

16.2.2.1 Listing of Important Protocol Deviations – Phase 1, 2 Doses, 21 Days Apart

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
Inclusion/Exclusion	Participant met exclusion criterion #19 (Phase 1 only: any screening hematology and/or blood chemistry laboratory value that meets the definition of a \geq grade 1 abnormality)	1	C4591001 1002 10021053
Inclusion/Exclusion	Participant met exclusion criterion #19 (Phase 1 only: any screening hematology and/or blood chemistry laboratory value that meets the definition of a \geq grade 1 abnormality)	1	C4591001 1003 10031021
Inclusion/Exclusion	Participant met exclusion criterion #19 (Phase 1 only: any screening hematology and/or blood chemistry laboratory value that meets the definition of a \geq grade 1 abnormality)	1	C4591001 1003 10031047
Inclusion/Exclusion	Participant met exclusion criterion #19 (Phase 1 only: any screening hematology and/or blood chemistry laboratory value that meets the definition of a \geq grade 1 abnormality)	2	C4591001 1003 10031017 C4591001 1003 10031070
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adv Table Generation: 31AUG2020 (09:18) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adsl_1005_pd_p1			

16.2.2.1.1 Listing of Important Protocol Deviations – Phase 1 – BNT162b1 (100 µg)			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
No subject meets the reporting criteria.			
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adv Table Generation: 19SEP2020 (10:20) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adsl_1005_pd_100_p1			