

DS=Disposition

DM=Demographics

CRS Study Code: 049/20

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Informed Consent (2.1)

Sponsor Study Code: BNT162-01

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Category DSCAT='PROTOCOL MILESTONE'

Date RFICDTC DSSTDTC DSTERM/DSDECOD='INFORMED CONSENT OBTAINED'

Time

PID SUBJID

Protocol Version SUPPDS.QVAL when QNAM = 'PROTVERS'

Was the subject re screened? No Yes [NOT SUBMITTED] DSTERM/DSDECOD='FIRST INFORMED CONSENT OBTAINED'

Any previous TSNs (e.g. 276 0 234) SUPPDS.QVAL when QNAM = 'PREV_TSN'

Date of first Informed Consent DSSTDTC

DM=Demographics

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Demographic Data (2.1)

AGE Age years **AGEU='YEARS'**
 months **SUPPDM.QVAL when QNAM='AGE_M'**

Sex
SEX Male
 Female

Race, *select all that apply*
RACE White
 Black or African American
 Asian
 American Indian or Alaska Native
 Native Hawaiian or Other Pacific Islander
 Not reported
 Unknown
 Other

If Other, please specify **SUPPDM.QVAL when QNAM='RACEOTH'**

Ethnicity
ETHNIC Not Hispanic or Latino
 Hispanic or Latino
 Not reported
 Unknown

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If more than one option is selected:
RACE = 'MULTIPLE', and individual responses
in SUPPDM with QNAM = 'RACE1', 'RACE2',...

VS=Vital Signs

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

Sponsor Study Code: BNT162-01

Not done	Reason not done	Date	Time	Height (cm)	Weight (kg)	Body Mass Index (kg/m ²)	BMI (calculated) (kg/m ²)
<input type="checkbox"/>							
VSSTAT='NOT DONE' when VSTESTCD='VSALL'			VSDTC				[NOT SUBMITTED]
	VSREASND						

More rows: 5 0

VSORRESU/ VSORRES when VSTESTCD= 'HEIGHT'	VSORRESU/ VSORRES when VSTESTCD= 'WEIGHT'	VSORRESU/ VSORRES when VSTESTCD= 'BMI'
--	--	---

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

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RP=Reproductive System Findings

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Childbearing Potential (2.0)

Sponsor Study Code: BNT162-01

Reproductive Test

RPORRES when RPTTESTCD='CHILDPOT'

Childbearing potential

No Yes NA

[NOT SUBMITTED]

RPTTEST='Childbearing Potential'

Non childbearing potential

Postmenopausa (>= 2 months)

Surgically sterilized

Other

RPORRES when RPTTESTCD='NON_REAS'

RPTTEST='Reason for Non-childbearing potential'

Date of Last menses

RPORRES when RPTTESTCD='LMPSTDTC'

RPTTEST='Last Menstrual Period Start Date'

Date of Sterilization

RPORRES when RPTTESTCD='STER_DTC'

RPTTEST='Date of Sterilization'

Other, please specify

SUPPRP.QVAL when QNAM='OTH_SPEC'

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LB=Laboratory Test Results

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Urine Pregnancy Test (2.0)

LBTEST='Choriogonadotropin Beta'

Category	Spec men	NA	Not done	Reason not done	Date	Time	Result
	LBSPEC	<input type="checkbox"/>	<input type="checkbox"/>	LBREASND		LBDTC	LBORRES when LBTESTCD='HCG'
LBCAT='CHEMISTRY'							<input type="radio"/> Negative
LBSCAT='PREGNANCY'				LBSTAT='NOT DONE'			<input type="radio"/> Positive

[NOT SUBMITTED]

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

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PE=Physical Examination

CRS Study Code: 049/20

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Physical Examination (2.1)

Sponsor Study Code: BNT162-01

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Not done PESTAT='NOT DONE' when PETESTCD='HEALTHY'

Reason not done

Date

Time

PECAT='GENERAL'

System/Organ	Norma /Abnorma /ND	Abnorma tes/Symptoms	C n ca S gn f cance	F nd ng (ca cu ated)
<input type="text" value="PESPID"/> <input type="text" value="PETEST"/>	<input type="text" value="PEORRES"/> <input type="text" value="[NOT SUBMITTED]"/>	<input type="text" value="PEORRES when..."/>		<input type="text" value="[NOT SUBMITTED]"/>
1 <input type="text" value="General cond t on/psyche"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='GENCON'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
2 <input type="text" value="Sk n"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='SKIN'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
3 <input type="text" value="Lymph nodes"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='LYMPHN'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
4 <input type="text" value="Head (eyes, ears, mouth)"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='HEAD'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
5 <input type="text" value="Neck/thyro d g and"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='NECK'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
6 <input type="text" value="Lungs"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='LUNGS'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
7 <input type="text" value="Heart"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='HEART'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
8 <input type="text" value="Abdomen"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='ABDOMEN'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
9 <input type="text" value="Muscu oske eta system"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='MUSCULO'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
0 <input type="text" value="Neuro og ca system"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='NEUROL'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
<input type="text" value="Vascu ar system"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='VASCUL'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
2 <input type="text" value="Card ovascu ar"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='CARDVASC'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
3 <input type="text" value="Gastro ntest na"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='GASTRO'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>
4 <input type="text" value="Other"/>	<input type="radio"/> Norma <input type="radio"/> Abnorma <input type="radio"/> ND	<input type="text" value="...PETESTCD='OTHER'"/>	<input type="radio"/> NCS <input type="radio"/> CS	<input type="text"/>

