219	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1101 11011024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1107 11071160	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1107 11071178	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091127	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091335	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091478	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091515	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091518	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1109 11091526	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091547	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091556	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101072	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101085	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101110	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101155	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101156	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1110 11101229	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1110 11101247	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1110 11101250	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1110 11101342	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1111 11111104	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1114 11141065	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161292	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1117 11171186	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1117 11171190	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1120 11201013	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1120 11201038	Evaluable efficacy (7 days) Dose 1 all-available efficacy Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive at least 1 vaccination. Did not receive 2 vaccinations.
		C4591001 1120 11201085	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1120 11201104	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1120 11201249	Evaluable efficacy (7 days) Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1120 11201252	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1122 11221006	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231290	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231313	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1124 11241003	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1124 11241084	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1125 11251160	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1125 11251238	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1126 11261074	Evaluable efficacy (7 days) Dose 1 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive at least 1 vaccination.
		C4591001 1127 11271099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1128 11281012	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1128 11281093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281146	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1128 11281368	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1129 11291048	Evaluable efficacy (7 days) Dose 1 all-available efficacy Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive at least 1 vaccination. Did not receive 2 vaccinations.
		C4591001 1129 11291165	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311193	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1133 11331037	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1133 11331042	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1133 11331059	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331087	Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331120	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331162	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331170	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331207	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331291	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331338	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331510	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331512	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1133 11331562	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1133 11331568	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1133 11331583	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1133 11331598	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1133 11331635	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1135 11351132	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351200	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1135 11351212	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1135 11351420	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1136 11361045	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1136 11361095	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401306	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1141 11411146	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1142 11421303	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1145 11451063	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1147 11471035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491108	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491172	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491230	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491344†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1152 11521085	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561200	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571003	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571135	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571156	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611004	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611005	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Did not receive 2 vaccinations; data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611007	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Did not receive 2 vaccinations; data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611008	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Did not receive 2 vaccinations; data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Randomized but did not meet all eligibility criteria; data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611010	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Did not receive 2 vaccinations; data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611015	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611016	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611018	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations; data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611023	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations; data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611024	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations; data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611027	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611028	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611033	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611040	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1162 11621024	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive at least 1 vaccination. Did not receive 2 vaccinations.
		C4591001 1162 11621217	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621294	Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621310	Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621356	Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621514	Dose 2 all-available efficacy Evaluable efficacy (7 days)	Did not receive 2 vaccinations. Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621515	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631039	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631064	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631096	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1166 11661047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661091	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1167 11671003	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1167 11671223	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1168 11681104	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681227	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1169 11691058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701015	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701059	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701064	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701117	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701201	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701308	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701311	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701334†	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1170 11701364	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701427†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701453	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711131	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711154	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711159	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711189	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711216	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711221	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711224	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711226	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1171 11711228	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711231	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711241	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711247	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711248	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711250	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711301	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771139	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771292	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851055	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1197 11971040	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971041	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031048	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1204 12041197†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1204 12041280	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1205 12051078	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101053	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141020	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141038	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141048	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1217 12171044	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1218 12181036	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Unblinded prior to 7 days post Dose 2.
		C4591001 1218 12181041	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2. Did not receive 2 vaccinations.
		C4591001 1218 12181042	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1218 12181044	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Unblinded prior to 7 days post Dose 2.
		C4591001 1218 12181048	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2. Did not receive 2 vaccinations.
		C4591001 1218 12181050	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1218 12181052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191056	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191062	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201041	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201051	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1220 12201056	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1220 12201061	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1220 12201065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211002	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1221 12211007	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211053	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1221 12211072	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1221 12211078	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1223 12231174	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241158†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1224 12241167	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241170	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241175	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261380	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261391	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261894	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262063	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262108	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1226 12262189	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1226 12262267	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1230 12301065	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301150	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1231 12311031	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12311054	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12311087	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12311088	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311147	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311191	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311195	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311301	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311356	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311374	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311391	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12311402	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311420	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311431	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311441	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311473	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311516	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311559	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311568	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12311656	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12311816	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12311858	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311885	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311926	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria.
		C4591001 1231 12312176	Dose 1 all-available efficacy Dose 2 all-available efficacy	Did not receive at least 1 vaccination. Did not receive 2 vaccinations.
		C4591001 1231 12312244	Evaluable efficacy (7 days) Dose 1 all-available efficacy Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive at least 1 vaccination. Did not receive 2 vaccinations.
			Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12312320	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312326	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312334	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312426	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312439	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312483	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312594	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312623	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12312660	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12312752	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12312763	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12312848	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12312868	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12312916	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313068	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1231 12313069	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313098	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313115	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313125	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313376	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313395	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313443	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313454	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313510	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313516	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313527	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313657	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313758	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313939	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314134	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12314266	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314381	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314492	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314679	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314738	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314848	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314857	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314923	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12314984	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315322	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315357	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315681	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321100	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321142	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321213	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321220	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1232 12321244	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321287	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321310	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321378	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321400	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321429	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351071	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351167	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351187	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411260	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411273	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411279	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411688	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411695	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412355	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471244	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1248 12481018	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481060	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481110	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481170	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481199	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1248 12481218	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511207	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541116	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541145	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1260 12601070	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641018	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1269 12691081	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1270 12701056	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701170	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441007	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441079	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441179	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441522	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44441560	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441912	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441931	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441938	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441979	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442059	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442069	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442071	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442072	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442077	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442081	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442086	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442090	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442091	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442095	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442100	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442105	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442107	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442115	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442117	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442119	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442140	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442142	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442151	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442156	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442160	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442161	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442162	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442165	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442168	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442170	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442196	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442205	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442212	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442215	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442233	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442237	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442249	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442253	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442256	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442263	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442274	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442279	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442281	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442284	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442285	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442292	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442294	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442297	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442301	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442303	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442304	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442307	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442308	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442310	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442315	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442322	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	>55	C4591001 1005 10051338	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071114	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071315	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1007 10071347	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1008 10081639	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081725	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091089	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091157	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111029	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111085	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111086	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131097	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1013 10131192	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161166	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161282	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191033	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191300	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1022 10221015	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1022 10221057	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1024 10241130†	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1036 10361133	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1037 10371117	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1037 10371195	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371303	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371333†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria.
		C4591001 1038 10381056	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1042 10421010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1044 10441116	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461126	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461259	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461301	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471252	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541024	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1054 10541186	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1055 10551039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561015	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561032	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561079	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561099	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561275	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561276	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561302	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561337	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561371	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561381	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561415	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561426	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571128	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661350	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1068 10681043	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1068 10681063	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1071 10711049	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711063	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1071 10711216	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1072 10721037	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791158	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791266	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1080 10801222	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811093	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1082 10821007	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821164	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841006	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1084 10841366	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871033	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871228	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871505	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871560	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891004	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891344	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1090 10901146	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901415	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901519	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911006	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921123	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921191	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931128	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931191	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1094 10941080	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1094 10941130	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1094 10941191†	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951107	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1096 10961048	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Had other important protocol deviations on or prior to 7 days after Dose 2. Did not receive 2 vaccinations.
		C4591001 1096 10961082	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1096 10961086	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
		C4591001 1096 10961160	Evaluable efficacy (7 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1096 10961282	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971060	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1101 11011077	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1107 11071093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091248	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091313	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091407	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101241	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111106	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1112 11121052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121337	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161118	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161253	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1117 11171040	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1117 11171052	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1118 11181065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1120 11201073	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201127	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201213	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201227	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201335	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201351	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201436	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1124 11241048	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1125 11251107	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261147	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1127 11271003	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281023	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281109	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281138	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1129 11291082	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291237	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311145	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311164	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331426	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331469	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331481	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341067	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria.
		C4591001 1134 11341087	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341130	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341339	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351128	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361104	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361105	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401082	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411196	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421305	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1145 11451076	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1147 11471004	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491100	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1156 11561044	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1156 11561092	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571028	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1157 11571131	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1161 11611003	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611021	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611025	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611029	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611031	Dose 1 all-available efficacy Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event. Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611038	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611043	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611044	Dose 1 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Dose 2 all-available efficacy	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event.
			Evaluable efficacy (7 days)	Data considered potentially unreliable due to lack of PI oversight identified as significant quality event; did not receive all vaccinations as randomized or did not receive Dose 2 within the

