

<b>Site:</b>	CRS Mannheim
<b>Group:</b>	Part A
<b>Subject Identifier:</b>	276-01-0075
<b>Status:</b>	Allocated

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	[ ]				11/05/2020 11 May 2020	09:22	65	[x] No a [ ] Ab o a	[ ] NCS [ ] CS						

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time	Result
1		[ ]		11/05/2020 11-May-2020	08:51	[x] Negative [ ] Positive

**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"/>		11/05/2020 11-May-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!**

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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	[ ]			11/05/2020 11-May-2020	08:40	179	82,4	25,7	25,7

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

Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		11/05/2020 11-May-2020	09:24	Oral		36,3	<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")!

Childbearing potential  No  Yes  NA

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

Date of Last menses

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   
11-May-2020

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

Inclusion Criteria:

Exclusion Criteria:

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Date  \*  
11-May-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

[ ]  
Not done

Reason not done

Date

11-May-2020

Time

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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

U' ab&ca) ca:Kİ İ EEİ İ

U'ab&ca) ca:Kİ İ EEİ İ  
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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	Methadone	Tricyclic antidepressants	Amphetamines
1	[ ]			11/05/2020 11-May-2020	08 53	[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	[ ]	[ ]		11/05/2020 11-May-2020	08:53	[x] 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	[ ]			11/05/2020 11-May-2020	08:53

**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 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	[ ]			11/05/2020 11 May 2020	09:23	[ ] R g [x] Lef	129	[ ] NCS [ ] CS	82	[ ] NCS [ ] CS	69	[ ] NCS [ ] CS	12	[ ] 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	No do e	Reason do e	Date	Time	Headline (beats/)	Repeat	Category	Fields, select all that apply
1	[ ]		22/05/2020 22 May 2020	08:10	71	[x] No a [ ] Ab o a	[ ] NCS [ ] CS	

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Not done

Reason not done

Other, specify

Date   
22-May-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		[ ]		22/05/2020 22-May-2020	07:41	[x] Negative [ ] Positive

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

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U' ab & (A) ca: K G I E F E E I

U' ab & (A) ca: K G I E F E E I  
X a a K a a F

O: [ ~ ] K U a o C E  
Q: [ { K O E [ & e e a ] A C E D

Date   
22-May-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

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

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			22/05/2020 22-May-2020	08:42

**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	[ ]			22/05/2020 22-May-2020	08:41

**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"/>		<input type="text" value="22/05/2020"/> 22-May-2020	<input type="text" value="08:16"/>	<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	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"/>		22/05/2020 22-May-2020	08:04	Oral		36,5	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		22/05/2020 22-May-2020	09:48	Oral		36,3	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		22/05/2020 22-May-2020	11:49	Oral		36,5	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		22/05/2020 22-May-2020	14:48	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")!**



[ ] No [x] Yes

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

Date   
22-May-2020

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

Inclusion Criteria:

Exclusion Criteria:

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[ ]

Row	oos	Scheduled e	No do e	Reason do e	o	Date	e	I e s y of a	I e s y of e de ess	I e s y of E y e a/Red ess	I e s y of I du a o /Swe g
1		1 ou	[ ]			22/05/2020 22 May 2020	09:52	[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	[ ]			22/05/2020 22 May 2020	11:52	[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	[ ]			22/05/2020 22 May 2020	14:54	[x] No e [ ] M d [ ] Mode a e [ ] Seve e [ ] o e a y fe ea e g	[ ] No e [ ] M d [x] 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")!

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[ ]

Row	Tools	Not done	Reason not done	Date	Time	Test name	Result
1	[ ]			21/05/2020 21-May-2020	07:25	On site: Bosch	[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

22-May-2020

Time

Overall health judgement -  No  Yes  
subject healthy?

