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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Informed Consent (2.1)

Sponsor Study Code: BNT162-01

Category

Date

Time

PID

Protocol Version ▾

Was the subject re-screened? No Yes

All previous TSNs (e.g. 276-01-1234)

Date of first Informed Consent

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Demographic Data (2.1)Age years monthsSex Male FemaleRace,
select all that apply White Black or African American Asian American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Not reported Unknown OtherIf Other, please specify Ethnicity Not Hispanic or Latino Hispanic or Latino Not reported Unknown

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Body Height/Weight + BMI (2.0)

Sponsor Study Code: BNT162-01

Reason not done	Date	Time	Height (cm)	Weight (kg)	Body Mass Index		BMI (calculated) (kg/m ²)
Not done							

1

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Childbearing Potential (2.0)

Sponsor Study Code: BNT162-01

Reproductive Test

Childbearing potential No Yes NA

Non-childbearing potential Postmenopausal (>=12 months)
 Surgically sterilized
 Other

Date of Last menses

Date of Sterilization

Other, please specify

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Pregnancy Test (2.0)

Sponsor Study Code: BNT162-01

Category	Specimen	NA	Not done	Reason not done	Date	Time	Result
1	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Negative <input type="radio"/> Positive

More rows: 1 5 10

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<input type="checkbox"/> Not done					
Reason not done <input type="text"/>					
Date <input type="text"/>					
Time <input type="text"/>					
System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance	Finding (calculated)	
1 General condition/psyche	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
2 Skin	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
3 Lymph nodes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
4 Head (eyes, ears, mouth)	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
5 Neck/thyroid gland	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
6 Lungs	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
7 Heart	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
8 Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
9 Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
10 Neurological system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
11 Vascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
12 Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
13 Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	
14 Other	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance
1 <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Right <input type="radio"/> Left	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1	<input type="checkbox"/>						<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CCS

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
12-lead ECG (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position	Heart Rate (beats/min)	Interpretation	Clinical Significance	Findings, select all that apply
<input type="checkbox"/> 1					<input type="checkbox"/>	Normal <input checked="" type="checkbox"/> Abnormal <input type="checkbox"/>	NCS <input type="checkbox"/> CS	<input type="checkbox"/>

More rows: 1 5 10

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Category	Specimen	Not done	Reason not done	Date	Time	Drug Test Results											
						Methamphetamines	Opiates	Cocaine	Cannabinoids	Phencyclidine	Benzodiazepines	Barbiturates	Methadone	Tricyclic antidepressants	Amphetamines		
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Negative <input type="radio"/> Positive											

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Alcohol Breath Test (2.0)

Sponsor Study Code: BNT162-01

Category	Specimen	Not done	Reason not done	Date	Time	Result
1	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Negative <input type="radio"/> Positive

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Sampling for Urinalysis (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for Safety Lab (2.0)

Sponsor Study Code: BNT162-01



Blood samples for safety lab includes Serology, SARS-CoV-2 antibodies and FSH (only women if not WOCBP) at Visit 0

Category	Specimen	Not done	Reason not done	Date	Time	Fasting?
----------	----------	----------	-----------------	------	------	----------

1 No Yes

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
In-/Exclusion Criteria (2.0)

Sponsor Study Code: BNT162-01

No Yes

Subject meets all inclusion criteria and does not meet any exclusion criteria?

Date

If No, please select all violated In-/Exclusion criteria:

Inclusion Criteria:

Exclusion Criteria:

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Visit:
Visit 1

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Pregnancy Test (2.0)

Sponsor Study Code: BNT162-01

Category	Specimen	NA	Not done	Reason not done	Date	Time	Result
1	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Negative <input type="radio"/> Positive

More rows: 1 5 10

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<input type="checkbox"/>	Not done
Reason not done	<input type="text"/>
Date	<input type="text"/>
Time	<input type="text"/>

Overall health judgement - subject healthy? No Yes

System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance	Finding (calculated)
				NCS
1 General condition/psyche	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
2 Skin	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
3 Lymph nodes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
4 Head (eyes, ears, mouth)	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
5 Neck/thyroid gland	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
6 Lungs	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
7 Heart	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
8 Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
9 Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
10 Neurological system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
11 Vascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
12 Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
13 Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
14 Other	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>

Category	Specimen	Not done	Reason not done	Date	Time	Methamphetamines		Opiates		Cocaine		Cannabinoids		Phencyclidine		Benzodiazepines		Barbiturates		Methadone		Tricyclic antidepressants		Amphetamines			
						<input type="radio"/> Negative	<input type="radio"/> Positive																				
1						<input type="radio"/>																					

