

<b>Site:</b>	CRS Berlin
<b>Group:</b>	Part A
<b>Subject Identifier:</b>	276-02-0242
<b>Status:</b>	Allocated

Row	No do e	Reaso do e	Da e	e	Hea Ra e (bea s/ )	I e p e a o	C ca Sg f ca ce	F d gs, select all that apply
1	[ ]		28/08/2020 28 Aug 2020	09:30	88	[x] No a [ ] Ab o a	[ ] NCS [ ] CS	

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time	Result
1		[ ]		28/08/2020 28-Aug-2020	09:08	[x] Negative [ ] Positive

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		28/08/2020 28-Aug-2020	09:38	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

**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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Row	Tools done	Not done	Reason not done	Date	Time	Height (cm)	Weight (kg)	Body Mass Index (kg/m <sup>2</sup> )	BMI (calculated) (kg/m <sup>2</sup> )
1	[ ]			28/08/2020 28-Aug-2020	09:21	166	67,5	24,5	24,5

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

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Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		28/08/2020 28-Aug-2020	09:37	Oral		36,9	<input type="checkbox"/> NCS <input type="checkbox"/> CS

**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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Childbearing potential  No  Yes  NA

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

Date of Last menses   
  
UN-UNK-2004

Date of Sterilization

Other, *please specify*

Age  years

months

Sex  Male  
 Female

Race, *select all that apply*  
 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

Ethnicity  Not Hispanic or Latino  
 Hispanic or Latino  
 Not reported  
 Unknown



[ ] No [x] Yes

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

Date   
04-Sep-2020

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

Inclusion Criteria:

Exclusion Criteria:

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U' ab & (a^} ca: H G I E C E G G

Ua^k OÜÜÁ: Hã  
Xaãkãã€

Ö: [ ^ ] kUãó€  
Ø: { kQ- { { ^ãÁ [ ] • ^ } ó€

Date  \*  
28-Aug-2020

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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[ ]  
Not done

Reason not done

Date

28-Aug-2020

Time

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	<input type="text" value="General condition/p syche"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2	<input type="text" value="Skin"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3	<input type="text" value="Lymph nodes"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4	<input type="text" value="Head (eyes, ears, mouth)"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
5	<input type="text" value="Neck/thyroid gland"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
6	<input type="text" value="Lungs"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
7	<input type="text" value="Heart"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
8	<input type="text" value="Abdomen"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
9	<input type="text" value="Musculoskeletal system"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
10	<input type="text" value="Neurological system"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS

11	Vascular system	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
12	Cardiovascular	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
13	Gastrointestinal	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
14	Other	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS

[ ]

Row	Tools	Not done	Reason not done	Date	Time	Methamphetamines	Opiates	Cocaine	Cannabinoids	Phencyclidine	Benzodiazepines	Barbiturates	Methodone	Tricyclic antidepressants	Amphetamines
1	[ ]			28/08/2020 28-Aug-2020	09 05	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive

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

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[ ]

Row	Tools NA	Not done	Reason not done	Date	Time	Result
1	[x]	[ ]				[ ] Negative [ ] Positive

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			28/08/2020 28-Aug-2020	09:05

**All comments will be entered on comment page!**

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Row	No o o s d o e	Reaso d o e	o	Da e	e	Measu e e s de (A )	Sys o c B ood essu e ( Hg)	C ca Sg fca ce	Das o c B ood essu e ( Hg)	C ca Sg fca ce	use Ra e (bea s/ )	C ca Sg fca ce	Resp a o y Ra e (b ea s/ )	C ca Sg fca ce
1	[ ]			28/08/2020 28 Aug 2020	09:32	[ ] R g [x] Lef	142	[x] NCS [ ] CS	81	[ ] NCS [ ] CS	83	[ ] NCS [ ] CS	17	[ ] NCS [ ] CS

