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14.3 Safety
14.3.1 Primary endpoints

14.3.1-1 Local reactions

Table 14.3.1-1.2.1-3: Frequency of subjects with solicited local reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Prime up to Day 7 after prime		nn	12	12
	Any	Any n (%)	10 (83)	9 (75)
		Mild n (%)	7 (58)	8 (67)
		Moderate n (%)	3 (25)	1 (8)
	Pain	Any n (%)	8 (67)	7 (58)
		Mild n (%)	7 (58)	7 (58)
		Moderate n (%)	1 (8)	0 (0)
	Tenderness	Any n (%)	10 (83)	8 (67)
		Mild n (%)	7 (58)	7 (58)
		Moderate n (%)	3 (25)	1 (8)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)
		Mild n (%)	0 (0)	0 (0)
	Induration/Swelling	Any n (%)	2 (17)	0 (0)
		Mild n (%)	2 (17)	0 (0)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.2.1-3: Frequency of subjects with solicited local reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Boost up to Day 7 after boost		nn	12	12
	Any	Any n (%)	11 (92)	10 (83)
		Mild n (%)	11 (92)	5 (42)
		Moderate n (%)	0 (0)	4 (33)
		Severe n (%)	0 (0)	1 (8)
	Pain	Any n (%)	9 (75)	8 (67)
		Mild n (%)	9 (75)	4 (33)
		Moderate n (%)	0 (0)	3 (25)
		Severe n (%)	0 (0)	1 (8)
	Tenderness	Any n (%)	11 (92)	8 (67)
		Mild n (%)	11 (92)	5 (42)
		Moderate n (%)	0 (0)	3 (25)
	Erythema/Redness	Any n (%)	1 (8)	2 (17)
		Mild n (%)	1 (8)	2 (17)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.2.1-3: Frequency of subjects with solicited local reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Boost up to Day 7 after boost	Erythema/Redness	Moderate n (%)	0 (0)	0 (0)
	Induration/Swelling	Any n (%)	2 (17)	1 (8)
		Mild n (%)	2 (17)	1 (8)
Combined interval		nn	12	12
	Any	Any n (%)	11 (92)	11 (92)
		Mild n (%)	8 (67)	5 (42)
		Moderate n (%)	3 (25)	5 (42)
		Severe n (%)	0 (0)	1 (8)
	Pain	Any n (%)	10 (83)	11 (92)
		Mild n (%)	9 (75)	7 (58)
		Moderate n (%)	1 (8)	3 (25)
		Severe n (%)	0 (0)	1 (8)
	Tenderness	Any n (%)	11 (92)	9 (75)
		Mild n (%)	8 (67)	5 (42)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.2.1-3: Frequency of subjects with solicited local reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Combined interval	Tenderness	Moderate n (%)	3 (25)	4 (33)
	Erythema/Redness	Any n (%)	1 (8)	2 (17)
		Mild n (%)	1 (8)	2 (17)
		Moderate n (%)	0 (0)	0 (0)
	Induration/Swelling	Any n (%)	3 (25)	1 (8)
		Mild n (%)	3 (25)	1 (8)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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14.3.1-2 Systemic reactions