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Alcohol Breath Test (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time	Result
1	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Negative <input type="radio"/> Positive

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Scheduled time	Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance											
1 <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Right	<input checked="" type="radio"/> Left	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/> NCS	<input checked="" type="checkbox"/> CS	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/> NCS	<input checked="" type="checkbox"/> CS	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/> NCS	<input checked="" type="checkbox"/> CS	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/> NCS	<input checked="" type="checkbox"/> CS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Scheduled time	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1 <input type="button" value="▼"/> <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	NCS <input type="checkbox"/> CS <input type="checkbox"/>				

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
12-lead ECG (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position	Heart Rate (beats/min)	Interpretation	Clinical Significance	Findings, select all that apply
<input type="checkbox"/> 1					<input type="checkbox"/>	Normal <input checked="" type="checkbox"/> Abnormal <input type="checkbox"/>	NCS <input type="checkbox"/> CS	<input type="checkbox"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Sampling for Urinalysis (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for Safety Lab (2.0)

Sponsor Study Code: BNT162-01



Blood samples for safety lab includes Serology, SARS-CoV-2 antibodies and FSH (only women if not WOCBP) at Visit 0

Category	Specimen	Not done	Reason not done	Date	Time	Fasting?
----------	----------	----------	-----------------	------	------	----------

1 No Yes

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Oral Swipe for SARS-CoV-2 Testing (2.1)

Sponsor Study Code: BNT162-01

Category	Specimen	Not done	Reason not done	Date	Time	Test name	Result
1	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="▼"/>	<input checked="" type="radio"/> Negative <input type="radio"/> Positive

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
In-/Exclusion Criteria (2.0)

Sponsor Study Code: BNT162-01

No Yes

Subject meets all inclusion criteria and does not meet any exclusion criteria?

Date

If No, please select all violated In-/Exclusion criteria:

Inclusion Criteria:

Exclusion Criteria:

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Allocation (2.1)

Sponsor Study Code: BNT162-01

Category

Date

Time

Subject is allocated to Cohort 1
 Cohort 2
 Cohort 3
 Cohort 4
 Cohort 5
 Cohort 6
 Cohort 7
 Cohort 8
 Cohort 9
 Cohort 10

Group A (BNT162a1)
 B (BNT162b1)
 C (BNT162b2)
 D (BNT162c2)
 E (BNT162c2 P/B)

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20 DEV
Blood Samples for Immunogenicity (2.1)

Sponsor Study Code: BNT162-01

Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for CMI (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Administration (2.1)

Sponsor Study Code: BNT162-01

Scheduled time

Not done

Reason not done

Other, specify

Date

Time

Route of Administration

Treatment

Medication Number

Dose Form

Planned dose ug

Other, specify ug

Unit

Total Dose (Volume of Injection) mL

Unit

Total Dose given? No Yes

 mL

If No, rest volume

Application site right left upper arm

CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV

Sponsor Study Code: BNT162-01

Administration according to protocol? No Yes

If No, please specify

Epi/Pandemic related adjustment No Yes

Epi/Pandemic related interruption No Yes

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Category	Scheduled time	Not done	Reason not done	Date	Time	Test Name	Evaluator	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
1	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

Category	Scheduled time	Not done	Reason not done	Date	Time	Test Name	Evaluator	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Intensity of Fatigue/Tiredness
1	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None										
								<input type="radio"/> Mild										
								<input type="radio"/> Moderate										
								<input type="radio"/> Severe										
								<input type="radio"/> Potentially life threatening										

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

Visit:
Visit 2

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<input type="checkbox"/>	Not done
Reason not done	<input type="text"/>
Date	<input type="text"/>
Time	<input type="text"/>

Overall health judgement - subject healthy? No Yes

System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance	Finding (calculated)
				NCS
1 General condition/psyche	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
2 Skin	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
3 Lymph nodes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
4 Head (eyes, ears, mouth)	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
5 Neck/thyroid gland	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
6 Lungs	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
7 Heart	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
8 Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
9 Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
10 Neurological system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
11 Vascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
12 Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
13 Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
14 Other	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance
1 <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Right <input type="radio"/> Left	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1	<input type="checkbox"/>						<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CCS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Sampling for Urinalysis (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for Safety Lab (2.0)

Sponsor Study Code: BNT162-01



Blood samples for safety lab includes Serology, SARS-CoV-2 antibodies and FSH (only women if not WOCBP) at Visit 0

Category	Specimen	Not done	Reason not done	Date	Time	Fasting?
----------	----------	----------	-----------------	------	------	----------

1 No Yes

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01 CRS_049_20_DEV
Local Tolerability at Injection Site (2.1)

Sponsor Study Code: BNT162-01



Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
1	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening

More rows: 1 5 10

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Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of appetite	Intensity of Malaise	Intensity of Fatigue/Tiredness
1	<input type="checkbox"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening						

More rows: 1 5 10

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**Visit:
Phone Call at 48h**

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Phone Call (2.0)

Sponsor Study Code: BNT162-01

Phone call only valid for the first 6 subjects per cohort. For the last 6 subjects please tick NA.

