

Site:	CRS Mannheim
Group:	Part A
Subject Identifier:	276-01-0010
Status:	Discontinued

Row	oos	No do e	Reaso do e	o	Da e	e	Hea Ra e (beas/)	I e p e a o	C ca Sg f ca ce	F d gs, select all that apply					
1	[]				22/04/2020	09:35	59	[x] No a [] Ab o a	[] NCS [] CS						
					22 Ap 2020										

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

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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"/>		22/04/2020 22-Apr-2020	09:22	<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 ²)	BMI (calculated) (kg/m ²)
1	[]			22/04/2020 22-Apr-2020	08:57	166	65,1	23,6	23,6

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"/>		22/04/2020 22-Apr-2020	09:37	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")!

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
23-Apr-2020

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

Inclusion Criteria:

Exclusion Criteria:

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

U' ab & (A) caa H G I E F E E F E
X a a a a a

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

Date *
22-Apr-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

22-Apr-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

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Ua:KÜÜA a) @ã
XaãKaã€

Ö: [] KÜaóE
Q: { KÜ@ããÖcaããã } (EED

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
1	[]			22/04/2020 22-Apr-2020	09:16

All comments will be entered on comment page!

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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 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	[]			22/04/2020	09:36	[x] R g [] Lef	131	[] NCS [] CS	88	[] NCS [] CS	57	[] NCS [] CS	12	[] NCS [] CS

22 Ap 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	oos	No do e	Reaso do e	o	Da e	e	Hea Ra e (beas/)	I e p e a o	C ca Sg f ca ce	F d gs, select all that apply					
1	[]				24/04/2020 24 Ap 2020	08:34	60	[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
24-Apr-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		[]		24/04/2020 24-Apr-2020	08:13	[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 I E F E E E

U' a K O U U A a) @ a
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
24-Apr-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	[]			24/04/2020 24-Apr-2020	12:00

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	[]			24/04/2020 24-Apr-2020	08:41

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

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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"/>		24/04/2020 24-Apr-2020	08:41	<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"/>		24/04/2020 24-Apr-2020	08:36	Oral		36,2	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		24/04/2020 24-Apr-2020	13:14	Oral		36,3	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		24/04/2020 24-Apr-2020	15:14	Oral		36,3	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		24/04/2020 24-Apr-2020	18:14	Oral		36,2	<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")!

[] No [x] Yes

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

Date
24-Apr-2020

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

Inclusion Criteria:

Exclusion Criteria:

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Row	Sc	edu	No	Reaso	o	Da e	e	I e s y of a	I e s y of e de ess	I e s y of Ey e a/Red ess	I e s y of I du a o /Swe g
1	1	ou	[]			24/04/2020 24 Ap 2020	13:15	[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	[]			24/04/2020 24 Ap 2020	15:17	[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	[]			24/04/2020 24 Ap 2020	18:15	[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	[]			23/04/2020 23-Apr-2020	10:23	On site: Bosch	[x] Negative [] Positive

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[]

Not done

Reason not done

Date

24-Apr-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

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U' ab&ca) ca: K I E E E E E

Ua KOUUA } @a
Xa aKa aF

O: [~] K U a O E
Q : { K U @ • a a O a a a } A G E D

14

Normal Abnormal ND

NCS CS

[]

Row	Tools	Not done	Reason not done	Date	Time	Methamphetamines	Opiates	Cocaine	Cannabinoids	Phencyclidine	Benzodiazepines	Barbiturates	Methodone	Tricyclic antidepressants	Amphetamines
1	[]			24/04/2020 24-Apr-2020	08 10	[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!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			24/04/2020 24-Apr-2020	08:10

All comments will be entered on comment page!

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

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090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

U' ab & (A) caa KGI EEEFE

Ua KOUUA a) @a
Xa aKa aF

O: [^] K U a o C E
Q: { K a a U a } • A & E X U V U V A C E D

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"/>		24/04/2020 24-Apr-2020	08 38	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	124	<input type="checkbox"/> NCS <input type="checkbox"/> CS	90	<input type="checkbox"/> NCS <input type="checkbox"/> CS	56	<input type="checkbox"/> NCS <input type="checkbox"/> CS	12	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		24/04/2020 24-Apr-2020	13 14	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	115	<input type="checkbox"/> NCS <input type="checkbox"/> CS	69	<input type="checkbox"/> NCS <input type="checkbox"/> CS	61	<input type="checkbox"/> NCS <input type="checkbox"/> CS	15	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		24/04/2020 24-Apr-2020	15 14	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	129	<input type="checkbox"/> NCS <input type="checkbox"/> CS	79	<input type="checkbox"/> NCS <input type="checkbox"/> CS	58	<input type="checkbox"/> NCS <input type="checkbox"/> CS	11	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		24/04/2020 24-Apr-2020	18 14	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	105	<input type="checkbox"/> NCS <input type="checkbox"/> CS	65	<input type="checkbox"/> NCS <input type="checkbox"/> CS	68	<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")!