SUPPPE.QVAL='N' when QNAM='PECLSIG'

SUPPPE.QVAL='Y' when QNAM='PECLSIG'

VS=Vital Signs

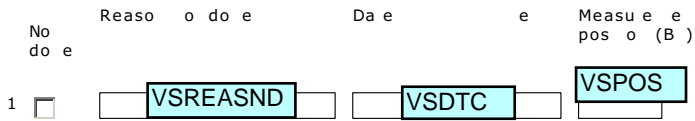
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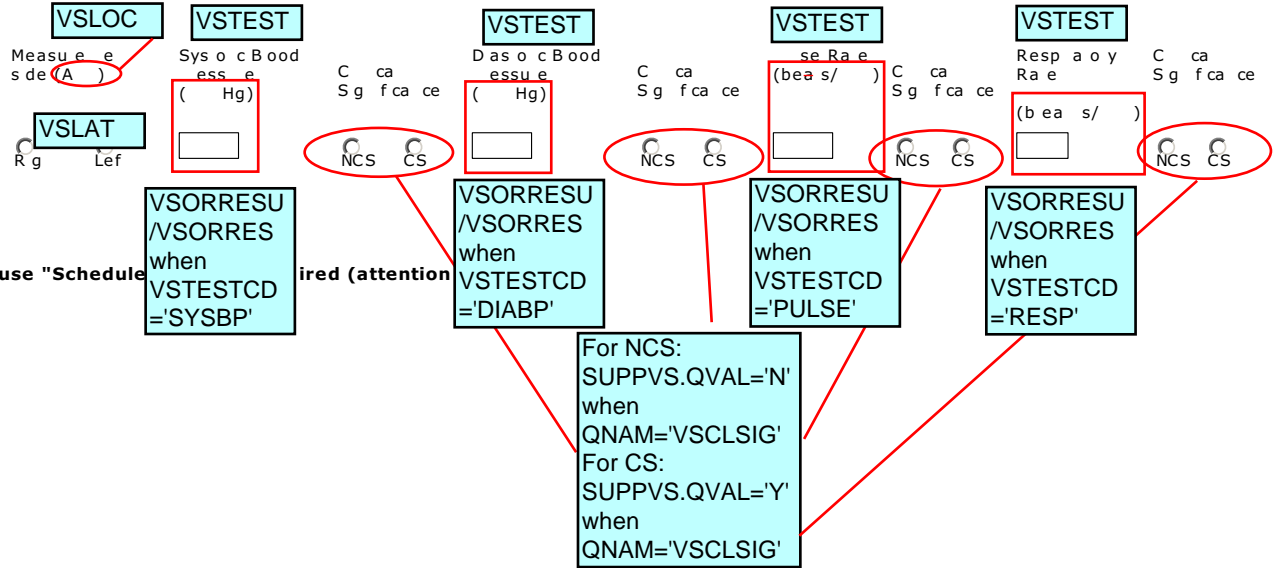
Vital Signs incl. VSTPT (2.0)

VSTPT



VSSTAT='NOT DONE'
when
VSTESTCD='VSALL'

Please insert as many new rows as needed for the according visits and use "Schedule" as a reference



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VS=Vital Signs

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Body Temperature (2.1)

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

VSSTAT='NOT DONE'

5 0

VSORRESU /VSORRES when VSTESTCD='TEMP'

For NCS: SUPPVS.QVAL='N' when QNAM='VSCLSIG' For CS: SUPPVS.QVAL='Y' when QNAM='VSCLSIG'

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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EG=ECG Test Results

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

12-lead ECG (2.0) EGMETHOD='12 LEAD STANDARD'

EGTEST='ECG Mean Heart Rate'

EGTEST

No do e	Reaso o do e	Da e e	Measu e e pos o	Hea Ra e (bea s/)	I e p e a o	C ca S g f ca ce	F d gs, select all that apply
1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EGREASND

EGDTC

EGPOS

SUPPEG.QVAL when QNAM='CODE'

EGSTAT='NOT DONE' when EGTESTCD='EGALL'

EGORRESU/EGORRES when EGTESTCD='EGHRMN'

EGORRES when EGTESTCD='INTP'

For NCS: SUPPEG.QVAL='N' when QNAM='EGCLSIG' For CS: SUPPEG.QVAL='Y' when QNAM='EGCLSIG'

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

EGCAT='MEASUREMENT'

EGCAT='FINDING'

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LB=Laboratory Test Results

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Urine Drug Screen (2.0)

LBSPEC

LBTEST

Category Specimen Number Reason for doing Date

Marijuana Opioids Cocaine Cannabinoids Benzodiazepines Barbiturates Meadone cyclophosphamide Antidepressants

LBCAT='URINALYSIS'

LBSCAT='DRUG OF ABUSE'

LBSTAT='NOT DONE'
when
LBTESTCD='LBALL'