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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

14

[ ] Normal [ ] Abnormal [ ] ND

[ ] NCS [ ] CS

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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	[ ]			22/05/2020 22-May-2020	07:38	[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	[ ]	[ ]		22/05/2020 22-May-2020	07:38	[x] 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	[ ]			22/05/2020 22-May-2020	07:38

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**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 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"/>		22/05/2020 22-May-2020	08:11	<input type="checkbox"/> Right <input checked="" type="checkbox"/> Left	113	<input type="checkbox"/> NCS <input type="checkbox"/> CS	68	<input type="checkbox"/> NCS <input type="checkbox"/> CS	69	<input type="checkbox"/> NCS <input type="checkbox"/> CS	13	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		22/05/2020 22-May-2020	09:48	<input type="checkbox"/> Right <input checked="" type="checkbox"/> Left	125	<input type="checkbox"/> NCS <input type="checkbox"/> CS	69	<input type="checkbox"/> NCS <input type="checkbox"/> CS	78	<input type="checkbox"/> NCS <input type="checkbox"/> CS	14	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		22/05/2020 22-May-2020	11:49	<input type="checkbox"/> Right <input checked="" type="checkbox"/> Left	119	<input type="checkbox"/> NCS <input type="checkbox"/> CS	64	<input type="checkbox"/> NCS <input type="checkbox"/> CS	71	<input type="checkbox"/> NCS <input type="checkbox"/> CS	12	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		22/05/2020 22-May-2020	14:49	<input type="checkbox"/> Right <input checked="" type="checkbox"/> Left	115	<input type="checkbox"/> NCS <input type="checkbox"/> CS	64	<input type="checkbox"/> NCS <input type="checkbox"/> CS	82	<input type="checkbox"/> NCS <input type="checkbox"/> CS	18	<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"/>		23/05/2020 23-May-2020	07:55	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

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

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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"/>		23/05/2020 23-May-2020	07:53	Oral		37,2	<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")!

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[ ]

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
[ ]			23/05/2020 23 May 2020	08:25	<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")!

Not done

Reason not done

Date

23-May-2020

Time

Overall health judgement -  No  Yes  
subject healthy?

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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

14

[ ] Normal [ ] Abnormal [ ] ND

[ ] NCS [ ] CS

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			23/05/2020 23-May-2020	07:25

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

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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	[ ]			23/05/2020 23 May 2020		[ ] R g [x] Lef	113	[ ] NCS [ ] CS	67	[ ] NCS [ ] CS	88	[ ] NCS [ ] CS	12	[ ] NCS [ ] CS

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)



**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!**

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			29/05/2020 29-May-2020	07:55

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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"/>		29/05/2020 29-May-2020	07:55	<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!**

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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"/>		28/05/2020 28-May-2020	07:53	Oral		36,1	<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")!

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

U' ab & a^ ca: K i E F E e i

U' ab & a^ ca: K i E F E e i  
X a a a a H

Ö: [ ^ ] K U a o C E  
Q: [ K S] & a^ [ ^: a a a a a Q b & a^ ] U' ab & a^

[ ]

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
[ ]			29/05/2020 29 May 2020	08:0	<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

29-May-2020

Time

Overall health judgement -  No  Yes  
subject healthy?

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

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

14

Normal  Abnormal  ND

NCS  CS

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			29/05/2020 29-May-2020	07:29

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

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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	[ ]			29/05/2020 29 May 2020		[ ] R g [x] Lef	108	[ ] NCS [ ] CS	66	[ ] NCS [ ] CS	68	[ ] NCS [ ] CS	13	[ ] NCS [ ] CS

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			12/06/2020 12-Jun-2020	07:56

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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"/>		12/06/2020 12-Jun-2020	07:50	Oral		36,1	<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")!

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Row	oos	Scheduled e	No do e	Reason do e	o	Date	Time	Issues of a	Issues of e de ess	Issues of Eye a/Red ess	Issues of I du a o /Swe g
1		edose	[ ]			12/06/2020 12 Ju 2020	08:23	[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")!

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

Not done

Reason not done

Date

12-Jun-2020

Time

Overall health judgement -  No  Yes  
subject healthy?

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

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

14

[ ] Normal [ ] Abnormal [ ] ND

[ ] NCS [ ] CS

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Row	Tools NA	Not done	Reason not done	Date	Time	Result
1	[ ]	[ ]		12/06/2020 12-Jun-2020	07:39	[x] Negative [ ] Positive

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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		Pre-dose	<input type="checkbox"/>		12/06/2020 12-Jun-2020	07:50	<input type="checkbox"/> Right <input checked="" type="checkbox"/> Left	113	<input type="checkbox"/> NCS <input type="checkbox"/> CS	71	<input type="checkbox"/> NCS <input type="checkbox"/> CS	66	<input type="checkbox"/> NCS <input type="checkbox"/> CS	14	<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")!