NA	Not done	Reason not done	Date	Time	Outcome of the call (e.g. No findings or new AEs/CMs reported)
1	<input type="checkbox"/>	<input type="checkbox"/>			

More rows: 1 5 10

Please document any additional information / changes in the appropriate forms!

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Visit:
Visit 3

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<input type="checkbox"/>	Not done
Reason not done	<input type="text"/>
Date	<input type="text"/>
Time	<input type="text"/>

Overall health judgement - subject healthy? No Yes

System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance	Finding (calculated)
				NCS
1 General condition/psyche	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
2 Skin	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
3 Lymph nodes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
4 Head (eyes, ears, mouth)	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
5 Neck/thyroid gland	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
6 Lungs	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
7 Heart	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
8 Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
9 Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
10 Neurological system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
11 Vascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
12 Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
13 Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
14 Other	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance
1 <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Right <input type="radio"/> Left	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1	<input type="checkbox"/>						<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CCS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Sampling for Urinalysis (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for Safety Lab (2.0)

Sponsor Study Code: BNT162-01



Blood samples for safety lab includes Serology, SARS-CoV-2 antibodies and FSH (only women if not WOCBP) at Visit 0

Category	Specimen	Not done	Reason not done	Date	Time	Fasting?
----------	----------	----------	-----------------	------	------	----------

1 No Yes

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Blood Samples for Immunogenicity (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01 CRS_049_20_DEV
Local Tolerability at Injection Site (2.1)

Sponsor Study Code: BNT162-01



Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
1	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening

More rows: 1 5 10

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Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of appetite	Intensity of Malaise	Intensity of Fatigue/Tiredness
1	<input type="checkbox"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening						

More rows: 1 5 10

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Visit:
Visit 4

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Pregnancy Test (2.0)

Sponsor Study Code: BNT162-01

Category	Specimen	NA	Not done	Reason not done	Date	Time	Result
1	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Negative <input type="radio"/> Positive

More rows: 1 5 10

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Not done

Reason not done

Date

Time

Overall health judgement - subject healthy? No Yes

	System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance	Finding (calculated)
					NCS CS
1	General condition/psyche	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
2	Skin	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
3	Lymph nodes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
4	Head (eyes, ears, mouth)	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
5	Neck/thyroid gland	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
6	Lungs	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
7	Heart	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
8	Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
9	Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
10	Neurological system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
11	Vascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
12	Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
13	Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>
14	Other	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input checked="" type="radio"/> CS	<input type="text"/>

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Scheduled time	Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance							
1	<input type="button" value=""/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Right	<input type="radio"/> Left	<input type="text"/>	<input type="radio"/> NCS	<input type="radio"/> CS	<input type="text"/>	<input type="radio"/> NCS	<input type="radio"/> CS	<input type="text"/>	<input type="radio"/> NCS	<input type="radio"/> CS	<input type="text"/>	<input type="radio"/> NCS	<input type="radio"/> CS	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Scheduled time	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1 <input type="button" value="▼"/> <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	NCS <input type="checkbox"/> CS <input type="checkbox"/>				

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Administration (2.1)

Sponsor Study Code: BNT162-01

Scheduled time

Not done

Reason not done

Other, specify

Date

Time

Route of Administration

Treatment

Medication Number

Dose Form

Planned dose ug

Other, specify ug

Unit

Total Dose (Volume of Injection) mL

Unit

Total Dose given? No Yes

 mL

If No, rest volume

Application site right left upper arm

CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV

Sponsor Study Code: BNT162-01

Administration according to protocol? No Yes

If No, please specify

Epi/Pandemic related adjustment No Yes

Epi/Pandemic related interruption No Yes

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Blood Samples for Immunogenicity (2.1)

Sponsor Study Code: BNT162-01

Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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Category	Scheduled time	Not done	Reason not done	Date	Time	Test Name	Evaluator	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
1	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

Category	Scheduled time	Not done	Reason not done	Date	Time	Test Name	Evaluator	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Intensity of Fatigue/Tiredness
1	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None										
								<input type="radio"/> Mild										
								<input type="radio"/> Moderate										
								<input type="radio"/> Severe										
								<input type="radio"/> Potentially life threatening										

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

Visit:
Phone Call at 48h (a1, b1, b2, c2P/B)

CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Phone Call (2.0)

Sponsor Study Code: BNT162-01

Phone call only valid for the first 6 subjects per cohort. For the last 6 subjects please tick NA.