Negative Positive Negative Positive Negative Positive Negative Positive Negative Positive Negative Positive Negative Positive Negative Positive

LBORRES
when
LBTESTCD=
'METHAMPH'

LBORRES
when
LBTESTCD=
'COCAINE'

LBORRES
when
LBTESTCD=
'PCP'

LBORRES
when
LBTESTCD=
'BARB'

LBORRES
when
LBTESTCD=
'TRCYANDP'

LBORRES
when
LBTESTCD=
'OPIATE'

LBORRES
when
LBTESTCD=
'CANNAB'

LBORRES
when
LBTESTCD=
'BNZDZPN'

LBORRES
when
LBTESTCD=
'METHDN'

LBORRES
when
LBTESTCD=
'AMPHET'

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

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LB=Laboratory Test Results

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Alcohol Breath Test (2.0)

LBTEST='Ethanol'

Sponsor Study Code: BNT162-01

LBSPEC='EXPIRED AIR'

Category

Spec men

Not done

Reason not done

Date

T me

Resu t

LBREASND

LBDC

Negat ve

**LBORRES when
LBTESTCD='ETHANOL'**

Pos t ve

LBCAT='CHEMISTRY'

**LBSTAT=
'NOT
DONE'**

LBSCAT='DRUG OF ABUSE'

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

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LB=Laboratory Test Results

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Sponsor Study Code: BNT162-01

Urine Sampling for Urinalysis (2.0)

LBSPEC='URINE'

Category	Spec men	Not done	Reason not done	Date	Time
		<input type="checkbox"/>	LBREASND		LB DTC

LBCAT='URINALYSIS'

LBSTAT='NOT DONE'
when
LBTESTCD='LBALL'

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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LB=Laboratory Test Results

MB=Microbiology Specimen

CRS Study Code: 049/20
BioNTech BNT162 01 CRS 049 20 DEV
Blood Samples for Safety Lab (2.0)

Sponsor Study Code: BNT162-01

MBCAT='SEROLOGY'

MBCAT='SARS-CoV-2 Antibodies'

Blood samples for safety lab includes Serology, SARS-CoV-2 antibodies and FSH at Visit 0

Category	Specimen	Not done	Reason not done	Date	Time	Fasting?
LBCAT	LBSPEC	<input type="checkbox"/>	LBREASND		LBDTC	<input type="radio"/> No <input type="radio"/> Yes
MBCAT	MBSPEC	<input type="checkbox"/>	MBREASND		MBDTC	LBFAST

More rows: 5 0

LBSTAT='NOT DONE'
when LBTESTCD='LBALL'

MBSTAT='NOT DONE'
when MBTESTCD='MBALL'

All comments will be entered in the "Comments" field.

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

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IE=Inclusion/Exclusion Criteria Not Met

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 a n c us on cr ter a and does
not meet any exc us on cr ter a?

[NOT SUBMITTED]

Date

IEDTC

If No, please select a v o ated
In /Exc us on cr ter a:

In c us on Cr ter a:

IECAT='INCLUSION'

[Five dropdown menus for inclusion criteria]

**IEORRES='N' when
IETESTCD='INxx'**

Exc us on Cr ter a:

IECAT='EXCLUSION'

[Five dropdown menus for exclusion criteria]

**IEORRES='Y' when
IETESTCD='EXxx'**

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PE=Physical Examination

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Physical Examination (2.1)

Sponsor Study Code: BNT162-01

PESTAT='NOT DONE' when PETESTCD='HEALTHY'

Not done

Reason not done

Date

Time

Time

PETEST='Overall Health Judgement-Subj. healthy?'

Overall health judgement subject healthy? No Yes

PEORRES when PETESTCD='HEALTHY'

PECAT='GENERAL'

System/Organ

Normal/Abnormal/ND

Abnormalities/Symptoms

Concomitance

Finding (catalogued)

PESPID

PETEST

PEORRES

[NOT SUBMITTED]

PEORRES when...

[NOT SUBMITTED]

System/Organ	Normal	Abnormal	ND	Abnormalities/Symptoms	Concomitance	Finding (catalogued)
1 General condition/psyche	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='GENCON'	NCS <input type="radio"/> CS	[NOT SUBMITTED]
2 Skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='SKIN'	NCS <input type="radio"/> CS	
3 Lymph nodes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='LYMPHN'	NCS <input type="radio"/> CS	
4 Head (eyes, ears, mouth)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='HEAD'	NCS <input type="radio"/> CS	
5 Neck/thyroid gland	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='NECK'	NCS <input type="radio"/> CS	
6 Lungs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='LUNGS'	NCS <input type="radio"/> CS	
7 Heart	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='HEART'	NCS <input type="radio"/> CS	
8 Abdomen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='ABDOMEN'	NCS <input type="radio"/> CS	
9 Musculoskeletal system	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='MUSCULO'	NCS <input type="radio"/> CS	
10 Neurological system	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='NEUROL'	NCS <input type="radio"/> CS	
Vascular system	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='VASCUL'	NCS <input type="radio"/> CS	
12 Cardiovascular	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='CARDVASC'	NCS <input type="radio"/> CS	
13 Gastrointestinal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='GASTRO'	NCS <input type="radio"/> CS	
14 Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	...PETESTCD='OTHER'	NCS <input type="radio"/> CS	

