

Data Fitness Findings Report

IND27034

BioNTech SE and Pfizer, April 2021

Findings			Notes
C4591001 EUA Amendment (12-15 Years of Age)			
Title: <i>A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals.</i>			
Document / Standard	Version	Notes	
annotated CRF		Seems fine	
SDTM Implementation Guide	SDTM-IG v3.2		
SDTM Controlled Terminology	2020-03-27		
SDTM define.xml	V2.0	Seems fine	
Medications Dictionary	WHODD GLOBALV3Mar20, WHO DDE v202003		
Medical Events Dictionary (MedDRA)	V23.1		
SDTM Reviewer's Guide	PhUSE template	Seems fine	

Data Issues							
Adverse event marked as AEREL = RELATED, but subject didn't receive dose yet							
<ul style="list-style-type: none"> USUBJID = C4591001 1226 12261520, AETERM = Pain at injection site, AESTDTC = 2020-09-02T21:00 <ul style="list-style-type: none"> 2 EX records: EXSTDTC = 2020-09-03T15:06:00 and 2020-09-22T10:22:00 							
Subjects have AE records with AEACN = DRUG WITHDRAWN but no ADVERSE EVENT record in DS							
<ul style="list-style-type: none"> 20 subjects – see report "IND27034 - 12-15years - AEACN of DRUG WITHDRAWN but no DS ADVERSE EVENT record.xlsx" 							
Value for CEHLGT not found in MedDRA dictionary							
<ul style="list-style-type: none"> 1 record (0%) cSDRG explanation: "Manually coded as "Virus infectious disorders"." The correct value per the MedDRA dictionary is: Viral infectious disorders 							
Inconsistent coding of MHTERM							
mhterm	mhdecod	mhhlt	mhhigt	mhbodsys	STUDYID	count_of_mhs	meddrav
SKIN CANCER	SKIN CANCER	SKIN NEOPLASMS MALIGNANT AND UNSPECIFIED (EXCL MELANOMA)	SKIN NEOPLASMS MALIGNANT AND UNSPECIFIED	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	C4591001	2	23.1
SKIN CANCER	SKIN NEOPLASM EXCISION	SKIN LESION EXCISIONS	SKIN AND SUBCUTANEOUS TISSUE THERAPEUTIC PROCEDURES	SURGICAL AND MEDICAL PROCEDURES	C4591001	1	23.1