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1162 11621059	Dose 2 all-available efficacy	predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2. Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1162 11621213	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621278	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621297	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631003	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631007	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631010	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631030	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631062	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1163 11631092	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1163 11631100	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711215	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711220	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711222	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711230	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711235	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711244	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771089	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1178 11781056	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1179 11791169	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971038	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971046	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971052	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1204 12041057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1219 12191060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201055	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1220 12201058	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1221 12211057	Dose 2 all-available efficacy	Unblinded prior to 7 days post Dose 2.
			Evaluable efficacy (7 days)	Unblinded prior to 7 days post Dose 2.
		C4591001 1221 12211085	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241057	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241157	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1226 12261613	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262240	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1229 12291080	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311057	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12311549	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311672	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311723	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311935	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311979	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12312130	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312347	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312571	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313090	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313103	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313457	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314120	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12314189	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314863	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314972	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315608	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315625	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315672	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321127	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321234	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1232 12321242	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321281	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412568	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471135	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471166	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481049	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511067	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511078	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1260 12601030	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601121	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641195	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1265 12651026	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1270 12701057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441152	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442061	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442074	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442075	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442096	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
– Blinded Placebo-Controlled Follow-up Period**

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442108	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442116	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442126	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442127	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442132	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442134	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442141	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442150	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442164	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442166	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442169	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442179	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442243	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population
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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442282	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442290	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442296	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442309	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

Note: HIV-positive subjects are included in this listing but not included in the analyses of the overall study objectives.

Note: † = HIV-positive subject.

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