SUPPPE.QVAL='N' when QNAM='PECLSIG'

SUPPPE.QVAL='Y' when QNAM='PECLSIG'

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MB=Microbiology Specimen

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Oral Swipe for SARS-CoV-2 Testing (2.1)

MBCAT='SARS-CoV-2 Test (Oral Swipe)'

MBMETHOD='QUANTITATIVE
REVERSE TRANSCRIPTASE
POLYMERASE CHAIN REACTION'

MBLOC='ORAL CAVITY'

MBTSTDTL='DETECTION'

Category

Specimen

Not done

Reason not done

Date

Time

Test name

Result

MBSPEC='SWABBED
MATERIAL'

Negative

MBORRES
when
MBTESTCD=
'SARSCOV2'

Positive

MBTEST='Severe Acute Resp
Syndrome Coronavirus 2'

More rows: 5 0

MBSTAT
='NOT
DONE'

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

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DS=Disposition

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Allocation (2.1)

DSTERM/DSDECOD='ALLOCATED'

Category DSCAT='PROTOCOL MILESTONE'

Date [2]

Time [3] DSSTDTC

Subjects allocated to Cohort [4]

Cohort 2

Cohort 3

Cohort 4

Cohort 5

Cohort 6

Cohort 7

Cohort 8

Cohort 9

Cohort 0

SUPPDS.QVAL when QNAM = 'COHORT'

Group A (BNT 62a) [5]

B (BNT 62b)

C (BNT 62b2)

D (BNT 62c2)

E (BNT 62c2 P/B)

SUPPDS.QVAL when QNAM = 'GROUP'

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IS=Immunogenicity Specimen Assessments

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Blood Samples for Immunogenicity (2.1)

ISCAT='IMMUNOGENICITY'

ISSPEC='SERUM'

Category

Specimen

Not done

Reason not done

Date

Time

More rows: 5 0

ISSTAT='NOT DONE'
when
ISTESTCD='ISALL'

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

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[NOT SUBMITTED]

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Blood Samples for CMI (2.1)

Sponsor Study Code: BNT162-01



Category	Spec men	Not done	Reason not done	Date	T me
<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

More rows: 5 0

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

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EC=Exposure as Collected

EX=Exposure

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Scheduled time

Not done If 'Not Done'='No' then ECOCCUR='Y'
If 'Not Done'='Yes' then ECOCCUR='N'

Reason not done if ECOCCUR='N':
SUPPEC.QVAL when
QNAM='ECREASOC'

Other, specify

Date

Time ECSTDTC EXSTDTC

Route of Administration ECROUTE EXROUTE

Treatment ECTRT EXTRT

Medication Number SUPPEC.QVAL when
QNAM='MED_NO' SUPPEX.QVAL when
QNAM='MED_NO'

Dose Form ECDOSFRM EXDOSFRM

Planned dose ug

Other, specify ug EXDOSE if 'Total
Dose given?' is 'Yes' If 'Total Dose given?' is 'No' then
EXDOSE='Total Dose (Volume of
Injection)' - 'Rest Volume' * 'Planned
Dose' / 'Total Dose (Volume of Injection)'

Unit EXDOSU

Total Dose (Volume of Injection) mL ECDOSE

Unit ECDOSU

Total Dose given? No Yes SUPPEC.QVAL when QNAM='TOTDOS' SUPPEX.QVAL when QNAM='TOTDOS'

If No, rest volume mL SUPPEC.QVAL when QNAM='RESTVOL' SUPPEX.QVAL when QNAM='RESTVOL'

Application site Right Left Upper arm Lower arm
ECLOC EXLOC
ECLAT EXLAT
ECDIR EXDIR

Adm n strat on accord ng to protoco ?

No Yes

SUPPEX.QVAL when QNAM='ADMPPROT'

SUPPEC.QVAL when QNAM='ADMPPROT'

If No, please specify

SUPPEX.QVAL when QNAM='ADMNPPSP'

SUPPEC.QVAL when QNAM='ADMNPPSP'

Ep /Pandem c re ated adjustment

No Yes

SUPPEX.QVAL when QNAM='EXEPADJI'

SUPPEC.QVAL when QNAM='ECEPADJI'

Ep /Pandem c re ated interrupt on

No Yes

SUPPEX.QVAL when QNAM='EXEPINTI'

SUPPEC.QVAL when QNAM='ECEPINTI'

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FACE=Findings About Clinical Events

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Local Tolerability at Injection Site (2.1)

FACAT=REACTOGENICITY

Sponsor Study Code: BNT162-01

FAOBJ

[NOT SUBMITTED]

FASCAT=ADMINISTRATION SITE

FAEVAL=INVESTIGATOR

FASTAT=NOT DONE when
FAOBJ=All Objects of the Observation

FAORRES='N' when
FATESTCD='OCCUR'

FATEST=Occurrence Indicator

FAORRES='Y' when
FATESTCD='OCCUR'

FAORRES
when
FATESTCD='SEV'

FATEST=Severity/Intensity

Category	Scheduled	Reason Done	Date	Event Name	Evaluation	Intensity of Adverse Event	Intensity of Eye/Ear/Redness	Intensity of Injection/Swelling
1	<input type="text"/>	<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"/> Life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life threatening