NA	Not done	Reason not done	Date	Time	Outcome of the call (e.g. No findings or new AEs/CMs reported)
1	<input type="checkbox"/>	<input type="checkbox"/>			

More rows: 1 5 10

Please document any additional information / changes in the appropriate forms!

Please insert new row(s), if you are in visit "Unscheduled Forms" only!

Visit:
Visit 5

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<input type="checkbox"/>	Not done
Reason not done	<input type="text"/>
Date	<input type="text"/>
Time	<input type="text"/>

Overall health judgement - subject healthy? No Yes

System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance	Finding (calculated)
				NCS
1 General condition/psyche	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
2 Skin	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
3 Lymph nodes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
4 Head (eyes, ears, mouth)	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
5 Neck/thyroid gland	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
6 Lungs	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
7 Heart	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
8 Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
9 Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
10 Neurological system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
11 Vascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
12 Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
13 Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
14 Other	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance
1 <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Right <input type="radio"/> Left	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1	<input type="checkbox"/>						<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CCS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Sampling for Urinalysis (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for Safety Lab (2.0)

Sponsor Study Code: BNT162-01



Blood samples for safety lab includes Serology, SARS-CoV-2 antibodies and FSH (only women if not WOCBP) at Visit 0

Category	Specimen	Not done	Reason not done	Date	Time	Fasting?
----------	----------	----------	-----------------	------	------	----------

1 No Yes

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Blood Samples for Immunogenicity (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for CMI (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01 CRS_049_20_DEV
Local Tolerability at Injection Site (2.1)

Sponsor Study Code: BNT162-01

Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
							<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None
1	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Mild	<input type="radio"/> Mild	<input type="radio"/> Mild	<input type="radio"/> Mild
							<input type="radio"/> Moderate	<input type="radio"/> Moderate	<input type="radio"/> Moderate	<input type="radio"/> Moderate
							<input type="radio"/> Severe	<input type="radio"/> Severe	<input type="radio"/> Severe	<input type="radio"/> Severe
							<input type="radio"/> Potentially life threatening			

More rows: 1 5 10

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Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of appetite	Intensity of Malaise	Intensity of Fatigue/Tiredness
1	<input type="checkbox"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening						

More rows: 1 5 10

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Visit:
Visit 6 (a1, b1, b2, c2P/B) / (c2) (EoT)

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<input type="checkbox"/>	Not done
Reason not done	<input type="text"/>
Date	<input type="text"/>
Time	<input type="text"/>

Overall health judgement - subject healthy? No Yes

System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance	Finding (calculated)
				NCS
1 General condition/psyche	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
2 Skin	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
3 Lymph nodes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
4 Head (eyes, ears, mouth)	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
5 Neck/thyroid gland	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
6 Lungs	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
7 Heart	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
8 Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
9 Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
10 Neurological system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
11 Vascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
12 Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
13 Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
14 Other	<input type="radio"/> Normal <input type="radio"/> Abnormal <input checked="" type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance
1 <input type="checkbox"/>					<input checked="" type="radio"/> Right <input type="radio"/> Left		<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS		<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS		<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS		<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1	<input type="checkbox"/>						<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CCS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Sampling for Urinalysis (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for Safety Lab (2.0)

Sponsor Study Code: BNT162-01



Blood samples for safety lab includes Serology, SARS-CoV-2 antibodies and FSH (only women if not WOCBP) at Visit 0

Category	Specimen	Not done	Reason not done	Date	Time	Fasting?
----------	----------	----------	-----------------	------	------	----------

1 No Yes

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Blood Samples for Immunogenicity (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for CMI (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01 CRS_049_20_DEV
Local Tolerability at Injection Site (2.1)

Sponsor Study Code: BNT162-01



Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
1	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

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Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of appetite	Intensity of Malaise	Intensity of Fatigue/Tiredness
1	<input type="checkbox"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening						

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

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Visit:

Visit 7 (a1, b1, b2, c2P/B) (EoT)

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<input type="checkbox"/>	Not done
Reason not done	<input type="text"/>
Date	<input type="text"/>
Time	<input type="text"/>

Overall health judgement - subject healthy? No Yes

	System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance	Finding (calculated)
					NCS CS
1	General condition/psyche	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
2	Skin	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
3	Lymph nodes	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
4	Head (eyes, ears, mouth)	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
5	Neck/thyroid gland	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
6	Lungs	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
7	Heart	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
8	Abdomen	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
9	Musculoskeletal system	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
10	Neurological system	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
11	Vascular system	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
12	Cardiovascular	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
13	Gastrointestinal	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
14	Other	<input type="radio"/> Normal <input checked="" type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance
1 <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Right <input type="radio"/> Left	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1	<input type="checkbox"/>						<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CCS

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Sampling for Urinalysis (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

All comments will be entered on comment page!

