

Site:	CRS Berlin
Group:	Part A
Subject Identifier:	276-02-0116
Status:	Discontinued

Row	No do e	Reason do e	Date	Time	Headline (beats/)	Repeat	Category	Findings, select all that apply
1	[]	[]	20/05/2020 20 May 2020	08:21	71	[x] No a [] Ab o a	[] NCS [] CS	[] [] [] [] []

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time	Result
1		[]		20/05/2020 20-May-2020	08:06	[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"/>		20/05/2020 20-May-2020	08:33	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

All comments will be entered on comment page!

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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	[]			20/05/2020 20-May-2020	08:07	166	60,6	22	22,0

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"/>		20/05/2020 20-May-2020	08:08	Oral		36,5	<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
04-Jun-2020

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

Inclusion Criteria:

Exclusion Criteria:

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Date *
20-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

20-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 & (a) caa K G I E C F F I

Ua K O U U A O H a
X a a K a a E

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

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	[]			20/05/2020 20-May-2020	08:42	[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	[]	[]		20/05/2020 20-May-2020	08:42	[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	[]			20/05/2020 20-May-2020	08:42

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	[]			20/05/2020 20 May 2020		[x] R g [] Lef	100	[] NCS [] CS	54	[] NCS [] CS	75	[] NCS [] CS	9	[] NCS [] CS

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

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Row	oos	No do e	Reaso do e	o	Da e	e	Hea Ra e (bea s/)	I e p e a o	C ca Sg f ca ce	F d gs, select all that apply					
1	[]				18/06/2020 18 Ju 2020	11:23	59	[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
18-Jun-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		[]		18/06/2020 18-Jun-2020	10:57	[x] Negative [] Positive

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

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Date
18-Jun-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	[]			18/06/2020 18-Jun-2020	11:13

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		[]		18/06/2020 18-Jun-2020	11:13

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"/>		18/06/2020 18-Jun-2020	11:13	<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"/>		18/06/2020 18-Jun-2020	10:55	Oral		36,3	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		18/06/2020 18-Jun-2020	12:58	Oral		36,3	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		18/06/2020 18-Jun-2020	14:56	Oral		36,5	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		18/06/2020 18-Jun-2020	17:56	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")!

[] No [x] Yes

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

Date
18-Jun-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	Time	Issues of a	Issues of e de ess	Issues of Ey e a/Red ess	Issues of I du a o /Swe g
1		1 ou	[]			18/06/2020 18 Ju 2020	13:00	[x] No e [] M d [] Mode a e [] Seve e [] o e a y fe ea e g	[x] No e [] M d [] Mode a e [] Seve e [] o e a y fe ea e g	[x] No e [] M d [] Mode a e [] Seve e [] o e a y fe ea e g	[x] No e [] M d [] Mode a e [] Seve e [] o e a y fe ea e g
2		3 ou s	[]			18/06/2020 18 Ju 2020	15:02	[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
3		6 ou s	[]			18/06/2020 18 Ju 2020	17:57	[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 done	Not done	Reason not done	Date	Time	Test name	Result
1	[]			17/06/2020 17-Jun-2020	09:53	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

18-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

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U' ab & (a^} caa: K G I E C F F I

Ua K O U U A O : i a
Xa a K a a F

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

14

[] Normal [] Abnormal [] ND

[] NCS [] CS

[]

Row	Tools	Not done	Reason not done	Date	Time	Methamphetamines	Opiates	Cocaine	Cannabinoids	Phencyclidine	Benzodiazepines	Barbiturates	Methadone	Tricyclic antidepressants	Amphetamines
1	[]			18/06/2020 18-Jun-2020	11 02	[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	[]	[]		18/06/2020 18-Jun-2020	11:02	[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	[]			18/06/2020 18-Jun-2020	11:02