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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Row	oos	No do e	Reaso do e	o	Da e	e	Hea Ra e (bea s/ )	I e p e a o	C ca Sg f ca ce	F d gs, select all that apply					
1	[ ]				09/09/2020 09 Sep 2020	09:05	80	[x] No a [ ] Ab o a	[ ] NCS [ ] CS						

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

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Not done

Reason not done

Other, specify

Date   
09-Sep-2020

Time

Medication Number

Planned dose  ug

Other, specify  ug

Total Dose (Volume of Injection)  mL

Total Dose given?  No  Yes

If No, rest volume  mL

Application site  right  left upper arm

Administration according to protocol?  No  Yes

If No, please specify

Epi/Pandemic related adjustment  No  Yes

Epi/Pandemic related interruption  No  Yes

[ ]

Row	Tools	Not done	Reason not done	Date	Time	Result
1		<input type="checkbox"/>		<input type="text" value="09/09/2020"/> 09-Sep-2020	<input type="text" value="08:52"/>	<input checked="" type="checkbox"/> Negative <input type="checkbox"/> Positive

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Date   
09-Sep-2020

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  
 Cohort 11  
 Cohort 12  
 Cohort 13

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

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			09/09/2020 09-Sep-2020	09:30

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

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[ ]

Row	Tools	Not done	Reason not done	Date	Time
1		[ ]		09/09/2020 09-Sep-2020	09:30

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

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[ ]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		09/09/2020 09-Sep-2020	09:30	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes

**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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Row	Tools	Scheduled time	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		Predose	<input type="checkbox"/>		09/09/2020 09-Sep-2020	09:05	Oral		37	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		09/09/2020 09-Sep-2020	10:58	Oral		36,5	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		09/09/2020 09-Sep-2020	12:55	Oral		36,6	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		09/09/2020 09-Sep-2020	15:50	Oral		36,8	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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



[ ] No [x] Yes

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

Date   
09-Sep-2020

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

Inclusion Criteria:

Exclusion Criteria:

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U' ab & (a) ca H G I E C E G G

Ua K O U U A O N H a  
Xa a K a a F

O: [ ^ ] K U a o C E  
Q [ { K S [ & a V [ ^ : a a a a A e Q b & a } U a A C E D

[ ]

Row	oos	Scheduled e	No do e	Reason do e	o	Date	Time	Issues of a	Issues of e de ess	Issues of Eye e a/Red ess	Issues of I du a o /Swe g
1		1 ou	[ ]			09/09/2020 09 Sep 2020	11:00	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g
2		3 ou s	[ ]			09/09/2020 09 Sep 2020	13:00	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g
3		6 ou s	[ ]			09/09/2020 09 Sep 2020	15:57	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g

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

[ ]

Row	Tools	Not done	Reason not done	Date	Time	Test name	Result
1	[ ]			08/09/2020 08-Sep-2020	10:04	On site: Qiagen	[x] Negative [ ] Positive

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

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[ ]

Not done

Reason not done

Date

09-Sep-2020

Time

Overall health judgement -  No  Yes  
subject healthy?

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
5	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
6	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
7	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
8	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
9	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
10	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
11	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
12	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
13	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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U' ab & (A) caa HGI ECE G

Ua KOUUO:ia  
Xa aKa aF

O: [ ] KUa oCE  
Q: { KU@ aA Oca a aa } AED

14

[ ] Normal [ ] Abnormal [ ] ND

[ ] NCS [ ] CS

[ ]

Row	tools	Scheduled time	Not done	Reason not done	Date	Time	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	Fatigue/ redness	
		hour	<input type="checkbox"/>		09/09/2020 09 Sep 2020	:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening
2		3 hours	<input type="checkbox"/>		09/09/2020 09 Sep 2020	3:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	
3		6 hours	<input type="checkbox"/>		09/09/2020 09 Sep 2020	5:58	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	

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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[ ]

Row	Tools	Not done	Reason not done	Date	Time	Methamphetamines	Opiates	Cocaine	Cannabinoids	Phencyclidine	Benzodiazepines	Barbiturates	Methadone	Tricyclic antidepressants	Amphetamines
1	[ ]			09/09/2020 09-Sep-2020	08 50	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive	[x] Negative [ ] Positive