[]

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"/>		25/04/2020 25-Apr-2020	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!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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"/>		25/04/2020 25-Apr-2020	08:53	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")!

[]

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
[]			25/04/2020 25 Apr 2020	0:30	<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")!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

[]
Not done

Reason not done

Date

25-Apr-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	[]			25/04/2020 25-Apr-2020	08:35

All comments will be entered on comment page!

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

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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	[]			25/04/2020	08:52	[x] R g [] Lef	126	[] NCS [] CS	77	[] NCS [] CS	64	[] NCS [] CS	14	[] NCS [] CS

25 Ap 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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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"/>		26/04/2020 26-Apr-2020	12:30	Findings or new AEs/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!

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[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			30/04/2020 30-Apr-2020	09:15

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

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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"/>		30/04/2020 30-Apr-2020	09:15	<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!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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"/>		30/04/2020 30-Apr-2020	09:13	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")!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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
[]			30/04/2020 30 Apr 2020	0:03	<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 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")!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

[]

Not done

Reason not done

Date

30-Apr-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

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			30/04/2020 30-Apr-2020	08:30

All comments will be entered on comment page!

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

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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	[]			30/04/2020 30 Ap 2020	09:12	[x] R g [] Lef	129	[] NCS [] CS	87	[] NCS [] CS	60	[] 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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[]

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"/>		19/05/2020 19-May-2020	09:53	<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!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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"/>		19/05/2020 19-May-2020	09:46	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")!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (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
[]			9/05/2020 9 May 2020	0:08	<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")!

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

[]
Not done

Reason not done

Date

19-May-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

U' ab&ca\ ca:Kİ İ EEE€

Ua KOUUA @
Xa aKa aA qEFA G&U BDC VD

Ö: [] KUsOE
Q: { KÚ@ • aA Oca q aa } AED

14

[] Normal [] Abnormal [] ND

[] NCS [] CS

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			19/05/2020 19-May-2020	09:36

090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

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 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	[]			19/05/2020 19 May 2020		[x] R g [] Lef	123	[] NCS [] CS	81	[] NCS [] CS	62	[] NCS [] CS	13	[] NCS [] CS

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090177e195024bfd\Final\Final On: 25-Sep-2020 01:41 (GMT)

Trial fully completed? No Yes

Date of Completion or Early Withdrawal
19-May-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
22-May-2020

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 interest	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)	treatment emergent E	Relationship to BMP treatment	DL (Dose limiting toxic ty)	ction taken with IMP treatment	Concomitant medication or therapy	Outcome of E	E Group ID
3			Fu like symptoms	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	25/0 /2020 25 pr 2020	0: 0		07/05/2020 07 May 2020		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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 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	
5			Loose stool	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	25/0 /2020 25 pr 2020	2 :00		26/0 /2020 26 pr 2020	20:00	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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 type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input checked="" type="checkbox"/> Recovering/resolving <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
6			Loose stool	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	26/0 /2020 26 pr 2020	20:00		27/0 /2020 27 pr 2020	2 :00	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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 type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolving <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
9			stress dyspnea	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	27/0 /2020 27 pr 2020		<input checked="" type="checkbox"/>	07/05/2020 07 May 2020		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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 type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolving <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
0			redness	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	2 /0 /2020 2 pr 2020		<input checked="" type="checkbox"/>	07/05/2020 07 May 2020		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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 type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolving <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
0			Cough	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	06/05/2020 06 May 2020	07:00		07/05/2020 07 May 2020		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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 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			Verruca > operation in local anesthesia	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	08/05/2020 08 May 2020		<input checked="" type="checkbox"/>	08/05/2020 08 May 2020		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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	
3			Shivering	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	2/05/2020 2 May 2020	22:00		3/05/2020 3 May 2020		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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 type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovered/resolved with sequelae <input type="checkbox"/> Recovering/resolving <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	
3			Intermittent Fe or up to 39.3 degree C	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	2/05/2020 2 May 2020	22:00		/05/2020 May 2020	9:00	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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	
5			Malaise	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	2/05/2020 2 May 2020		<input checked="" type="checkbox"/>	6/05/2020 6 May 2020	9:00	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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	
6			myalgia (both arms and legs)	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	2/05/2020 2 May 2020		<input checked="" type="checkbox"/>	6/05/2020 6 May 2020	9:00	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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	
7			Injection site reactions (pain tenderness discomfort with movement)	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly 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 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	25/0 /2020 25 pr 2020	3:00		03/05/2020 03 May 2020	07:00	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" 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"/> Potentially 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 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 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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Any Comments? [] No [x] Yes *