Table 14.3.1-2.2.1-3: Frequency of subjects with solicited systemic reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Prime up to Day 7 after prime		nn	12	12
	Any	Any n (%)	9 (75)	9 (75)
		Mild n (%)	7 (58)	8 (67)
		Moderate n (%)	2 (17)	1 (8)
		Severe n (%)	0 (0)	0 (0)
	Nausea	Any n (%)	2 (17)	1 (8)
		Mild n (%)	2 (17)	1 (8)
	Diarrhea	Any n (%)	2 (17)	1 (8)
		Mild n (%)	2 (17)	1 (8)
	Headache	Any n (%)	5 (42)	5 (42)
		Mild n (%)	5 (42)	4 (33)
		Moderate n (%)	0 (0)	1 (8)
		Severe n (%)	0 (0)	0 (0)
	Fatigue	Any n (%)	5 (42)	7 (58)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.2.1-3: Frequency of subjects with solicited systemic reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Prime up to Day 7 after prime	Fatigue	Mild n (%)	3 (25)	7 (58)
		Moderate n (%)	2 (17)	0 (0)
		Severe n (%)	0 (0)	0 (0)
	Myalgia	Any n (%)	2 (17)	2 (17)
		Mild n (%)	1 (8)	2 (17)
		Moderate n (%)	1 (8)	0 (0)
	Arthralgia	Any n (%)	0 (0)	0 (0)
		Mild n (%)	0 (0)	0 (0)
		Moderate n (%)	0 (0)	0 (0)
	Chills	Any n (%)	1 (8)	1 (8)
		Mild n (%)	1 (8)	1 (8)
	Loss of Appetite	Any n (%)	0 (0)	0 (0)
		Mild n (%)	0 (0)	0 (0)
	Malaise	Any n (%)	4 (33)	2 (17)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.2.1-3: Frequency of subjects with solicited systemic reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Prime up to Day 7 after prime	Malaise	Mild n (%)	3 (25)	2 (17)
		Moderate n (%)	1 (8)	0 (0)
Boost up to Day 7 after boost		nn	12	12
	Any	Any n (%)	10 (83)	11 (92)
		Mild n (%)	4 (33)	4 (33)
		Moderate n (%)	3 (25)	5 (42)
		Severe n (%)	3 (25)	2 (17)
	Nausea	Any n (%)	1 (8)	2 (17)
		Mild n (%)	0 (0)	2 (17)
		Severe n (%)	1 (8)	0 (0)
	Diarrhea	Any n (%)	0 (0)	1 (8)
		Mild n (%)	0 (0)	1 (8)
	Headache	Any n (%)	5 (42)	8 (67)
		Mild n (%)	3 (25)	4 (33)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.2.1-3: Frequency of subjects with solicited systemic reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Boost up to Day 7 after boost	Headache	Moderate n (%)	2 (17)	3 (25)
		Severe n (%)	0 (0)	1 (8)
	Fatigue	Any n (%)	8 (67)	7 (58)
		Mild n (%)	4 (33)	4 (33)
		Moderate n (%)	2 (17)	3 (25)
		Severe n (%)	2 (17)	0 (0)
	Myalgia	Any n (%)	6 (50)	4 (33)
		Mild n (%)	3 (25)	3 (25)
		Moderate n (%)	1 (8)	1 (8)
		Severe n (%)	2 (17)	0 (0)
	Arthralgia	Any n (%)	6 (50)	3 (25)
		Mild n (%)	2 (17)	3 (25)
		Moderate n (%)	1 (8)	0 (0)
		Severe n (%)	3 (25)	0 (0)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.2.1-3: Frequency of subjects with solicited systemic reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Boost up to Day 7 after boost	Chills	Any n (%)	6 (50)	4 (33)
		Mild n (%)	4 (33)	1 (8)
		Moderate n (%)	1 (8)	2 (17)
		Severe n (%)	1 (8)	1 (8)
	Loss of Appetite	Any n (%)	2 (17)	3 (25)
		Mild n (%)	1 (8)	2 (17)
		Moderate n (%)	1 (8)	1 (8)
	Malaise	Any n (%)	6 (50)	5 (42)
		Mild n (%)	1 (8)	2 (17)
		Moderate n (%)	4 (33)	3 (25)
		Severe n (%)	1 (8)	0 (0)
	Fever	Any n (%)	0 (0)	3 (25)
		Mild n (%)	0 (0)	3 (25)
Combined interval		nn	12	12

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.2.1-3: Frequency of subjects with solicited systemic reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Combined interval	Any	Any n (%)	12 (100)	11 (92)
		Mild n (%)	5 (42)	4 (33)
		Moderate n (%)	4 (33)	5 (42)
		Severe n (%)	3 (25)	2 (17)
	Nausea	Any n (%)	2 (17)	3 (25)
		Mild n (%)	1 (8)	3 (25)
		Severe n (%)	1 (8)	0 (0)
	Diarrhea	Any n (%)	2 (17)	2 (17)
		Mild n (%)	2 (17)	2 (17)
	Headache	Any n (%)	7 (58)	8 (67)
		Mild n (%)	5 (42)	4 (33)
		Moderate n (%)	2 (17)	3 (25)
		Severe n (%)	0 (0)	1 (8)
	Fatigue	Any n (%)	9 (75)	9 (75)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.2.1-3: Frequency of subjects with solicited systemic reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Combined interval	Fatigue	Mild n (%)	4 (33)	6 (50)
		Moderate n (%)	3 (25)	3 (25)
		Severe n (%)	2 (17)	0 (0)
	Myalgia	Any n (%)	7 (58)	5 (42)
		Mild n (%)	3 (25)	4 (33)
		Moderate n (%)	2 (17)	1 (8)
		Severe n (%)	2 (17)	0 (0)
	Arthralgia	Any n (%)	6 (50)	3 (25)
		Mild n (%)	2 (17)	3 (25)
		Moderate n (%)	1 (8)	0 (0)
		Severe n (%)	3 (25)	0 (0)
	Chills	Any n (%)	6 (50)	4 (33)
		Mild n (%)	4 (33)	1 (8)
		Moderate n (%)	1 (8)	2 (17)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.2.1-3: Frequency of subjects with solicited systemic reactions (assessed by subject) by worst grade - BNT162b2

Safety set

Time interval			30 µg Younger (N=12)	30 µg Older (N=12)
Combined interval	Chills	Severe n (%)	1 (8)	1 (8)
	Loss of Appetite	Any n (%)	2 (17)	3 (25)
		Mild n (%)	1 (8)	2 (17)
		Moderate n (%)	1 (8)	1 (8)
	Malaise	Any n (%)	7 (58)	7 (58)
		Mild n (%)	1 (8)	4 (33)
		Moderate n (%)	5 (42)	3 (25)
		Severe n (%)	1 (8)	0 (0)
	Fever	Any n (%)	0 (0)	3 (25)
		Mild n (%)	0 (0)	3 (25)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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