

Table 1: Summary of Differences Between CSR Reactogenicity Data and Updated Reactogenicity Data for Study C4591001 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population 2

Table 2: Summary of Differences Between CSR Reactogenicity Data and Updated Reactogenicity Data for Study C4591001 – Phase 2/3 Subjects >55 Years of Age – Safety Population 3

**Summary of Differences Between CSR Reactogenicity Data and Updated Reactogenicity Data for Study C4591001 – Phase 2/3
Subjects 16-55 Years of Age – Safety Population**

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	Placebo
Number of total reactogenicity records	447303	447749
Number (%) records affected ^a	536 (0.12)	140 (0.03)
Number of subjects	2923	2941
Number (%) subjects with any records affected	109 (3.73)	48 (1.63)
Maximum difference (updated data-CSR data) across any local reaction term of the percentage of subjects with a local reaction within 7 days of first vaccination ^b	0.1	0.2
Maximum difference (updated data-CSR data) across any local reaction term of the percentage of subjects with a local reaction within 7 days of second vaccination ^b	0.1	0.1
Maximum difference (updated data-CSR data) across any systemic event term of the percentage of subjects with a systemic event within 7 days of first vaccination ^b	0.1	0.0
Maximum difference (updated data-CSR data) across any systemic event term of the percentage of subjects with a systemic event within 7 days of second vaccination ^b	0.3	0.2
Maximum difference (updated data-CSR data) across any local reaction term of the duration in mean days following first vaccination ^b	0.01	0.0
Maximum difference (updated data-CSR data) across any local reaction term of the duration in mean days following second vaccination ^b	0.0	0.0
Maximum difference (updated data-CSR data) across any systemic event term of the duration in mean days following first vaccination ^b	0.01	0.0
Maximum difference (updated data-CSR data) across any systemic event term of the duration in mean days following second vaccination ^b	0.02	0.01
Difference (updated data-CSR data) of number of subjects with a duration of any local reaction >7 days following either vaccination	1	0
Difference (updated data-CSR data) of number of subjects with a duration of any systemic event >7 days following either vaccination	5	3

Abbreviations: CRF = case report form; CSR = clinical study report

Note: CSR data is data reported in the CSR that was entered into the electronic diary by the subject and symptom resolved page by the investigator. Updated data is the CSR data and the reactogenicity data entered in the AE log CRF page by the investigator.

a. An affected record is any record that changed during the reactogenicity update.

b. Maximum difference is displayed as a percentage and is for reactogenicity data.

**Summary of Differences Between CSR Reactogenicity Data and Updated Reactogenicity Data for Study C4591001 – Phase 2/3
Subjects >55 Years of Age – Safety Population**

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	Placebo
Number of total reactogenicity records	311695	307249
Number (%) records affected ^a	207 (0.07)	79 (0.03)
Number of subjects	2025	2007
Number (%) subjects with any records affected	49 (2.42)	22 (1.10)
Maximum difference (updated data-CSR data) across any local reaction term of the percentage of subjects with a local reaction within 7 days of first vaccination ^b	0.1	0.2
Maximum difference (updated data-CSR data) across any local reaction term of the percentage of subjects with a local reaction within 7 days of second vaccination ^b	0.2	0.2
Maximum difference (updated data-CSR data) across any systemic event term of the percentage of subjects with a systemic event within 7 days of first vaccination ^b	0.1	0.0
Maximum difference (updated data-CSR data) across any systemic event term of the percentage of subjects with a systemic event within 7 days of second vaccination ^b	0.3	0.0
Maximum difference (updated data-CSR data) across any local reaction term of the duration in mean days following first vaccination ^b	0.01	0.03
Maximum difference (updated data-CSR data) across any local reaction term of the duration in mean days following second vaccination ^b	0.0	0.17
Maximum difference (updated data-CSR data) across any systemic event term of the duration in mean days following first vaccination ^b	0.01	0.01
Maximum difference (updated data-CSR data) across any systemic event term of the duration in mean days following second vaccination ^b	0.02	0.02
Difference (updated data-CSR data) of number of subjects with a duration of any local reaction >7 days following either vaccination	1	1
Difference (updated data-CSR data) of number of subjects with a duration of any systemic event >7 days following either vaccination	2	1

Abbreviations: CRF = case report form; CSR = clinical study report

Note: CSR data is data reported in the CSR that was entered into the electronic diary by the subject and symptom resolved page by the investigator. Updated data is the CSR data and the reactogenicity data entered in the AE log CRF page by the investigator.

a. An affected record is any record that changed during the reactogenicity update.

b. Maximum difference is displayed as a percentage and is for reactogenicity data.