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 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"/>		18/06/2020 18-Jun-2020	11 24	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	94	<input type="checkbox"/> NCS <input type="checkbox"/> CS	54	<input type="checkbox"/> NCS <input type="checkbox"/> CS	64	<input type="checkbox"/> NCS <input type="checkbox"/> CS	16	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		18/06/2020 18-Jun-2020	13 00	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	98	<input type="checkbox"/> NCS <input type="checkbox"/> CS	65	<input type="checkbox"/> NCS <input type="checkbox"/> CS	58	<input type="checkbox"/> NCS <input type="checkbox"/> CS	14	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		18/06/2020 18-Jun-2020	15 00	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	101	<input type="checkbox"/> NCS <input type="checkbox"/> CS	53	<input type="checkbox"/> NCS <input type="checkbox"/> CS	75	<input type="checkbox"/> NCS <input type="checkbox"/> CS	15	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		18/06/2020 18-Jun-2020	17 59	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	100	<input type="checkbox"/> NCS <input type="checkbox"/> CS	55	<input type="checkbox"/> NCS <input type="checkbox"/> CS	66	<input type="checkbox"/> NCS <input type="checkbox"/> CS	19	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

[]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		19/06/2020 19-Jun-2020	10:27	<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	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	10:20	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")!

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090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (GMT)

U' ab & (a) caa K G I E C F F I

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

O i [~] K U a o C E
Q i { K S i & a V [^ i a a a a A e Q b & a } U a A C 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	0: 4	<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

19-Jun-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
1	[]			19/06/2020 19-Jun-2020	10:05

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 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 19 Ju 2020	10:23	[x] R g [] Lef	95	[] NCS [] CS	52	[] NCS [] CS	71	[] NCS [] CS	20	[] NCS [] CS

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

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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	[x]	[]				

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

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (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"/>		24/06/2020 24-Jun-2020	08:17	<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!

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (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"/>		24/06/2020 24-Jun-2020	08:00	Oral		35,8	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (GMT)

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (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
[]			24/06/2020 24 Jun 2020	08:03	<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 24/06/2020

24-Jun-2020

Time 08:01

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

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	General condition/p syche	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
2	Skin	[] Normal [] Abnormal [x] ND	[]	[] NCS [] CS
3	Lymph nodes	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
4	Head (eyes, ears, mouth)	[] Normal [x] Abnormal [] ND	inflammation left ear (upper auricle)	[] NCS [x] CS
5	Neck/thyroid gland	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
6	Lungs	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
7	Heart	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
8	Abdomen	[] Normal [] Abnormal [x] ND	[]	[] NCS [] CS
9	Musculoskeletal system	[] Normal [] Abnormal [x] ND	[]	[] NCS [] CS

10	Neurological system	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
11	Vascular system	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
12	Cardiovascular	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" type="checkbox"/> ND	<input type="checkbox"/> NCS <input type="checkbox"/> CS
13	Gastrointestinal	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" 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	[]			24/06/2020 24-Jun-2020	08:26

All comments will be entered on comment page!

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (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	[]			24/06/2020	08:08	[x] R g [] Lef	98	[] NCS [] CS	50	[] NCS [] CS	56	[] NCS [] CS	18	[] NCS [] CS
				24 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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[x]

Not done

Reason not done

Adverse
Event

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	[]			16/07/2020 16-Jul-2020	09:35

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (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"/>		16/07/2020 16-Jul-2020	09:35	<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!

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (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"/>		16/07/2020 16-Jul-2020	09:28	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")!

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (GMT)

U' ab & a) ca : K I E C F F I

Ua K O U U A O N i a
X a a K a a A

O i [^] K U a o C E
Q i { K S i & a V [^ i : a a p a e Q b & a } U a A C 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
[]			6/07/2020 6 Ju 2020	09:42	<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

16-Jul-2020

Time

Overall health judgement - No Yes
subject healthy?

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 type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" 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 type="checkbox"/> Normal <input checked="" type="checkbox"/> Abnormal <input type="checkbox"/> ND	<input type="text" value="throat redness, mild"/>	<input type="checkbox"/> NCS <input checked="" type="checkbox"/> CS
5	<input type="text" value="Neck/thyroid gland"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" 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 type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS
9	<input type="text" value="Musculoskeletal system"/>	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input checked="" type="checkbox"/> ND	<input type="text"/>	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			16/07/2020 16-Jul-2020	09:17

All comments will be entered on comment page!

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (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 Boo d essu e (Hg)	C ca S g f ca ce	Das o c Boo d 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	[]			16/07/2020	09:26	[x] R g [] Lef	102	[] NCS [] CS	54	[] NCS [] CS	71	[] NCS [] CS	10	[] NCS [] CS
				16 Ju 2020										

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			30/07/2020 30-Jul-2020	08:38

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (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"/>		30/07/2020 30-Jul-2020	08:38	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

All comments will be entered on comment page!