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

**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!**

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			19/06/2020 19-Jun-2020	07:56

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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"/>		19/06/2020 19-Jun-2020	07:56	<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!**

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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"/>		19/06/2020 19-Jun-2020	07:53	Oral		36,1	<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")!

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

U' ab & (A) caa KÜ I E F E E I

U' ab & (A) caa KÜ I E F E E I  
Xa a K a a A

Ö: [ ~ ] KÜ a O E  
Q: [ KÜ & a V [ ^: 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
[ ]			9/06/2020 9 Jun 2020	08:30	<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")!

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Not done

Reason not done

Date

19-Jun-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





[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			19/06/2020 19-Jun-2020	07:28

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

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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	[ ]			19/06/2020	07:53	[ ] R g [x] Lef	119	[ ] NCS [ ] CS	77	[ ] NCS [ ] CS	72	[ ] NCS [ ] CS	15	[ ] NCS [ ] CS

19 Ju 2020

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			03/07/2020 03-Jul-2020	07:47

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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"/>		03/07/2020 03-Jul-2020	07:44	Oral		36	<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")!

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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
[ ]			03/07/2020 03 Ju 2020	07:52	<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")!

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (GMT)

[ ]

Not done

Reason not done

Date

03-Jul-2020

Time

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

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

U' ab & (a^ } ca: kG i E E E i

Xa a k a a A c F a F a G & U B D A G G D C V D

Q ; { k U @ . a a O c a a a a } A G E D

14

[ ] Normal [ ] Abnormal [ ] ND

[ ] NCS [ ] CS

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 S g f ca ce	Das o c B ood essu e ( Hg)	C ca S g f ca ce	u se Ra e (bea s/ )	C ca S g f ca ce	Resp a o y Ra e (b ea s/ )	C ca S g f ca ce
1	[ ]			03/07/2020 03 Ju 2020	07:43	[ ] R g [x] Lef	108	[ ] NCS [ ] CS	66	[ ] NCS [ ] CS	66	[ ] NCS [ ] CS	14	[ ] NCS [ ] CS

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

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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"/>		10/07/2020 10-Jul-2020	07:50	<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!**

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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"/>		10/07/2020 10-Jul-2020	07:41	Oral		36,1	<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")!

090177e19503a726\Final\Final On: 25-Sep-2020 14:16 (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
[ ]			0/07/2020 0 Ju 2020	08:20	<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")!

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Not done

Reason not done

Date

10-Jul-2020

Time

Overall health judgement -  No  Yes  
subject healthy?

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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



[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			10/07/2020 10-Jul-2020	07:21

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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 do e	o	Da e	e	Measu e e s de (A )	Sys o c B ood essu e ( Hg)	C ca S g f ca ce	Das o c B ood essu e ( Hg)	C ca S g f ca ce	u se Ra e (bea s/ )	C ca S g f ca ce	Resp a o y Ra e (b ea s/ )	C ca S g f ca ce
1	[ ]			10/07/2020	07:46	[ ] R g [x] Lef	111	[ ] NCS [ ] CS	64	[ ] NCS [ ] CS	63	[ ] NCS [ ] CS	16	[ ] NCS [ ] CS

10 Ju 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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[ ]

Row	Tools	Not done	Reason not done	Date	Time
1	[ ]			14/08/2020 14-Aug-2020	10:54

**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"/>		14/08/2020 14-Aug-2020	10:46	Oral		35,9	<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")!