Maximums: 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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FACE=Findings About Clinical Events

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Systemic Events Assessment

FACAT='REACTOGENICITY'

[1]

[NOT SUBMITTED]

Category [2] Scheduled time [3] Not done [4] Reason not done [5] Date [6] Time [7] Investigator Name [8] Evaluator [9] Fever [10]

FASCAT='SYSTEMIC' FATPT FAREASND FADTC FAEVAL='INVESTIGATOR'

FASTAT='NOT DONE' when FAOBJ='All Objects of the Observation'

FAORRES='N' when FATESTCD='OCCUR'

FATEST='Occurrence Indicator'

FAORRES='Y' when FATESTCD='OCCUR'

Intensity of Headache [11]	New or worsened muscle pain [12]	New or worsened joint pain [13]	Intensity of Nausea [14]	Intensity of Vomiting [15]	Intensity of Diarrhea [16]	Intensity of Chills [17]	Intensity of Loss of appetite [18]	Intensity of Malaise [19]	Fatigue/Irritability [20]
<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None	<input type="radio"/> None
<input type="radio"/> Mild	<input type="radio"/> Mild	<input type="radio"/> Mild	<input type="radio"/> Mild	<input type="radio"/> Mild	<input type="radio"/> Mild	<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"/> Moderate	<input type="radio"/> Moderate	<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"/> Severe	<input type="radio"/> Severe	<input type="radio"/> Severe	<input type="radio"/> Severe	<input type="radio"/> Severe	<input type="radio"/> Severe
<input type="radio"/> Potentially life threatening	<input type="radio"/> Potentially life threatening	<input type="radio"/> Potentially life threatening	<input type="radio"/> Potentially life threatening	<input type="radio"/> Potentially life threatening	<input type="radio"/> Potentially life threatening	<input type="radio"/> Potentially life threatening	<input type="radio"/> Potentially life threatening	<input type="radio"/> Potentially life threatening	<input type="radio"/> Potentially life threatening

FAORRES when FATESTCD='SEV'

FATEST='Severity/Intensity'

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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XA=Ancillary Analysis and Visit Details

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Phone Call (2.0)

XACAT='PHONE CALL'

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	XATEST	XATEST	XATEST
Not done	Reason not done	Date	Time
Outcome of the call (e.g. No findings or new AEs/CMs reported)			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
<p>More rows: 5 0</p> <p>XAORRES when XATESTCD='REAS_ND'</p>		XADTC	XAORRES when XATESTCD='OUT_CALL'

[NOT SUBMITTED]

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

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

XAORRES when XATESTCD='ND' when 'Yes'

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DS=Disposition

DM=Demographics

CRS Study Code: 049/20

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Sponsor Study Code: BNT162-01

End of Trial (2.1)

DSSCAT='END OF TRIAL'

Category

DSCAT='DISPOSITION EVENT'

Tr a fu y completed?

No Yes

DSTERM='END OF TRIAL COMPLETED' when Yes

[NOT SUBMITTED]

DSDECOD='COMPLETED' when Yes

Date of Comp et on or Ear y W thdrawa

DSSTDTC

Ma n Reason for premature term nat on

- Adverse Event
- Death
- Lost to Fo ow up
- Phys c an Dec s on
- Pregnancy
- Protoco Dev at on
- Screen Fa ure
- S te Term nated by Sponsor
- Study Term nated by Sponsor
- Techn ca Prob ems
- W thdrawa by Subject
- Other

DSTERM when not Other
[Note: If Epi-Pandemic related response is 'Yes', " due to COVID-19" is appended to DSTERM]

DSDECOD

Date of Death

DTHDTC

Other, spec fy:

DSTERM when DSDECOD is OTHER

SUPPDS.QVAL when QNAM = 'DSEPRELI'

Epi /Pandem c re ated

No Yes

SUPPDS.QVAL when QNAM = 'LASTCONT' for non-completer

Date of ast v s t/contact

[NOT SUBMITTED] for completer

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DS=Disposition

see CRF page 25

Sponsor Study Code: BNT162-01

CRS Study Code: 049/20
BioNTech BNT162 01 CRS 049 20 DEV
End of Follow-up (2.1)

DSSCAT='END OF FOLLOW-UP'

Category

DSCAT='DISPOSITION EVENT'

Follow up fully completed? No Yes

DSTERM='END OF FOLLOW-UP COMPLETED' when Yes

Date of Completion or Early Withdrawal

DSDECOD = 'COMPLETED' when Yes

Main Reason for premature termination

- Adverse Event
- Death
- Lost to Follow up
- Physcian 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:

Epidemic/Pandemic related No Yes

Date of last visit/contact

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MH=Medical History

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Medical History (2.0)

Sponsor Study Code: BNT162-01

No Yes [1]

Any Medical History?