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (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"/>		30/07/2020 30-Jul-2020	08:37	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")!

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (GMT)

[]

Not done

Reason not done

Date

30-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&ca\ ca:Kİ İ ECFİ

Ua KÜÜA:İa
Xa aKa aA ÇE Fİ ÇE ÇÜBÜÇ VD

Ö: [] KÜaÖE
Q: { KÜ@ • aAÖca a aa } ÇE D

14

Normal Abnormal ND

NCS CS

U' ab & (a^} caa kG i EGEFFI

Ua KOUUO:ijā
Xā ākā ā Ā Ā Fā Fā Gē Gē Uō Dō C VD

Ö: [^] Kū aō ē
Q: { Kū • c { B C ^ } o A E • ^ • • { ^ } c

[]

Row	Tools	Not done	Reason not done	Date	Time	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Fatigue/ Irritability	
[]				30/07/2020	08:30	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening

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

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			30/07/2020 30-Jul-2020	08:25

All comments will be entered on comment page!

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

090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (GMT)

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

Any Adverse Events? [] No [x] 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)	treatment emergent E	Relationship to BMP treatment	DL (Dose limiting toxicity)	ction taken with IMP treatment	Concomitant medication or therapy	Outcome of E	E Group ID
5			inflammatio n left ear (upper auricle)	[x] No [] Yes	[] Congenital normaly or Birth Defect [] Persist or Signf Disability/Incapacity [] Results in Death [] Requires or Prolongs Hospitalzation [] Is Life hreatening [] Other Medicaly Important Serious Event	[x] No [] Yes	[x] No [] Yes	2 /06/2020 2 un 2020	:00	[]	28/06/2020 28 un 2020	23:00	[]	[x] No [] Yes	[x] Mid [] Moderate [] Severe	[] Mild [] Moderate [] Severe [] Potentia ly L fe hreatening	[] No [x] Yes	[x] Not related [] Related	[x] No [] Yes	[x] Dose not changed [] Dose reduced [] Drug interrupted [] Drug wthdrawn [] Not applic able [] Unknown	[] No [x] Yes	[] Not reco ered/not resolved [x] Recovered/resolved [] Recovered/resolved with sequelae [] Recovering/resolv ng [] Fatal [] Unknown	
6			injection site reaction	[x] No [] Yes	[] Congenital normaly or Birth Defect [] Persist or Signf Disability/Incapacity [] Results in Death [] Requires or Prolongs Hospitalzation [] Is Life hreatening [] Other Medicaly Important Serious Event	[x] No [] Yes	[x] No [] Yes	8/06/2020 8 un 2020	5:02	[]	20/06/2020 20 un 2020	0:00	[]	[x] No [] Yes	[x] Mid [] Moderate [] Severe	[] Mild [] Moderate [] Severe [] Potentia ly L fe hreatening	[] No [x] Yes	[] Not related [x] Related	[x] No [] Yes	[x] Dose not changed [] Dose reduced [] Drug interrupted [] Drug wthdrawn [] Not applic able [] Unknown	[x] No [] Yes	[] Not reco ered/not resolved [x] Recovered/resolved [] Recovered/resolved with sequelae [] Recovering/resolv ng [] Fatal [] Unknown	
7			flu like symptoms	[x] No [] Yes	[] Congenital normaly or Birth Defect [] Persist or Signf Disability/Incapacity [] Results in Death [] Requires or Prolongs Hospitalzation [] Is Life hreatening [] Other Medicaly Important Serious Event	[x] No [] Yes	[x] No [] Yes	8/06/2020 8 un 2020	2:00	[]	9/06/2020 9 un 2020	2 :00	[]	[x] No [] Yes	[x] Mid [] Moderate [] Severe	[] Mild [] Moderate [] Severe [] Potentia ly L fe hreatening	[] No [x] Yes	[] Not related [x] Related	[x] No [] Yes	[x] Dose not changed [] Dose reduced [] Drug interrupted [] Drug wthdrawn [] Not applic able [] Unknown	[x] No [] Yes	[] Not reco ered/not resolved [x] Recovered/resolved [] Recovered/resolved with sequelae [] Recovering/resolv ng [] Fatal [] Unknown	
9			diarrhea	[x] No [] Yes	[] Congenital normaly or Birth Defect [] Persist or Signf Disability/Incapacity [] Results in Death [] Requires or Prolongs Hospitalzation [] Is Life hreatening [] Other Medicaly Important Serious Event	[x] No [] Yes	[x] No [] Yes	29/06/2020 29 un 2020	0:00	[]	30/06/2020 0 un 2020	7:00	[]	[x] No [] Yes	[x] Mid [] Moderate [] Severe	[] Mild [] Moderate [] Severe [] Potentia ly L fe hreatening	[] No [x] Yes	[x] Not related [] Related	[x] No [] Yes	[x] Dose not changed [] Dose reduced [] Drug interrupted [] Drug wthdrawn [] Not applic able [] Unknown	[x] No [] Yes	[] Not reco ered/not resolved [x] Recovered/resolved [] Recovered/resolved with sequelae [] Recovering/resolv ng [] Fatal [] Unknown	
0			common cold	[x] No [] Yes	[] Congenital normaly or Birth Defect [] Persist or Signf Disability/Incapacity [] Results in Death [] Requires or Prolongs Hospitalzation [] Is Life hreatening [] Other Medicaly Important Serious Event	[x] No [] Yes	[x] No [] Yes	0 /07/2020 0 ul 2020	8:00	[]	22/07/2020 22 ul 2020	22:00	[]	[x] No [] Yes	[] Mild [x] Moderate [] Severe	[] Mild [] Moderate [] Severe [] Potentia ly L fe hreatening	[] No [x] Yes	[x] Not related [] Related	[x] No [] Yes	[] Dose not changed [] Dose reduced [] Drug interrupted [x] Drug wthdrawn [] Not applic able [] Unknown	[] No [x] Yes	[] Not reco ered/not resolved [x] Recovered/resolved [] Recovered/resolved with sequelae [] Recovering/resolv ng [] Fatal [] Unknown	
2			vaginal mycosis	[x] No [] Yes	[] Congenital normaly or Birth Defect [] Persist or Signf Disability/Incapacity [] Results in Death [] Requires or Prolongs Hospitalzation [] Is Life hreatening [] Other Medicaly Important Serious Event	[x] No [] Yes	[x] No [] Yes	29/07/2020 29 ul 2020	5:00	[]	3 /07/2020 3 ul 2020	8:00	[]	[x] No [] Yes	[x] Mid [] Moderate [] Severe	[] Mild [] Moderate [] Severe [] Potentia ly L fe hreatening	[] No [x] Yes	[x] Not related [] Related	[x] No [] Yes	[] Dose not changed [] Dose reduced [] Drug interrupted [] Drug wthdrawn [x] Not applic able [] Unknown	[] No [x] Yes	[] Not reco ered/not resolved [x] Recovered/resolved [] Recovered/resolved with sequelae [] Recovering/resolv ng [] Fatal [] Unknown	