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

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[ ]

Row	Tools NA	Not done	Reason not done	Date	Time	Result
1	[x]	[ ]	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] Negative [ ] Positive

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

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[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			09/09/2020 09-Sep-2020	08:50

**All comments will be entered on comment page!**

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U' ab & (a) ca HK I ECE G

Ua KOUUA:ia  
Xa aKa aF

O: [ ^ ] K U a o E  
Q: { K a a U a } • A & B XUVUVA CED

Row	Tools	Scheduled time	Not done	Reason not done	Date	Time	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		Predose	<input type="checkbox"/>		09/09/2020 09-Sep-2020	09 06	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	140	<input type="checkbox"/> NCS <input type="checkbox"/> CS	70	<input type="checkbox"/> NCS <input type="checkbox"/> CS	82	<input type="checkbox"/> NCS <input type="checkbox"/> CS	20	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		09/09/2020 09-Sep-2020	10 57	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	142	<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CS	75	<input type="checkbox"/> NCS <input type="checkbox"/> CS	67	<input type="checkbox"/> NCS <input type="checkbox"/> CS	18	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		09/09/2020 09-Sep-2020	12 57	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	140	<input type="checkbox"/> NCS <input type="checkbox"/> CS	70	<input type="checkbox"/> NCS <input type="checkbox"/> CS	64	<input type="checkbox"/> NCS <input type="checkbox"/> CS	15	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		09/09/2020 09-Sep-2020	15 53	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	131	<input type="checkbox"/> NCS <input type="checkbox"/> CS	69	<input type="checkbox"/> NCS <input type="checkbox"/> CS	66	<input type="checkbox"/> NCS <input type="checkbox"/> CS	19	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

[ ]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		10/09/2020 10-Sep-2020	09:00	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

**All comments will be entered on comment page!**

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		10/09/2020 10-Sep-2020	08:55	Oral		37,4	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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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U' ab & (A) caa H G I E C E G

Ua K O U U A O N i a  
Xa a K a a G

O i [ ^ ] K U a o C E  
Q i { K S i & a V [ ^ i a a a A a Q b & a } U a A G E D

[ ]

Row	Not Too s done	Reason not done	Date	T me	Intens ty of Pa n	Intens ty of Tenderness	Intens ty of Erythema/Redness	Intens ty of Indurat on/Swe ng
[ ]			0/09/2020 0 Sep 2020	08:59	<input type="checkbox"/> None <input checked="" type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input type="checkbox"/> None <input type="checkbox"/> M d <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Not done

Reason not done

Date

10-Sep-2020

Time

Overall health judgement - subject healthy? [ ] No [x] Yes

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
2	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
3	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
4	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
5	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
6	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
7	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
8	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
9	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
10	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
11	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
12	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
13	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS

14

[ ] Normal [ ] Abnormal [ ] ND

[ ] NCS [ ] CS

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time	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	Fatigue/ Irritability	
[ ]				0/09/2020	08:59	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)



[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			10/09/2020 10-Sep-2020	07:30

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**All comments will be entered on comment page!**

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

Row	No o o s d o e	Reaso d o e	o	Da e	e	Measu e e s de (A )	Sys o c Bood essu e ( Hg)	C ca Sg fca ce	Das o c Bood essu e ( Hg)	C ca Sg fca ce	use Ra e (bea s/ )	C ca Sg fca ce	Resp a o y Ra e (b ea s/ )	C ca Sg fca ce
1	[ ]			10/09/2020	09:56	[x] R g [ ] Lef	134	[ ] NCS [ ] CS	74	[ ] NCS [ ] CS	83	[ ] NCS [ ] CS	18	[ ] NCS [ ] CS

10 Sep 2020

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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**Only cohort 1-10: Phone call only valid for the first 6 subjects per cohort. For the last 6 subjects please tick NA.**