Row	Tools Visit	Modul	Timepoint	Comment	Date of Comment
1	Visit 7 (a1, b1, b2) (EoT)			Due to AE study was early terminated, therefore visit 7 was performed earlier.	19/05/2020 19-May-2020

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

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

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="24/04/2020"/> 24 Apr 2020	<input type="text" value="8: 5"/>	<input type="checkbox"/> None <input 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 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 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="25/04/2020"/> 25 Apr 2020	<input type="text" value="8: 5"/>	<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 type="checkbox"/> Moderate <input checked="" 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 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="26/04/2020"/> 26 Apr 2020	<input type="text" value="8: 5"/>	<input type="checkbox"/> None <input type="checkbox"/> Mild <input checked="" 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 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="27/04/2020"/> 27 Apr 2020	<input type="text" value="8: 5"/>	<input type="checkbox"/> None <input type="checkbox"/> Mild <input checked="" 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 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="28/04/2020"/> 28 Apr 2020	<input type="text" value="8:30"/>	<input type="checkbox"/> None <input type="checkbox"/> Mild <input checked="" 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 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="29/04/2020"/> 29 Apr 2020	<input type="text" value="8:30"/>	<input type="checkbox"/> None <input type="checkbox"/> Mild <input checked="" 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 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="30/04/2020"/> 30 Apr 2020	<input type="text" value="8: 5"/>	<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 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="0 /05/2020"/> 0 May 2020	<input type="text" value="8:45"/>	<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 type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening

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

U' ab & (A) caa: K G I E F E E F E
X a a i M, i ^ a e a A i i { •

O i [~] K U a s O C E
Q i i { K O a s ^ A S i & a U ^ a a i } • A C E D

9

[]
02 May 2020

[] None
[x] M d
[] Moderate
[] Severe
[] Potent a y fe threaten ng

[] None
[x] M d
[] Moderate
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[x] None
[] M d
[] Moderate
[] Severe
[] Potent a y fe threaten ng

[x] None
[] M d
[] Moderate
[] Severe
[] Potent a y fe threaten ng

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	24 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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U' ab & (A) caa | K G I E F E E F E

U' a K O U U A T a } @ a
X a a i A V | ^ | a e a A Q | { •

O: [~] K U a o C E
Q: { K U i a: H D [] & { a a } A ^ a a a a } E V @: a ^ A G E D

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	25/04/2020 25 Apr 2020	00	<input type="checkbox"/>	25/04/2020 25 Apr 2020	00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		ONCE		Flu like symptoms	3
2	Paracetamol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	26/04/2020 26 Apr 2020		<input checked="" type="checkbox"/>	26/04/2020 26 Apr 2020		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		ONCE		Flu like symptoms	3
3	Paracetamol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	02/05/2020 02 May 2020	8 30	<input type="checkbox"/>	05/05/2020 05 May 2020	20 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		500	mg		OTHER	3x2 Tbl	Flu like symptoms	3
4	Scandicain %	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	08/05/2020 08 May 2020		<input checked="" type="checkbox"/>	08/05/2020 08 May 2020		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	SUBCUTANEOUS		30	mg		ONCE		Verruca operation in local anesthesia	
5	Ibuprofen	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	2/05/2020 2 May 2020	23 00	<input type="checkbox"/>	2/05/2020 2 May 2020	23 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		400	mg		ONCE		Intermittent Fever up to 39.3 degree C	3
6	Ibuprofen	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	3/05/2020 3 May 2020	09 00	<input type="checkbox"/>	6/05/2020 6 May 2020	9 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		400	mg		BID		Malaise / Myalgia	4 5

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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Row	Too s Date	T me	Heart Rate (beats/m n)	Interpretat on	C n ca S gn f cance	F nd ngs, select all that apply				
	06/05/2020 06 May 2020	09: 4	6	[x] Norma [] Abnorma	[] NCS [] CS					

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

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[]

Row Tools Date

Time

1

19/05/2020

09:53

19-May-2020

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	Date	Time	Fasting?
1		06/05/2020 06-May-2020	09:22	<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	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		06/05/2020 06-May-2020	09:16	Oral		36,1	[] 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	Time	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
06/05/2020 06 May 2020	09:35	<input checked="" type="checkbox"/> None <input 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 type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input 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

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	Date	Time	Test name	Result
1		06/05/2020 06-May-2020	08:45	On site: Bosch	<input checked="" type="checkbox"/> Negative <input type="checkbox"/> Positive

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

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Date
06-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	<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 Date

Time

1

06/05/2020

09:00

06-May-2020

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	oos Date	e	Measur 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	06/05/2020 06 May 2020	09:15	[x] R g [] Lef	120	[] NCS [] CS	80	[] NCS [] CS	61	[] 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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