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090177e19503b149\Final\Final On: 25-Sep-2020 14:21 (GMT)

Any Comments? [] No [x] Yes *

Row	Tools Visit	Modul	Timepoint	Comment	Date of Comment
1	Visit 4	Phone Call		Subject called on 07.Jul 2020 that sche suffered from common Cold and could not attend to the scheduled V4 (Booster)	07/07/2020 07-Jul-2020
2	Visit 5	Protocol Deviations		During V5 at 16. Jul. 2020 she reported to feel better but still not in the condition for Booster. After consultation with the Sponsor it was decided not to inject abooster at a later time Point even though she did not withdraw due to operational reason (subject too Long out of time Frame for Booster)	28/07/2020 28-Jul-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="checkbox"/>	8/06/2020 8 Jun 2020	22:04	<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 checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
2	2	<input type="checkbox"/>	9/06/2020 9 Jun 2020	22:52	<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
3	3	<input type="checkbox"/>	20/06/2020 20 Jun 2020	22: 3	<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
4	4	<input type="checkbox"/>	2 /06/2020 2 Jun 2020	22:07	<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
5	5	<input type="checkbox"/>	22/06/2020 22 Jun 2020	22:24	<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
6	6	<input type="checkbox"/>	23/06/2020 23 Jun 2020	22:02	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
7	7	<input type="checkbox"/>	24/06/2020 24 Jun 2020	08:00	<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

