

# Supplemental Analysis Reviewer Guide

sBLA for 12-15 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 sBLA for “12-15 Years of Age” esub package to revise the reactogenicity SDTM and ADaM data to address the agreements made with CBER during the teleconference of 08 April 2021.

Tabulation package and Analysis Package were sent under application number 125742 sequence number 0001 on 06May2021. The following are provided to address FDA query STN 125742/45: IR RE the datasets for adolescents 12 through 15 Years of Age item 3. Use the AGEGR1N =1 to subset for 12-15 years old.

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