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for Safety Lab (2.0)

Sponsor Study Code: BNT162-01



Blood samples for safety lab includes Serology, SARS-CoV-2 antibodies and FSH (only women if not WOCBP) at Visit 0

Category	Specimen	Not done	Reason not done	Date	Time	Fasting?
----------	----------	----------	-----------------	------	------	----------

1 No Yes

More rows: 1 5 10

All comments will be entered on comment page!

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Blood Samples for Immunogenicity (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01 CRS_049_20_DEV
Local Tolerability at Injection Site (2.1)

Sponsor Study Code: BNT162-01



Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
1	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening

More rows: 1 5 10

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Category	Not done	Reason not done	Date	Time	Test Name	Evaluator	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of appetite	Intensity of Malaise	Intensity of Fatigue/Tiredness
1	<input type="checkbox"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening						

More rows: 1 5 10

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Visit:

Visit 7 (c2) (FU) / V 8 (a1, b1, b2, c2P/B) (FU)

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CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance
1 <input type="checkbox"/>					<input checked="" type="radio"/> Right <input type="radio"/> Left		<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS		<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS		<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS		<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1	<input type="checkbox"/>						<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CCS

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Blood Samples for Immunogenicity (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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Visit:

Visit 8 (c2) (FU) / V 9 (a1, b1, b2, c2P/B) (FU)

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CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance
1 <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Right <input type="radio"/> Left	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1	<input type="checkbox"/>						<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CCS

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Blood Samples for Immunogenicity (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Not done	Reason not done	Date	Time
1	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

Please insert new row(s), if you are in visit "Unscheduled Forms" only!

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**Visit:
End of Trial**

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
End of Trial (2.1)

Sponsor Study Code: BNT162-01

Category

Trial fully completed? No Yes

Date of Completion or Early Withdrawal

Main Reason for premature termination Adverse Event
 Death
 Lost to Follow-up
 Physician Decision
 Pregnancy
 Protocol Deviation
 Screen Failure
 Site Terminated by Sponsor
 Study Terminated by Sponsor
 Technical Problems
 Withdrawal by Subject
 Other

Date of Death

Other, specify:

Epi-/Pandemic related No Yes

Date of last visit/contact

CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
End of Follow-up (2.1)

Sponsor Study Code: BNT162-01

Category

Follow-up fully completed? No Yes

Date of Completion or Early Withdrawal

Main Reason for premature termination Adverse Event
 Death
 Lost to Follow-up
 Physician Decision
 Pregnancy
 Protocol Deviation
 Screen Failure
 Site Terminated by Sponsor
 Study Terminated by Sponsor
 Technical Problems
 Withdrawal by Subject
 Other

Date of Death

Other, specify:

Epi-/Pandemic related No Yes

Date of last visit/contact

**Visit:
Unrelated Forms**

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Medical History (2.0)

Sponsor Study Code: BNT162-01

No Yes
 Any Medical History?

If Ongoing, please specify intensity (toxicity grading scale)

Abnormality/Disease	Start Date	End Date	Ongoing
1			<input type="radio"/> No <input checked="" type="radio"/> Yes
2			<input type="radio"/> No <input checked="" type="radio"/> Yes
3			<input type="radio"/> No <input checked="" type="radio"/> Yes
4			<input type="radio"/> No <input checked="" type="radio"/> Yes
5			<input type="radio"/> No <input checked="" type="radio"/> Yes
6			<input type="radio"/> No <input checked="" type="radio"/> Yes
7			<input type="radio"/> No <input checked="" type="radio"/> Yes
8			<input type="radio"/> No <input checked="" type="radio"/> Yes
9			<input type="radio"/> No <input checked="" type="radio"/> Yes
10			<input type="radio"/> No <input checked="" type="radio"/> Yes

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Observation Period (2.0)

Sponsor Study Code: BNT162-01

Vaccination Visit	Planned observation period	Other planned observation period (e.g. 8 hours)	Adherence to planned observation period?	If No, actual observation period (hours)	Reason	
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> No <input type="radio"/> Yes	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

Please insert as many new rows as needed for the according visits!

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If any grading of any reaction is not NONE and not related to IMP, please document on Adverse Event page.