Row	Tools 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"/>		<input type="text" value="11/09/2020"/> 11-Sep-2020	<input type="text" value="08:41"/>	<input type="text" value="Findings/CMs reported"/>

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

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			15/09/2020 15-Sep-2020	09:12

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		15/09/2020 15-Sep-2020	09:12	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

**All comments will be entered on comment page!**

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools done	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1	<input type="checkbox"/>	<input type="checkbox"/>		15/09/2020 15-Sep-2020	08:57	Oral		36,8	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Not Too s done	Reason not done	Date	T me	Intens ty of Pa n	Intens ty of Tenderness	Intens ty of Erythema/Redness	Intens ty of Indurat on/Swe ng
[ ]			5/09/2020 5 Sep 2020	09:08	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Not done

Reason not done

Date

15-Sep-2020

Time

Overall health judgement - subject healthy? [ ] No [x] Yes

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
2	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
3	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
4	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
5	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
6	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
7	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
8	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
9	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
10	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
11	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
12	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS
13	<input type="text"/>	[ ] Normal [ ] Abnormal [ ] ND	<input type="text"/>	[ ] NCS [ ] CS



14

[ ] Normal [ ] Abnormal [ ] ND

[ ] NCS [ ] CS

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time	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	Fatigue/ Irritability	
[ ]				5/09/2020	09:09	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			15/09/2020 15-Sep-2020	08:52

**All comments will be entered on comment page!**

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	No o o s d o e	Reaso do e	o	Da e	e	Measu e e s de (A )	Sys o c Bood essu e ( Hg)	C ca Sg fca ce	Das o c Bood essu e ( Hg)	C ca Sg fca ce	use Ra e (bea s/ )	C ca Sg fca ce	Resp a o y Ra e (b ea s/ )	C ca Sg fca ce
1	[ ]			15/09/2020 15 Sep 2020	09:06	[x] R g [ ] Lef	142	[x] NCS [ ] CS	74	[ ] NCS [ ] CS	76	[ ] NCS [ ] CS	20	[ ] NCS [ ] CS

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

Not done

Reason not done

Other, specify

Date

Time

Medication Number

Planned dose  ug

Other, specify  ug

Total Dose (Volume of Injection)  mL

Total Dose given?  No  Yes

If No, rest volume  mL

Application site  right  left upper arm

Administration according to protocol?  No  Yes

If No, please specify

Epi/Pandemic related adjustment  No  Yes

Epi/Pandemic related interruption  No  Yes

Cohort 11, 12, 13 only: Administration delay due to intercurrent illness?  No  Yes

Reason for delay [ ] Adverse Event  
[ ] Medical History  
[ ] Other

Adverse Event term

AE no.

Medical History term

Other, specification

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			02/10/2020 02-Oct-2020	09:00

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Scheduled time	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		Predose	<input type="checkbox"/>		02/10/2020 02-Oct-2020	08:50	Oral		36,1	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input checked="" type="checkbox"/>	AE No.1+2						<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input checked="" type="checkbox"/>	AE No.1+2						<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input checked="" type="checkbox"/>	AE No.1+2						<input type="checkbox"/> NCS <input type="checkbox"/> CS

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



[ ]

Row	Study ID	Scheduled	No. of Doses	Reason	Date	Time	Visit 1	Visit 2	Visit 3	Visit 4
1	edose	[ ]			02/10/2020	09:05	<input checked="" type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input checked="" type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input checked="" type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input checked="" type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g
2	1 ou	[x]	AE No 1+2				<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g
3	3 ou s	[x]	AE No 1+2				<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g
4	6 ou s	[x]	AE No 1+2				<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g	<input type="checkbox"/> No e <input type="checkbox"/> M d <input type="checkbox"/> Mode a e <input type="checkbox"/> Seve e <input type="checkbox"/> o e a y fe ea e g