Trial fully completed? [ ] No [x] Yes

Date of Completion or Early Withdrawal   
10-Jul-2020

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

Date of Death

Other, specify:

Epi-/Pandemic related [ ] No [ ] Yes

Date of last visit/contact

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

Any Adverse Events?  No  Yes \*

Row	ools	E No	diverse E ent	Serious	Reason select all that apply	E of special rterest	Epi /Pandemic related	Start Date	Start me	Start me unkn	End Date	End ime	End me unkn	Ongoing	Se erity/Intens ty	Intens ty (toxic ty grading scale)	reatment emergent E	Relationship to BMP reatment	DL (Dose limiting toxic ty)	ction taken with IMP reatment	Concomitant medication or therapy	Outcome of E	E Group ID
3			Pyrexia	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital /nomaly or Birth Defect <input type="checkbox"/> Persist or Signf Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life hreatening <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	22/05/2020 22 May 2020		<input checked="" type="checkbox"/>	2 /05/2020 2 May 2020	08:00		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentia ly L fe hreatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not related <input checked="" type="checkbox"/> Related	<input type="checkbox"/> No <input checked="" 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 applic able <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not reco ered/not resolved <input checked="" type="checkbox"/> Recovered/resolved <input checked="" type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolv ng <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
			Fu like symptoms (tiredness, myalgia, arthralgia, loss of appetite, chills, malaise)	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital /nomaly or Birth Defect <input type="checkbox"/> Persist or Signf Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life hreatening <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	22/05/2020 22 May 2020		<input checked="" type="checkbox"/>	26/05/2020 26 May 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 type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentia ly L fe hreatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not related <input checked="" 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 applic able <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not reco ered/not resolved <input checked="" type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolv ng <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown		
5			Headache	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital /nomaly or Birth Defect <input type="checkbox"/> Persist or Signf Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life hreatening <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	22/05/2020 22 May 2020		<input checked="" type="checkbox"/>	27/05/2020 27 May 2020	08:00		<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 type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentia ly L fe hreatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not related <input checked="" 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 applic able <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not reco ered/not resolved <input checked="" type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolv ng <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
6			Ear pain (both sides)	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital /nomaly or Birth Defect <input type="checkbox"/> Persist or Signf Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life hreatening <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	22/05/2020 22 May 2020	6:00		2 /05/2020 2 May 2020	08:00		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentia ly L fe hreatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not related <input checked="" 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 applic able <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not reco ered/not resolved <input checked="" type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolv ng <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
7			Flatulence	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital /nomaly or Birth Defect <input type="checkbox"/> Persist or Signf Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life hreatening <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	22/05/2020 22 May 2020		<input checked="" type="checkbox"/>	2 /05/2020 2 May 2020		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentia ly L fe hreatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not related <input checked="" 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 applic able <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not reco ered/not resolved <input checked="" type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolv ng <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
8			nea pedis right foot	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital /nomaly or Birth Defect <input type="checkbox"/> Persist or Signf Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life hreatening <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	08/06/2020 08 un 2020	20:00		27/06/2020 27 un 2020	8:00		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentia ly L fe hreatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input 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 checked="" type="checkbox"/> Not applic able <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not reco ered/not resolved <input checked="" type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolv ng <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
9			injection site reactions (discomfort with movement pain)	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital /nomaly or Birth Defect <input type="checkbox"/> Persist or Signf Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life hreatening <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	22/05/2020 22 May 2020	:30		28/05/2020 28 May 2020	08:00		<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 type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentia ly L fe hreatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not related <input checked="" 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 applic able <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not reco ered/not resolved <input checked="" type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolv ng <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
0			oedema wisdomtooth	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital /nomaly or Birth Defect <input type="checkbox"/> Persist or Signf Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life hreatening <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	2 /06/2020 2 un 2020	07:00		0 /07/2020 0 ul 2020	0:00		<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 type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentia ly L fe hreatening	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input 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 checked="" type="checkbox"/> Not applic able <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Not reco ered/not resolved <input checked="" type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolv ng <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	

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

Row	Tools Visit	Modul	Timepoint	Comment	Date of Comment
1	Visit 4			Due to SRC decision (05 June 2020) the boost vaccination was not administered. Therefore only the following assessments from visit 4 were performed - pregnancy test, physical examination, immunogenicity sampling. The local tolerability, vital signs and temperature were only performed for scheduled predose timepoint.	12/06/2020 12-Jun-2020