If any grading of any reaction is not NONE and related to IMP, please document as diagnosis on Adverse Event page.

Category	Study Day	Not done	Date	Time	Test Name	Evaluator	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
1	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening
2	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening
3	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening
4	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening
5	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV

Sponsor Study Code: BNT162-01

6	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None				
								<input type="radio"/> Mild				
								<input type="radio"/> Moderate				
								<input type="radio"/> Severe				
								<input type="radio"/> Potentially life threatening				
7	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None				
								<input type="radio"/> Mild				
								<input type="radio"/> Moderate				
								<input type="radio"/> Severe				
								<input type="radio"/> Potentially life threatening				
8	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None				
								<input type="radio"/> Mild				
								<input type="radio"/> Moderate				
								<input type="radio"/> Severe				
								<input type="radio"/> Potentially life threatening				
9	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None				
								<input type="radio"/> Mild				
								<input type="radio"/> Moderate				
								<input type="radio"/> Severe				
								<input type="radio"/> Potentially life threatening				

More rows: 1 5 10

If any grading of any reaction is not NONE and not related to IMP, or subject has fever [i.e., temperature is $\geq 38^{\circ}\text{C}$], please document on Adverse Event page.

If any grading of any reaction is not NONE and related to IMP, or subject has fever [i.e., temperature is $\geq 38^{\circ}\text{C}$], please document as diagnosis on Adverse Event Page.

Category	Study Day	Not done	Date	Time	Test Name	Evaluator	Body Temperature ($^{\circ}\text{C}$)	Intensity of Headache	Intensity of Myalgia	Intensity of Arthralgia	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Intensity of Fatigue
1	[]	[]	[]	[]	[]	[]	[]	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening
2	[]	[]	[]	[]	[]	[]	[]	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening
3	[]	[]	[]	[]	[]	[]	[]	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening
4	[]	[]	[]	[]	[]	[]	[]	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening
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6	[]	[]	[]	[]	[]	[]	[]	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening
7	[]	[]	[]	[]	[]	[]	[]	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe Potentially life threatening

CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV

8	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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<input type="radio"/> None															
<input type="radio"/> Mild															
<input type="radio"/> Moderate															
<input type="radio"/> Severe															
<input type="radio"/> Potentially life threatening															

9	<input type="text"/>	<input type="button" value="▼"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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More rows: 1 5 10

Sponsor Study Code: BNT162-01

CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Unrelated Clinical Events (2.0)

Sponsor Study Code: BNT162-01

No Yes

Any local/systemic reactions NOT RELATED to
IMP

Category	Study Day	Date	Time	Test Name	Local/systemic reaction
1	<input type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	<input type="text"/>	<input type="text"/>	<input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>

More rows: 1 5 10

Please insert as many new rows as needed.

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AE reporting according BNT 162 reporting of AE and reactions 03July2020

Any Adverse Events? No Yes

AE No.	Adverse Event	Serious	Reason, select all that apply	AE of special interest	Epi-/Pandemic related	Start Date	Start Time	End Date	End Time	End Time unkn.	Ongoing	Severity/Intensity	Intensity (toxicity grading scale)	Treatment emergent AE	Relationship to IMP Treatment	DLT (Dose limiting toxicity)	Action taken with IMP Treatment	Concomitant medication or therapy	Outcome of AE	AE Group ID
1	<input type="text"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life Threatening <input type="checkbox"/> Other Medically Important Serious Event	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="text"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Not related <input checked="" type="radio"/> Related	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Not recovered/not resolved <input type="radio"/> Recovered/resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Recovering/resolving <input type="radio"/> Fatal <input type="radio"/> Unknown	<input type="text"/>				
2	<input type="text"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life Threatening <input type="checkbox"/> Other Medically Important Serious Event	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="text"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Not related <input checked="" type="radio"/> Related	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Not recovered/not resolved <input type="radio"/> Recovered/resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Recovering/resolving <input type="radio"/> Fatal <input type="radio"/> Unknown	<input type="text"/>				
3	<input type="text"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life Threatening <input type="checkbox"/> Other Medically Important Serious Event	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="text"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Not related <input checked="" type="radio"/> Related	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Not recovered/not resolved <input type="radio"/> Recovered/resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Recovering/resolving <input type="radio"/> Fatal <input type="radio"/> Unknown	<input type="text"/>				
4	<input type="text"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life Threatening <input type="checkbox"/> Other Medically Important Serious Event	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="text"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Not related <input checked="" type="radio"/> Related	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="radio"/> Not recovered/not resolved <input type="radio"/> Recovered/resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Recovering/resolving <input type="radio"/> Fatal <input type="radio"/> Unknown	<input type="text"/>				

