

# Supplemental Analysis Reviewer Guide

BLA Analysis for Participants  $\geq 16$  Years of Age

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Study C4591001

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## 1. Introduction

This document provides details on the supplemental analysis package created as a supplement to the BLA esub package to revise the reactogenicity SDTM and ADaM data to address the agreements made with CBER during the teleconference of 08 April 2021.

SDTM includes DM, EX and updated domains (AE, CE, FACE, VS, SUPPAE, SUPPCE, SUPPFACE, SUPPVS, RELREC), define and aCRF. ADaM includes ADSL and updated datasets (ADAE, ADCEVD, ADFACEVD) and define in Module 5.3.5.1. The following are provided in Module 5.3.5.1 as well:

- A [roadmap](#) describing the SDTM dataset updates
- Table summary of changes ([CSR vs Update](#))
- Updated reactogenicity [TLFs](#)
- Final reactogenicity tables with [track changes](#)