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Not done

Reason not done

Date

02-Oct-2020

Time

Overall health judgement - subject healthy?  No  Yes

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	<input type="text" value="General condition/p syche"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2	<input type="text" value="Skin"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3	<input type="text" value="Lymph nodes"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4	<input type="text" value="Head (eyes, ears, mouth)"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
5	<input type="text" value="Neck/thyroid gland"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
6	<input type="text" value="Lungs"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
7	<input type="text" value="Heart"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
8	<input type="text" value="Abdomen"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
9	<input type="text" value="Musculoskeletal system"/>	<input type="checkbox"/> Normal <input checked="" type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text" value="mild pain left costale arch"/>	<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS

10	Neurological system	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
11	Vascular system	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
12	Cardiovascular	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
13	Gastrointestinal	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
14	Other	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS

[ ]

Row	Tools	Scheduled time	Not done	Reason not done	Date	Time	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	Fatigue/ tiredness	
		Pre-dose	<input type="checkbox"/>		02/ 0/2020	09:05	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening
2		hour	<input checked="" type="checkbox"/>	E No 2			<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	
3		3 hours	<input checked="" type="checkbox"/>	E No 2			<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	
		6 hours	<input checked="" type="checkbox"/>	E No 2			<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools NA	Not done	Reason not done	Date	Time	Result
1	[x]	[ ]	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] Negative [ ] Positive

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Scheduled time	Not done	Reason not done	Date	Time	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		Predose	<input type="checkbox"/>		02/10/2020 02-Oct-2020	08:55	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	140	<input type="checkbox"/> NCS <input type="checkbox"/> CS	75	<input type="checkbox"/> NCS <input type="checkbox"/> CS	74	<input type="checkbox"/> NCS <input type="checkbox"/> CS	20	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input checked="" type="checkbox"/>	AE No 1+2			<input type="checkbox"/> Right <input type="checkbox"/> Left		<input type="checkbox"/> NCS <input type="checkbox"/> CS		<input type="checkbox"/> NCS <input type="checkbox"/> CS		<input type="checkbox"/> NCS <input type="checkbox"/> CS		<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input checked="" type="checkbox"/>	AE No 1+2			<input type="checkbox"/> Right <input type="checkbox"/> Left		<input type="checkbox"/> NCS <input type="checkbox"/> CS		<input type="checkbox"/> NCS <input type="checkbox"/> CS		<input type="checkbox"/> NCS <input type="checkbox"/> CS		<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input checked="" type="checkbox"/>	AE No 1+2			<input type="checkbox"/> Right <input type="checkbox"/> Left		<input type="checkbox"/> NCS <input type="checkbox"/> CS		<input type="checkbox"/> NCS <input type="checkbox"/> CS		<input type="checkbox"/> NCS <input type="checkbox"/> CS		<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

**Only cohort 1-10: Phone call only valid for the first 6 subjects per cohort. For the last 6 subjects please tick NA.**

Row	Tools NA	Not done	Reason not done	Date	Time	Outcome of the call (e.g. No findings or new AEs/CMS reported)
1	[x]	[ ]				

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

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			07/10/2020 07-Oct-2020	08:55

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)



[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			07/10/2020 07-Oct-2020	08:55

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		<input type="text" value="07/10/2020"/> 07-Oct-2020	<input type="text" value="08:55"/>	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

**All comments will be entered on comment page!**

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		07/10/2020 07-Oct-2020	08:48	Oral		36,7	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Not Too s done	Reason not done	Date	T me	Intens ty of Pa n	Intens ty of Tenderness	Intens ty of Erythema/Redness	Intens ty of Indurat on/Swe ng
[ ]			07/ 0/2020 07 Oct 2020	09: 2	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Not done

Reason not done

Date

07-Oct-2020

Time

Overall health judgement - subject healthy?  No  Yes

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	<input type="text" value="General condition/p syche"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2	<input type="text" value="Skin"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3	<input type="text" value="Lymph nodes"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4	<input type="text" value="Head (eyes, ears, mouth)"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
5	<input type="text" value="Neck/thyroid gland"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
6	<input type="text" value="Lungs"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
7	<input type="text" value="Heart"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
8	<input type="text" value="Abdomen"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
9	<input type="text" value="Musculoskeletal system"/>	<input type="checkbox"/> Normal <input checked="" type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text" value="mild pain left costal arch"/>	<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS

10	Neurological system	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
11	Vascular system	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
12	Cardiovascular	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
13	Gastrointestinal	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
14	Other	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS

[ ]

Row	Tools	Not done	Reason not done	Date	Time	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	Fatigue/ Irritability
[ ]				07/ 0/2020	09: 2	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			07/10/2020 07-Oct-2020	08:45

**All comments will be entered on comment page!**

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)



Row	No o o s d o e	Reaso do e	o	Da e	e	Measu e e s de (A )	Sys o c B ood essu e ( Hg)	C ca Sg f ca ce	Das o c B ood essu e ( Hg)	C ca Sg f ca ce	u se Ra e (bea s/ )	C ca Sg f ca ce	Resp a o y Ra e (b ea s/ )	C ca Sg f ca ce
1	[ ]			07/10/2020	08:53	[x] R g [ ] Lef	132	[ ] NCS [ ] CS	68	[ ] NCS [ ] CS	74	[ ] NCS [ ] CS	18	[ ] NCS [ ] CS

07 Oc 2020

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			21/10/2020 21-Oct-2020	09:10

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		21/10/2020 21-Oct-2020	08:45	Oral		36,6	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

Row	Not Too s done	Reason not done	Date	T me	Intens ty of Pa n	Intens ty of Tenderness	Intens ty of Erythema/Redness	Intens ty of Indurat on/Swe ng
[ ]			2 / 0/2020 2 Oct 2020	09:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng

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

[ ]

Not done

Reason not done

Date

21-Oct-2020

Time

Overall health judgement - subject healthy?  No  Yes

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	<input type="text" value="General condition/p syche"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2	<input type="text" value="Skin"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3	<input type="text" value="Lymph nodes"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4	<input type="text" value="Head (eyes, ears, mouth)"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
5	<input type="text" value="Neck/thyroid gland"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
6	<input type="text" value="Lungs"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
7	<input type="text" value="Heart"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
8	<input type="text" value="Abdomen"/>	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS

9	Musculoskeletal system	<input type="checkbox"/> Normal <input checked="" type="checkbox"/> Abnormal <input type="checkbox"/> ND	pain at lower frontal rib cage upon touch	<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CS
10	Neurological system	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND		<input type="checkbox"/> NCS <input type="checkbox"/> CS
11	Vascular system	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND		<input type="checkbox"/> NCS <input type="checkbox"/> CS
12	Cardiovascular	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND		<input type="checkbox"/> NCS <input type="checkbox"/> CS
13	Gastrointestinal	<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND		<input type="checkbox"/> NCS <input type="checkbox"/> CS
14	Other	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" type="checkbox"/> ND		<input type="checkbox"/> NCS <input type="checkbox"/> CS

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Q !{ K U • c { B A C ^ } o A E • ^ • • { ^ } c

[ ]

Row	Tools	Not done	Reason not done	Date	Time	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	Fatigue/ Irritability	
[ ]				2 / 0/2020	09:0	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening

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

Row	No oos do e	Reason do e	Date	Time	Measure (A)	Side	Systolic Blood Pressure (Hg)	Clinical Significance	Diastolic Blood Pressure (Hg)	Clinical Significance	Use Rate (beats/)	Clinical Significance	Respiratory Rate (beats/)	Clinical Significance
1	[ ]		21/10/2020 21 Oc 2020	08:50	[x] R g	[ ] Lef	136	[ ] NCS [ ] CS	70	[ ] NCS [ ] CS	74	[ ] NCS [ ] CS	16	[ ] NCS [ ] CS

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)



[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			28/10/2020 28-Oct-2020	09:23

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

[ ]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		28/10/2020 28-Oct-2020	09:23	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

**All comments will be entered on comment page!**

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

090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

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Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		28/10/2020 28-Oct-2020	09:04	Oral		37	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

[ ]

Row	Not Too s done	Reason not done	Date	T me	Intens ty of Pa n	Intens ty of Tenderness	Intens ty of Erythema/Redness	Intens ty of Indurat on/Swe ng
[ ]			28/ 0/2020 28 Oct 2020	09:3	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng

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

[ ]

Not done

Reason not done

Date

28-Oct-2020

Time

Overall health judgement -  No  Yes  
subject healthy?