CRS Study Code: 049/20

BioNTech_BNT162_01_CRS_049_20_DEV

5	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Yes	<input type="radio"/> Mild	<input type="radio"/> Moderate	<input type="radio"/> Severe	<input type="radio"/> Mild	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> Not related	<input type="radio"/> Related	<input type="radio"/> Dose not changed	<input type="radio"/> Dose reduced	<input type="radio"/> Drug interrupted	<input type="radio"/> Drug withdrawn	<input type="radio"/> Not applicable	<input type="radio"/> Unknown	<input type="radio"/> Recovered/not resolved	<input type="radio"/> Recovered/resolved	<input type="radio"/> Recovered/resolved with sequelae	<input type="radio"/> Recovering/resolving	<input type="radio"/> Fatal	<input type="radio"/> Unknown		

Congenital Anomaly or Birth Defect

- Persist or Signif Disability/Incapacity
- Results in Death
- Requires or Prolongs Hospitalization
- Is Life Threatening
- Other Medically Important Serious Event

Mild Moderate Severe

Related

Dose

Severity

Status

Outcome

More rows: 1 5 10

CRS Study Code: 049/20
 BioNTech_BNT162_01 CRS_049_20_DEV
Prior/Concomitant Medication/Therapy (2.0)

Sponsor Study Code: BNT162-01

Any prior/concomitant medication/therapy? No Yes

Medication/Therapy	Taken prior to Study?	Start Date	Start Time	Start Time unkn.	End Date	End Time	End Time unkn.	Ongoing	Route	Other route, specify:	Individual dose	Unit	Other unit, specify:	Frequency	Other frequency, specify:	Indication	AE Nos.
1	<input type="radio"/> No <input checked="" type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2	<input type="radio"/> No <input checked="" type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3	<input type="radio"/> No <input checked="" type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4	<input type="radio"/> No <input checked="" type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5	<input type="radio"/> No <input checked="" type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Comments (2.0)

Sponsor Study Code: BNT162-01

No Yes

Any Comments?

Visit	Modul	Timepoint	Comment	Date of Comment
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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Any Protocol Deviations? No Yes

Visit	Modul	Timepoint	Description of Deviation	Reason for Deviation	Category	Date of Occurrence
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01 CRS_049_20_DEV
Informed Consent + Blood Sampling for HLA typing

Sponsor Study Code: BNT162-01

Category

Specimen

Informed Consent for pharmacogenetic analysis given? No Yes

Date of IC for pharmacogenetic analysis

Time of IC for pharmacogenetic analysis

Aliquot taken from previous CMI sampling

Date of previous CMI sampling for analysis Time of previous CMI sampling for analysis

1

More rows: 1 5 10

Please insert as many new rows as needed.

Informed Consent for separate HLA typing sampling given? No Yes

Date

Time

Separate Blood Sampling for HLA typing taken

Date of HLA typing sampling

Time of HLA typing sampling

HLA typing Blood Sampling aliquot taken from CMI sampling

Date of corresponding CMI sampling Time of corresponding CMI sampling

1

More rows: 1 5 10

Please insert as many new rows as needed.

**Visit:
Unscheduled Forms**

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Informed Consent (uns.) (2.1)

Sponsor Study Code: BNT162-01

Category	Date	Time	Protocol Version
1			

More rows: 1 5 10

Please insert as many new rows as needed.

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Date Time Overall health judgement - subject healthy? No Yes

System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance	Finding (calculated)
			<input type="radio"/> NCS <input type="radio"/> CS	
1 General condition/psyche	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
2 Skin	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
3 Lymph nodes	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
4 Head (eyes, ears, mouth)	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
5 Neck/thyroid gland	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
6 Lungs	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
7 Heart	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
8 Abdomen	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
9 Musculoskeletal system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
10 Neurological system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
11 Vascular system	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
12 Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
13 Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
14 Other	<input type="radio"/> Normal <input type="radio"/> Abnormal <input type="radio"/> ND	<input type="text"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>

CRS Study Code: 049/20

BioNTech_BNT162_01_CRS_049_20_DEV
Vital Signs incl. VSTPT (2.0)

Sponsor Study Code: BNT162-01

Date	Time	Measurement position (BP)	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance	
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Right <input type="radio"/> Left	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>	<input checked="" type="radio"/> NCS <input type="radio"/> CS

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Body Temperature (2.1)

Sponsor Study Code: BNT162-01

Date	Time	Measurement site	Other measurement site, specify: (°C)	Body Temperature	Clinical Significance
1					<input checked="" type="radio"/> NCS <input type="radio"/> CS

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Body Height/Weight + BMI (2.0)

Sponsor Study Code: BNT162-01

Date	Time	Weight (kg)
1 <input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

Please insert new row(s), if you are in visit "Unscheduled Forms" only!