[NOT SUBMITTED]

If Ongoing, please specify intensity (toxicity grading scale)

Abnormality/Disease [2] Start Date [3] End Date [4] Ongoing [5]

	Abnormality/Disease [2]	Start Date [3]	End Date [4]	Ongoing [5]
	MHTERM	MHSTDTC	MHENDTC	<input type="radio"/> No <input type="radio"/> Yes
2				<input type="radio"/> No <input type="radio"/> Yes
3				<input type="radio"/> No <input type="radio"/> Yes
4				<input type="radio"/> No <input type="radio"/> Yes
5				<input type="radio"/> No <input type="radio"/> Yes
6				<input type="radio"/> No <input type="radio"/> Yes
7				<input type="radio"/> No <input type="radio"/> Yes
8				<input type="radio"/> No <input type="radio"/> Yes
9				<input type="radio"/> No <input type="radio"/> Yes
0				<input type="radio"/> No <input type="radio"/> Yes

More rows: 5 0

MHENRTPT='BEFORE' MHENRTPT='ONGOING'

MHENTPT='SCREENING'

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XA=Ancillary Analysis and Visit Details

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

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Observation Period (2.0) **XACAT='OBSERVATION PERIOD'**

XATEST

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

VISIT [dropdown] [dropdown] [input]

No Yes

[input]

[input]

More rows: 5 0

XATPT

XAORRES when XATESTCD='VACCIN_V'

SUPPXA.QVAL when QNAM = 'ACT_TPT'

SUPPXA.QVAL when QNAM = 'REASON'

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

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Diary - Local Reactions (2.1)

CECAT='REACTOGENICITY'

FACAT='REACTOGENICITY'

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.

CETERM='Injection site reaction - <reaction type>'

FAOBJ='Injection site reaction - <reaction type>'

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Category [1] Study Day [2] Date [4] Time [5] Test Name [6] Evaluator [7] Intensity of Pain [8] Intensity of Tenderness [9] Intensity of Erythema/Redness [10] Intensity of Induration/Swelling [11]

SUPPFACE.QVAL when QNAM='STUDYDAY'

[NOT SUBMITTED]

FAEVAL='STUDY SUBJECT'

ASCAT='ADMINISTRATION SITE'

ASCAT='ADMINISTRATION SITE'

FASTAT='NOT DONE' when FAOBJ='All Objects of the Observation'

FAORRES='N' when FATESTCD='OCCUR'

FATEST='Occurrence Indicator'

FAORRES='Y' when FATESTCD='OCCUR'

FAORRES when FATESTCD='SEV'

FATEST='Severity/Intensity'

CEOCCUR='Y'

Category [1]	Study Day [2]	Date [4]	Time [5]	Test Name [6]	Evaluator [7]	Intensity of Pain [8]	Intensity of Tenderness [9]	Intensity of Erythema/Redness [10]	Intensity of Induration/Swelling [11]
						<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening
2						<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening
3						<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening
4						<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening
5						<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially threatening

6	<input type="text"/>	<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"/> None	<input type="radio"/> None	<input type="radio"/> None
								<input type="radio"/> M d	<input type="radio"/> M d	<input type="radio"/> M d	<input type="radio"/> M d
								<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"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng
7	<input type="text"/>	<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"/> None	<input type="radio"/> None	<input type="radio"/> None
								<input type="radio"/> M d	<input type="radio"/> M d	<input type="radio"/> M d	<input type="radio"/> M d
								<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"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng
8	<input type="text"/>	<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"/> None	<input type="radio"/> None	<input type="radio"/> None
								<input type="radio"/> M d	<input type="radio"/> M d	<input type="radio"/> M d	<input type="radio"/> M d
								<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"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng
9	<input type="text"/>	<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"/> None	<input type="radio"/> None	<input type="radio"/> None
								<input type="radio"/> M d	<input type="radio"/> M d	<input type="radio"/> M d	<input type="radio"/> M d
								<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"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng	<input type="radio"/> Potent a y fe threaten ng

More rows: 5 0

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CE=Clinical Events

FACE=Findings About Clinical Events

VS=Vital Signs

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Diary - Systemic Reactions (2.1)

CECAT='REACTOGENICITY'

FACAT='REACTOGENICITY'

VSCAT='REACTOGENICITY'

VSORRESU/VSORRES when VSTESTCD='TEMP'

CETERM
FAOBJ

If any grading of any reaction is not NONE and not related to IMP, or subject has fever [i.e., temperature is >= 38°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 >= 38°C], please document as diagnosis on Adverse Event Page.

CESCAT='SYSTEMIC'

FASCAT='SYSTEMIC'

VSSCAT='SYSTEMIC'

[NOT SUBMITTED]

VSTEST='Temperature'

CETERM='Fever'

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by	Date [4]	Time [5]	Test Name [6]	Evaluator [7]	Body Temperature (°C) [8]	Intensity of Headache [9]	Intensity of Myalgia [10]	Intensity of Arthralgia [11]	Intensity of Nausea [12]	Intensity of Vomiting [13]	Intensity of Diarrhea [14]	Intensity of Chills [15]	Intensity of Loss of appetite [16]	Intensity of Malaise [17]	Intensity of Fatigue [18]
1						None	None	None	None	None	None	None	None	None	None
						Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild
						Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
						Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe
						Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening
						None	None	None	None	None	None	None	None	None	None
						Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild
						Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
						Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe
						Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening
3						None	None	None	None	None	None	None	None	None	None
						Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild
						Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
						Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe
						Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening
4						None	None	None	None	None	None	None	None	None	None
						Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild
						Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
						Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe
						Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening
5						None	None	None	None	None	None	None	None	None	None
						Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild
						Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
						Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe
						Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening
6						None	None	None	None	None	None	None	None	None	None
						Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild
						Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
						Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe
						Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening
7						None	None	None	None	None	None	None	None	None	None
						Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild	Mild
						Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
						Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe	Severe
						Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening	Potentially life threatening