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
5	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
6	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
7	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
8	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
9	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
10	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
11	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
12	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
13	<input type="text"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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U' ab & (A^} caa H G I E C E G G

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X a a k a a A C e F a F a C e S U B D C [ V D

O: [ ^ ] K U a o C E  
Q : { K U @ • a a O c a a a a } A C E D

14

[ ] Normal [ ] Abnormal [ ] ND

[ ] NCS [ ] CS

[ ]

Row	Tools	Not done	Reason not done	Date	Time	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	Fatigue/ Irritability	
[ ]				28/ 0/2020	09:32	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening

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

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			28/10/2020 28-Oct-2020	09:26

**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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Row	No oos do e	Reaso do e	o	Da e	e	Measu e e s de (A )	Sys o c B ood essu e ( Hg)	C ca Sg f ca ce	Das o c B ood essu e ( Hg)	C ca Sg f ca ce	u se Ra e (bea s/ )	C ca Sg f ca ce	Resp a o y Ra e (b ea s/ )	C ca Sg f ca ce
1	[ ]			28/10/2020	09:16	[x] R g [ ] Lef	139	[ ] NCS [ ] CS	71	[ ] NCS [ ] CS	83	[ ] NCS [ ] CS	16	[ ] NCS [ ] CS
				28 Oc 2020										

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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E reporting according to 62 reporting of E and reactions 03 July 2020

Any Adverse Events? [ ] No [x] Yes \*

Row	Event No	Adverse Event	Serious	Reason select all that apply	E of special interest	Epi./Pandemic related	Start Date	Start time	Start unknown	End Date	End time	End unknown	Ongoing	Serious/Intensify	Intensity (toxicity grading scale)	Treatment emergent	Relationship to BHP treatment	DL (Dose limiting toxicity)	Action taken with IMP treatment	Concomitant medication or therapy	Outcome of E	E Group ID
		costal pain left (pain left costal arch partly radiating into left shoulder)	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly or Birth Defect <input type="checkbox"/> Persist or Significant 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 checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	8/09/2020 8 Sep 2020	9:00					<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Mild <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially Life threatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> Not related <input type="checkbox"/> Related	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Dose not changed <input type="checkbox"/> Dose reduced <input type="checkbox"/> Drug withdrawn <input type="checkbox"/> Not applicable <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not recovered/not resolved <input type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolving <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
2		syncope	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly or Birth Defect <input type="checkbox"/> Persist or Significant Disability/Incapacity <input type="checkbox"/> Results in Death <input checked="" type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life threatening <input type="checkbox"/> Other Medically Important Serious Event	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	20/09/2020 20 Sep 2020	03:05		2 /09/2020 2 Sep 2020		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Mild <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially Life threatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> Not related <input type="checkbox"/> Related	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Dose not changed <input type="checkbox"/> Dose reduced <input type="checkbox"/> Drug interrupted <input checked="" type="checkbox"/> Drug withdrawn <input type="checkbox"/> Not applicable <input type="checkbox"/> Unknown	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Not recovered/not resolved <input checked="" type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolving <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown		

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090177e195ec824a\Final\Final On: 04-Jan-2021 03:10 (GMT)

Any Comments? [ ] No [x] Yes \*

Row	Tools Visit	Modul	Timepoint	Comment	Date of Comment
1	Phone Call at 48h	Phone Call		yesterday systemic reaction (headache 2, chills 1)today recovered, max Body temperature 37,9 Degree C at 10 SEP 2020 21:20 Hours , intake of Paracetamol 500mg at 10 SEP 2020, 21:45, thereafter temperature under 37 Degree Celsius, local reaction recovering	11/09/2020 11-Sep-2020