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CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
12-lead ECG (2.0)

Sponsor Study Code: BNT162-01

Date	Time	Measurement position	Heart Rate (beats/min)	Interpretation	Clinical Significance	Findings, <i>select all that apply</i>
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> Normal <input type="radio"/> Abnormal	<input type="radio"/> NCS <input type="radio"/> CS	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

More rows: 1 5 10

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CRS Study Code: 049/20
 BioNTech_BNT162_01_CRS_049_20_DEV
Urine Drug Screen (2.0)

Sponsor Study Code: BNT162-01

Category	Specimen	Date	Time	Methamphetamines	Opiates	Cocaine	Cannabinoids	Phencyclidine	Benzodiazepines	Barbiturates	Methadone	Tricyclic antidepressants	Amphetamines
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Negative <input type="radio"/> Positive								

More rows: 1 5 10

Please insert new row(s), if you are in visit "Unscheduled Forms" only!

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Alcohol Breath Test (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Date	Time	Result
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> Negative <input type="radio"/> Positive

More rows: 1 5 10

Please insert new row(s), if you are in visit "Unscheduled Forms" only!

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Pregnancy Test (2.0)

Sponsor Study Code: BNT162-01



Category	Specimen	Date	Time	Result
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1 Negative
 Positive

More rows: 1 5 10

Please insert new row(s), if you are in visit "Unscheduled Forms" only!

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Urine Sampling for Urinalysis (2.0)

Sponsor Study Code: BNT162-01

	Category	Specimen	Date	Time
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

All comments will be entered on comment page!

Please insert new row(s), if you are in visit "Unscheduled Forms" only!

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for Safety Lab (2.0)

Sponsor Study Code: BNT162-01



Blood samples for safety lab includes Serology, SARS-CoV-2 antibodies and FSH (only women if not WOCBP) at Visit 0

Category	Specimen	Date	Time	Fasting?
----------	----------	------	------	----------

1 No Yes

More rows: 1 5 10

All comments will be entered on comment page!

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Oral Swipe for SARS-CoV-2 Testing (2.1)

Sponsor Study Code: BNT162-01

Category	Specimen	Date	Time	Test name	Result
1					<input type="radio"/> Negative <input type="radio"/> Positive

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Blood Samples for Immunogenicity (2.1)

Sponsor Study Code: BNT162-01

Category	Specimen	Date	Time
1			

More rows: 1 5 10

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CRS Study Code: 049/20
BioNTech_BNT162_01 CRS_049_20_DEV
Blood Samples for CMI (2.1)

Sponsor Study Code: BNT162-01

	Category	Specimen	Date	Time
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
More rows: 1 5 10				

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CRS Study Code: 049/20
 BioNTech_BNT162_01 CRS_049_20_DEV
Local Tolerability at Injection Site (2.1)

Sponsor Study Code: BNT162-01



Category	Date	Time	Test Name	Evaluator	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
Phone Call (2.0)

Sponsor Study Code: BNT162-01

Phone call only valid for the first 6 subjects per cohort. For the last 6 subjects please tick NA.

	Date	Time	Outcome of the call (e.g. No findings or new AEs/CMs reported)
1	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

Please document any additional information / changes in the appropriate forms!

Please insert new row(s), if you are in visit "Unscheduled Forms" only!

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CRS Study Code: 049/20
BioNTech_BNT162_01_CRS_049_20_DEV
In-/Exclusion Criteria (2.0)

Sponsor Study Code: BNT162-01

No Yes

Subject meets all inclusion criteria and does not meet any exclusion criteria?

Date

If No, please select all violated In-/Exclusion criteria:

Inclusion Criteria:

Exclusion Criteria:

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Category	Date	Time	Test Name	Evaluator	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Intensity of Fatigue/Tiredness
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening	

More rows: 1 5 10

Please insert as many new rows as needed for the according visits and use "Scheduled time" if required (attention at "Visit 4")!

CRS Study Code: 049/20

BioNTech_BNT162_01 CRS_049_20_DEV
Informed Consent + Blood Sampling for Research

Sponsor Study Code: BNT162-01

Category	Specimen	Informed Consent for Blood sampling for research purposes?	Visit	Date	Time	Date of Blood sampling	Time of Blood sampling
1	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> No <input type="radio"/> Yes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 1 5 10

Please insert as many new rows as needed.

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