



Pfizer Regulatory Quality Assurance

Audit Certificate

I, the undersigned, confirm and certify that the following investigator site audit activities were performed.

Study C4591001

Twenty-Four (24) investigator site audits were performed between 29-Apr-2020 and 13-Mar-2021 for Study C4591001 Phase 2/3*.

Investigator Name	Center Number	Country	Dates of Audit	Type of Audit	Name of Auditor
Mulligan, Mark Joseph	1001	United States	27 Jul 2020 to 30 Jul 2020	Routine	Jefferies, Maria
Neuzil, Kathleen Maletic	1002	United States	10 Aug 2020 to 13 Aug 2020	Routine	Cutler, Robert
Seger, William Michael	1042	United States	10 Aug 2020 to 13 Aug 2020	Routine	Popelca, Bogdan
Rankin, Bruce Glenn	1109	United States	18 Aug 2020 to 21 Aug 2020	Routine	Patel, Frederic
Zerbini, Cristiano Augusto de Freitas	1226	Brazil	24 Aug 2020 to 27 Aug 2020	Routine	Tewes, Elisabeth
Polack, Fernando Pedro	1231	Argentina	27 Aug 2020 to 03 Sep 2020	Routine	Mohr, Andrea
Raad, George Louis	1079	United States	01 Sep 2020 to 04 Sep 2020	Routine	Jefferies, Maria
Arora, Samir	1091	United States	14 Sep 2020 to 17 Sep 2020	Routine	Samuels, Marilyn
Patel, Suchet R.	1077	United States	29 Sep 2020 to 02 Oct 2020	Routine	Tewes, Elisabeth
Fried, David L.	1124	United States	05 Oct 2020 to 07 Oct 2020	Non-Routine	Cutler, Robert
Winkle, Peter John	1135	United States	12 Oct 2020 to 14 Oct 2020	Non-Routine	Cutler, Robert
Polack, Fernando Pedro	1231	Argentina	13 Oct 2020 to 20 Oct 2020	Non-Routine	Mohr, Andrea
Reynolds, Steven H.	1149	United States	16 Oct 2020 to 20 Oct 2020	Non-Routine	Cutler, Robert
Rankin, Bruce Glenn	1109	United States	19 Oct 2020 to 22 Oct 2020	Non-Routine	Oprisko, Cheryl
Nell, Haylene	1247	South Africa	26 Oct 2020 to 29 Oct 2020	Routine	Tewes, Elisabeth
Koch, Mark	1128	United States	03 Nov 2020 to 06 Nov 2020	Non-Routine	Cutler, Robert
Schaefer, Axel	1195	Germany	16 Nov 2020 to 18 Nov 2020	Routine	Auner, Dagmar

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Williams, Hayes Taylor	1251	United States	16 Nov 2020 to 18 Nov 2020	Routine	Oprisko, Cheryl
Moreira Jr., Edson Duarte	1241	Brazil	24 Nov 2020 to 26 Nov 2020	Routine	Mohr, Andrea
Riesenberg, Robert Alan	1162	United States	30 Nov 2020 to 04 Dec 2020	Non-Routine	Tafurth, Maria
Finn, Daniel John	1016	United States	01 Dec 2020 to 03 Dec 2020	Routine	Jefferies, Maria
Akhan, Sila	1217	Turkey	01 Dec 2020 to 03 Dec 2020	Routine	Clayton, Simon
Jennings, Timothy William	1008	United States	07 Dec 2020 to 10 Dec 2020	Routine	Samuels, Marilyn
Christensen, Shane Glade	1009	United States	01 Mar 2021 to 04 Mar 2021	Routine	Jilla, Abilash

***Site 1001 and 1002 audited as part of Phase 1**

Approver:

Cecilia Gabarain
Senior Director, Regulatory Quality Assurance

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Robert N Cutler

7997eefb-6feb-4dbc-a232-c15936633467

REASON: I attest to the accuracy and integrity of this document.

16 Mar 2021
08:30:041-0400

Cecilia Gabarain

6809829b-f9ec-4ac9-bc23-e28cfba721dc

REASON: I approve this document.