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Row	Study Day	Not done	Date	Time	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
		<input type="checkbox"/>	09/09/2020 09 Sep 2020	22:00	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
2	2	<input type="checkbox"/>	10/09/2020 10 Sep 2020	23:00	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
3	3	<input type="checkbox"/>	11/09/2020 11 Sep 2020	22:30	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
4	4	<input type="checkbox"/>	12/09/2020 12 Sep 2020	23:00	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
5	5	<input type="checkbox"/>	13/09/2020 13 Sep 2020	22:30	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
6	6	<input type="checkbox"/>	14/09/2020 14 Sep 2020	23:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
7	7	<input type="checkbox"/>	15/09/2020 15 Sep 2020	08:57	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening

Row	cols	Study Day	Not done	Date	Time	Body temperature (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	
			<input type="checkbox"/>	09/09/2020 09 Sep 2020	22:00	36.9	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening
2			<input type="checkbox"/>	09/09/2020 10 Sep 2020	2:20	37.9	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	
3			<input type="checkbox"/>	09/09/2020 10 Sep 2020	22:30	36.7	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	
			<input type="checkbox"/>	09/09/2020 12 Sep 2020	23:00	37	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	
5			<input type="checkbox"/>	09/09/2020 13 Sep 2020	22:30	36.6	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	
6			<input type="checkbox"/>	09/09/2020 14 Sep 2020	23:00	36.9	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	
7			<input type="checkbox"/>	09/09/2020 15 Sep 2020	08:57	36.8	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	

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Any Medical History?

[ ] No [x] Yes \*

Row Tools Abnormality/Disease

Start Date

End Date

Ongoing

1

Menopause

UN/UN/2004

UN/UN/2004

[x] No [ ] Yes

UN-UNK-2004

UN-UNK-2004

Row	Tools 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	Visit 1	24 hours		<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		
2	Visit 4	6 hours		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	1	no immunizati on

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

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Any prior/concomitant medication/therapy?  No  Yes \*

Row	Tools	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
		paracetamol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	0/09/2020 0 Sep 2020	2 45	[ ]	0/09/2020 0 Sep 2020	2 45	[ ]	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		ONCE		headache, chills, increased temperature (see diary)	
2		paracetamol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	9/09/2020 9 Sep 2020	20 5	[ ]	9/09/2020 9 Sep 2020	20 5	[ ]	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		ONCE		pain left costal arch and shoulder	
3		paracetamol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	20/09/2020 20 Sep 2020	03 00	[ ]	20/09/2020 20 Sep 2020	03 00	[ ]	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		ONCE		left costal arch and shoulder	
4		Novalgín	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	2 /09/2020 2 Sep 2020	02 5	[ ]	23/09/2020 23 Sep 2020	08 30	[ ]	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		QD		pain left costal arch and shoulder	

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Ji



Any local/systemic reactions **NOT RELATED** to IMP  No  Yes \*

Row	Tools	Study Day	Date	Time	Local/systemic reaction
1					

**Please insert as many new rows as needed.**

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[ ]

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

Row	Tools	Date	Time	Fasting?
1		02/10/2020 02-Oct-2020	09:00	[ ] No [x] Yes

**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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Row	Tools	Informed Consent for Blood sampling for research purposes?	Visit	Date	Time	Date of Blood sampling	Time of Blood sampling	
1		<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Visit 6	21/10/2020 21-Oct-2020	*	08:56	21/10/2020 21-Oct-2020	09:10

**Please insert as many new rows as needed.**

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Row	Tools Date	Time	Protocol Version
1	15/09/2020 15-Sep-2020	08:49	8.0, 21 JUL 2020
2	28/10/2020 28-Oct-2020	08:59	9.0, 05 OCT 2020

**Please insert as many new rows as needed.**

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