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

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

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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="text"/>	<input type="checkbox"/>	<input type="text" value="22/05/2020"/> 22 May 2020	<input type="text" value="22:05"/>	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input checked="" 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	<input type="text" value="2"/>	<input type="checkbox"/>	<input type="text" value="23/05/2020"/> 23 May 2020	<input type="text" value="22:00"/>	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input checked="" 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	<input type="text" value="3"/>	<input type="checkbox"/>	<input type="text" value="24/05/2020"/> 24 May 2020	<input type="text" value="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 type="checkbox"/> None <input type="checkbox"/> Mild <input checked="" 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	<input type="text" value="4"/>	<input type="checkbox"/>	<input type="text" value="25/05/2020"/> 25 May 2020	<input type="text" value="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 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	<input type="text" value="5"/>	<input type="checkbox"/>	<input type="text" value="26/05/2020"/> 26 May 2020	<input type="text" value="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 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	<input type="text" value="6"/>	<input type="checkbox"/>	<input type="text" value="27/05/2020"/> 27 May 2020	<input type="text" value="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
7	<input type="text" value="7"/>	<input type="checkbox"/>	<input type="text" value="28/05/2020"/> 28 May 2020	<input type="text" value="22:00"/>	<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
8	<input type="text" value="8"/>	<input type="checkbox"/>	<input type="text" value="29/05/2020"/> 29 May 2020	<input type="text" value="05:00"/>	<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



Any Medical History?

[x] No [ ] Yes \*

Row	Tools Abnormality/Disease	Start Date	End Date	Ongoing
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes
4	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes
5	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes
6	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes
7	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes
8	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes
9	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes
10	<input type="text"/>	<input type="text"/>	<input type="text"/>	[ ] No [ ] Yes

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Row	Tools Vaccination Visit	Planned observation period	Other planned observation period (e.g. 8 hours)	Adherence to planned observation period? [ ] No [x] Yes	If No, actual observation period (hours)	Reason
1	Visit 1	6 hours		<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		

**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		
2		Paracetamol suppository	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	22/05/2020 22 May 2020	9 20	<input type="checkbox"/>	22/05/2020 22 May 2020	9 20	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	RECTAL		000	mg		ONCE		Pyrexia; Headache	3	5	
3		Paracetamol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	22/05/2020 22 May 2020	22 30	<input type="checkbox"/>	22/05/2020 22 May 2020	22 30	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		ONCE		Pyrexia; Headache	3	5	
3		Paracetamol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	23/05/2020 23 May 2020	04 00	<input type="checkbox"/>	23/05/2020 23 May 2020	04 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		ONCE		Pyrexia; Headache	3	5	
4		Paracetamol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	23/05/2020 23 May 2020	2 50	<input type="checkbox"/>	23/05/2020 23 May 2020	2 50	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		ONCE		Pyrexia; Headache	3	5	
5		Paracetamol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	23/05/2020 23 May 2020	22 30	<input type="checkbox"/>	23/05/2020 23 May 2020	22 30	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	RECTAL		000	mg		ONCE		Pyrexia; Headache	3	5	
6		Canesten Creme	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	2/06/2020 2 Jun 2020	22 00	<input type="checkbox"/>	27/06/2020 27 Jun 2020	22 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	TOPICAL		0.5	g		QD		Tinea pedis right foot	8		
7		Ultracain DS 200000 /7ml	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	26/06/2020 26 Jun 2020	0 00	<input type="checkbox"/>	26/06/2020 26 Jun 2020	0 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	OTHER	inj	7	mL		ONCE		Toothache wisdomtooth	0		
8		Dontsolon D 5mg/g	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	26/06/2020 26 Jun 2020	0 00	<input type="checkbox"/>	26/06/2020 26 Jun 2020	0 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	TOPICAL		0	g		ONCE		Toothache wisdomtooth	0		

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Any Protocol Deviations? [ ] No [x] Yes \*

Row	Tools Visit	Modul	Timepoint	Description of Deviation	Reason for Deviation	Category	Date of Occurrence
1	Visit 0	Blood Samples for Safety Lab		FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	11/05/2020 11-May-2020

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

Row Tools	Study Day	Date	Time	Local/systemic reaction
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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

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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 8	14/08/2020 14-Aug-2020	*	10:08	14/08/2020 14-Aug-2020	10:54

Please insert as many new rows as needed.