SUPPFACE.QVAL when QNAM='STUDYDAY'

FASTAT='NOT DONE' when FAOBJ='All Objects of the Observation'

VSSTAT='NOT DONE' when VSTESTCD='TEMP'

FAEVAL='STUDY SUBJECT'

FATEST='Occurrence Indicator'

FAORRES='N' when FATESTCD='OCCUR'

FAORRES='Y' when FATESTCD='OCCUR'

FAORRES when FATESTCD='SEV'

FATEST='Severity/Intensity'

CEOCCUR='Y'

8

- | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|
| <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None |
| <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <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"/> Moderate | <input type="radio"/> Moderate | <input type="radio"/> Moderate | <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"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe |
| <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening |

9

- | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|
| <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None | <input type="radio"/> None |
| <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <input type="radio"/> Mild | <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"/> Moderate | <input type="radio"/> Moderate | <input type="radio"/> Moderate | <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"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe | <input type="radio"/> Severe |
| <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening | <input type="radio"/> Potentially life threatening |

More rows 1 5 10

090177e196736676\Final\Final On: 08-Mar-2021 02:01 (GMT)

FACE=Findings About Clinical Events

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Sponsor Study Code: BNT162-01

Unrelated Clinical Events (2.0)

FACAT='REACTOGENICITY'

No Yes [1]

Any local/systemic reactions **NOT RELATED** to IMP

[NOT SUBMITTED]

Category [2] Study Day [3] Date [4] Time [5] Test Name [6] Local/systemic reaction [7]

FASCAT

FADTC

FAOBJ

More rows

SUPPFACE.QVAL when QNAM='STUDYDAY'

FATEST='Occurrence Indicator'

FAORRES='Y' when FATESTCD='OCCUR'

Please insert as many new rows as needed.

090177e196736676\Final\Final On: 08-Mar-2021 02:01 (GMT)

AE=Adverse Events

AE reporting according to BNT 62 reporting of AE and each on 03 July 2020

AECAT = 'GENERAL' when 'No'
AECAT = 'SPECIAL INTEREST' when 'Yes'

Any Adverse Events? No Yes [1]

[NOT SUBMITTED]

[NOT SUBMITTED]

SUPPAE.QVAL when QNAM='AETRTEM'

AECONTRT

AEGRPID

AESPID

AETERM

AESER

AESCONG

AE of special interest [6]

Epi/Pandemic related [7]

AESTDTC

Start time unkn. [10]

AEENDTC

End time unkn. [13]

Ongoing [14]

AESEV

AETOXGR

AEREL

AEACN

AEOUT

AE Group ID [23]

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AE No. [2]	Adverse Event [3]	Serious [4]	Reason, select all that apply [5]	AE of special interest [6]	Epi/Pandemic related [7]	Start Date [8]	Start time [9]	Start time unkn. [10]	End Date [11]	End time [12]	End time unkn. [13]	Ongoing [14]	Severity/intensity [15]	Intensity (toxicity grading scale) [16]	Relationship to treatment emergent AE [17]	Relationship to MP treatment [18]	DL (Dose limiting toxicity) [19]	Action taken with MP treatment [20]	Concomitant medication or therapy [21]	Outcome of AE [22]	AE Group ID [23]
1		<input type="radio"/> No <input checked="" type="radio"/> Yes	<input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/ncapacity <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 type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<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"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially Life threatening	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> Not related <input type="radio"/> Related	<input type="radio"/> No <input 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 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		
2		<input type="radio"/> No <input type="radio"/> Yes	<input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/ncapacity <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 type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<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"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially Life threatening	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> Not related <input type="radio"/> Related	<input type="radio"/> No <input 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 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		
3		<input type="radio"/> No <input type="radio"/> Yes	<input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/ncapacity <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 type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<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"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially Life threatening	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> Not related <input type="radio"/> Related	<input type="radio"/> No <input 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 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		
4		<input type="radio"/> No <input type="radio"/> Yes	<input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/ncapacity <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 type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<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"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially Life threatening	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> Not related <input type="radio"/> Related	<input type="radio"/> No <input 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 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		

SUPPAE.QVAL when QNAM='AEEPRESLI'

[NOT SUBMITTED]

AEENRTPT='ONGOING'
AEENTPT='END OF STUDY'

SUPPAE.QVAL when QNAM='AE_DLT'

CM=Concomitant/Prior Medications

CRS Study Code: 049/20

Sponsor Study Code: BNT162-01

BioNTech BNT162 01 CRS 049 20 DEV

Prior/Concomitant Medication/Therapy (2.0)

[NOT SUBMITTED]