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

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

Row	cols	Study Day	Not done	Date	Time	Body temperature (C)	Intensity of Headache	Intensity of Myalgia	Intensity of Arthralgia	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Intensity of Fatigue	
			<input type="checkbox"/>	8/06/2020 8 un 2020	22:0	36.5	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening
	2		<input type="checkbox"/>	9/06/2020 9 un 2020	22:52	36.5	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening
	3		<input type="checkbox"/>	20/06/2020 20 un 2020	22:3	36.3	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening
			<input type="checkbox"/>	2/06/2020 2 un 2020	22:07	36	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening
	5		<input type="checkbox"/>	22/06/2020 22 un 2020	22:2	35.9	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening
	6		<input type="checkbox"/>	23/06/2020 23 un 2020	22:02	35.9	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening
	7		<input type="checkbox"/>	2/06/2020 2 un 2020	08:00	35.8	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening

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Informed Consent for pharmacogenetic analysis given? [] No [x] Yes

Date of IC for pharmacogenetic analysis *
16-Jul-2020

Time of IC for pharmacogenetic analysis

Aliquot taken from previous CMI sampling

Row	Tools	Date of previous CMI sampling for analysis	Time of previous CMI sampling for analysis
1		<input type="text"/>	<input type="text"/>

Please insert as many new rows as needed.

Informed Consent for separate HLA typing sampling given? [] No [x] Yes

Date
16-Jul-2020

Time

Separate Blood Sampling for HLA typing taken

Date of HLA typing sampling

Time of HLA typing sampling

HLA typing Blood Sampling aliquot taken from CMI sampling

Row	Tools	Date of corresponding CMI sampling	Time of corresponding CMI sampling
-----	-------	------------------------------------	------------------------------------

1

Please insert as many new rows as needed.

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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
1		Arnica D 2	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	22/06/2020 22 Jun 2020	2 00	<input type="checkbox"/>	26/06/2020 26 Jun 2020	9 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		20	OTHER	Globuli	OTHER	per day	inflammation left ear (upper auricle)	5
2		Ruta D6	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	22/06/2020 22 Jun 2020	2 00	<input type="checkbox"/>	26/06/2020 26 Jun 2020	9 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		20	OTHER	Globuli	OTHER	per day	inflammation left ear (upper auricle)	5
3		Bromelain POS	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	22/06/2020 22 Jun 2020	2 00	<input type="checkbox"/>	22/06/2020 22 Jun 2020	9 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL			OTHER	pill	OTHER	per day	inflammation left ear (upper auricle)	5
4		Tyrosur Gel	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	23/06/2020 23 Jun 2020	0 00	<input type="checkbox"/>	26/06/2020 26 Jun 2020	9 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	TOPICAL		4	mm		TID		inflammation left ear (upper auricle)	5
5		Gelomyrtol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	06/07/2020 06 Jul 2020	0 00	<input type="checkbox"/>	07/2020 Jul 2020	8 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		3	TABLET		TID		common cold	9
6		Vagisan	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	29/07/2020 29 Jul 2020	22 00	<input type="checkbox"/>	29/07/2020 29 Jul 2020	22 00	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	VAGINAL			SUPPOSITO R		ONCE		vaginal mycosis	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 4		D22	Subject cancelled booster	due to feeling cold	Treatment Compliance	09/07/2020 09-Jul-2020
2	Visit 6 (a1, b1, b2, c2P/B) / (c2) (EoT)		D43	Visit 6 was skipped because subject prematurely terminated the Trial, so EoT Visit 7 was performed earlier than planned.	the subject ends the study by this day	Visit Schedule Compliance	30/07/2020 30-Jul-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					

Please insert as many new rows as needed.

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[]

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

Row	Tools	Date	Time	Fasting?
1		29/06/2020 29-Jun-2020	08:05	[] No [x] Yes

All comments will be entered on comment page!

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

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Row	Tools Date	Time	Protocol Version
1	17/06/2020 17-Jun-2020	09:45	5.0, 26 MAY 2020
2	16/07/2020 16-Jul-2020	09:11	7.0, 26 JUN 2020

Please insert as many new rows as needed.

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