16 Mar 2021
11:17:012-0400

MSB

Validation Report as of: 16 Mar 2021 11:20:016-0400

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Subject CN TAIGLE LLC
Subject DN EMAILADDRESS=operations@msbdocs.com,CN=TAIGLE LLC,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email operations@msbdocs.com
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Issuer DN CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
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FDA-CBER-2021-5683-0029228

Audit Trail Report

Date	User	Document	Action	Details
15 Mar 2021 19:02:025-0400	Christine Mina		Started	The custodian composed the ePak successfully. User UUID : a3b2e181-3aee-4aea-b101-ec31853d0033 User Email : christine.mina@pfizer.com
15 Mar 2021 19:02:025-0400	Robert N Cutler		RequestSent	Sign request sent to ePak recipient. User UUID : 7997eefb-6feb-4dbc-a232-c15936633467 User Email : robert.cutler@pfizer.com
16 Mar 2021 08:30:014-0400	Robert N Cutler	C4591001 Audit Cert 15-Mar-2021.pdf	DocumentViewed	Document viewed by signer. User UUID : 7997eefb-6feb-4dbc-a232-c15936633467 User Email : robert.cutler@pfizer.com Document UUID : 8ae50323-55c7-44d4-9a99-886930c6e127
16 Mar 2021 08:30:042-0400	Robert N Cutler	C4591001 Audit Cert 15-Mar-2021.pdf	SignerTagFilled	The signer filled Time Stamp. Value: 16 Mar 2021 08:30:041-0400 User UUID : 7997eefb-6feb-4dbc-a232-c15936633467 User Email : robert.cutler@pfizer.com Document UUID : 8ae50323-55c7-44d4-9a99-886930c6e127
16 Mar 2021 08:30:042-0400	Robert N Cutler	C4591001 Audit Cert 15-Mar-2021.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: None User UUID : 7997eefb-6feb-4dbc-a232-c15936633467 User Email : robert.cutler@pfizer.com Document UUID : 8ae50323-55c7-44d4-9a99-886930c6e127
16 Mar 2021 08:30:042-0400	Christine Mina		EPakStateChanged	The ePak progressed to the next workflow state . User UUID : a3b2e181-3aee-4aea-b101-ec31853d0033 User Email : christine.mina@pfizer.com
16 Mar 2021 08:30:042-0400	Christine Mina		RequestSent	Sign request sent to ePak recipient. User UUID : a3b2e181-3aee-4aea-b101-ec31853d0033 User Email : christine.mina@pfizer.com
16 Mar 2021 11:15:056-0400	Cecilia Beatriz Gabarain	C4591001 Audit Cert 15-Mar-2021.pdf	DocumentViewed	Document viewed by signer. User UUID : 6809829b-f9ec-4ac9-bc23-e28cfba721dc User Email : ceciliabeatriz.gabarain@pfizer.com Document UUID : 8ae50323-55c7-44d4-9a99-886930c6e127
16 Mar 2021 11:17:012-0400	Cecilia Beatriz Gabarain	C4591001 Audit Cert 15-Mar-2021.pdf	SignerTagFilled	The signer filled Time Stamp. Value: 16 Mar 2021 11:17:012-0400 User UUID : 6809829b-f9ec-4ac9-bc23-e28cfba721dc User Email : ceciliabeatriz.gabarain@pfizer.com Document UUID : 8ae50323-55c7-44d4-9a99-886930c6e127
16 Mar 2021 11:17:012-0400	Cecilia Beatriz Gabarain	C4591001 Audit Cert 15-Mar-2021.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: None User UUID : 6809829b-f9ec-4ac9-bc23-e28cfba721dc User Email : ceciliabeatriz.gabarain@pfizer.com Document UUID : 8ae50323-55c7-44d4-9a99-886930c6e127
16 Mar 2021 11:17:012-0400	Christine Mina		Completed	The ePak completed the workflow successfully custodian. User UUID : a3b2e181-3aee-4aea-b101-ec31853d0033 User Email : christine.mina@pfizer.com

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