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 CMTRT	<input type="radio"/> No <input type="radio"/> Yes	CMSTDTC		<input type="checkbox"/>	CMENDTC		<input type="checkbox"/>	<input type="radio"/> No <input type="radio"/> Yes	CMROUTE							CMINDC			
2	<input type="radio"/> No <input type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<input type="radio"/> No <input type="radio"/> Yes											
3	<input type="radio"/> No <input type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<input type="radio"/> No <input type="radio"/> Yes											
4	<input type="radio"/> No <input type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<input type="radio"/> No <input type="radio"/> Yes											
5	<input type="radio"/> No <input type="radio"/> Yes			<input type="checkbox"/>			<input type="checkbox"/>	<input type="radio"/> No <input type="radio"/> Yes											

CMDOSTXT

CMDOSU

CMDOSFRQ

CMROUTE

CMINDC

CMSTRPT='AFTER'
 CMSTRPT='BEFORE'
 CMSTTPT='STUDY START'

[NOT SUBMITTED]

[NOT SUBMITTED]

CMENRTPT='ONGOING'
 CMENRTPT='END OF STUDY'

SUPPCM.QVAL when QNAM='O_ROUTE'

SUPPCM.QVAL when QNAM='O_UNIT'

SUPPCM.QVAL when QNAM='O_FREQ'

SUPPCM.QVAL when QNAM='AE_NO1'

SUPPCM.QVAL when QNAM='AE_NO2'

SUPPCM.QVAL when QNAM='AE_NO3'

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CO=Comments

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Comments (2.0)

Sponsor Study Code: BNT162-01

No Yes [NOT SUBMITTED]

COREF Any Comments?

V s t	Modu	T mepo nt	Comment	Date of Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	COVAL COVAL1	CODTC
2	<input type="text"/>	<input type="text"/>		
3	<input type="text"/>	<input type="text"/>		
4	<input type="text"/>	<input type="text"/>		
5	<input type="text"/>	<input type="text"/>		

More rows: 5 0

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DV=Protocol Deviations

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Protocol Deviations (2.1)

Sponsor Study Code: BNT162-01

Any Protocol Deviations? No Yes

[NOT SUBMITTED]

DVREFID

V s t	Modu	T mepo nt	Descr pt on of Dev at on	Reason for Dev at on	Category	Date of Occurrence
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	SUPPDV.QVAL when QNAM='DVREAS'	<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: 5 0

if DVDECOD='COVID 19 IMPACT', SUPPDV.QVAL='Y' when QVAL='DVEPRELI'. Otherwise, SUPPDV.QVAL='N' when QVAL='DVEPRELI'

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XA=Ancillary Analysis and Visit Details

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 [1] XACAT='PHARMACOGENETIC ANALYSIS'

Spec men [2] [NOT SUBMITTED]

XATEST='Informed Consent given'

Informed Consent for pharmacogenetic analysis given? No Yes [3] XAORRES when XATESTCD='IC_GIVEN'

Date of IC for pharmacogenetic analysis [4]

XADTC

Time of IC for pharmacogenetic analysis [5]

Aliquot taken from previous CMI sampling

Date of previous CMI sampling for analysis [6] Time of previous CMI sampling for analysis [7]

SUPPXA.QVAL when QNAM='PG_CMI', QLABEL='PG Aliquot from previous CMI'

More rows: 5 0

Please insert as many new rows as needed. XACAT='HLA TYPING SAMPLING'

Informed Consent for separate HLA typing sampling given? No Yes [8] XAORRES when XATESTCD='IC_GIVEN'

XATEST='Informed Consent given'

Date [9]

XADTC

Time [10]

Separate Blood Sampling for HLA typing taken

Date of HLA typing sampling [11]

Time of HLA typing sampling [12]

SUPPXA.QVAL when QNAM='HLA_BS', QLABEL='Separate Blood Sampling for HLA'

HLA typing Blood Sampling aliquot taken from CMI sampling

Date of corresponding CMI sampling [13] Time of corresponding CMI sampling [14]

SUPPXA.QVAL when QNAM='HLA_CMI', QLABEL='HLA Aliquot from previous CMI'

More rows: 5 0

Please insert as many new rows as needed.

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DS=Disposition

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Sponsor Study Code: BNT162-01

Informed Consent (uns.) (2.1) DSTERM/DSDECOD='INFORMED CONSENT RECONSENTED'

DSCAT='PROTOCOL MILESTONE'

Category [1] Date [2] Time [3] Protocol Version [4]

SUPPDS.QVAL when QNAM = 'PROTVERS'

More rows: 5 0

Please insert as many new rows as needed.

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XA=Ancillary Analysis and Visit Details

CRS Study Code: 049/20

BioNTech BNT162 01 CRS 049 20 DEV

Informed Consent + Blood Sampling for Research

Sponsor Study Code: BNT162-01

Category [1] XACAT='BLOOD SAMPLING FOR RESEARCH'

Spec men [2] [NOT SUBMITTED]

XATEST='Informed Consent given'

Informed Consent for Blood sampling for research purposes? No Yes [3] XAORRES when XATESTCD='IC_GIVEN'

Date [4]

XADTC

Time [5]

Blood Sampling for Research purposes

Date of Blood sampling [6] Time of Blood sampling [7]

SUPPXA.QVAL when QNAM='RES_BS', QLABEL='Blood Sampling for Research Purposes'

More rows: 5 0

Please insert as many new rows as needed.

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