

Site:	CRS Berlin
Group:	Part A
Subject Identifier:	276-02-0215
Status:	Allocated

Row	oos	No do e	Reaso do e	Da e	e	Hea Ra e (bea s/)	I e p e a o	C ca Sg f ca ce	F d gs, select all that apply
1	[]			11/08/2020 11 Aug 2020	09:33	59	[] No a [x] Ab o a	[x] NCS [] CS	109

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time	Result
1		[]		11/08/2020 11-Aug-2020	09:25	[x] Negative [] Positive

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

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[]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		11/08/2020 11-Aug-2020	09:42	<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	[]			11/08/2020 11-Aug-2020	09:25	153	57,7	24,6	24,6

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"/>		11/08/2020 11-Aug-2020	09:36	Oral		36,4	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

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Childbearing potential No Yes NA

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

Date of Last menses

UN-UNK-1993

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
19-Aug-2020

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

Inclusion Criteria:

Exclusion Criteria:

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Date *
11-Aug-2020

Time

PID

Protocol Version

Was the subject re-screened? No Yes

All previous TSNs (e.g. 276-
01-1234)

Date of first Informed
Consent

Not done []

Reason not done []

Date 11/08/2020

11-Aug-2020

Time 09:26

Row	Tools System/Organ	Normal/Abnormal/ND	Abnormalities/Symptoms	Clinical Significance
1	General condition/p syche	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
2	Skin	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
3	Lymph nodes	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
4	Head (eyes, ears, mouth)	[x] Normal [] Abnormal [] ND	[]	[] NCS [] 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	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
9	Musculoskeletal system	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS
10	Neurological system	[x] Normal [] Abnormal [] ND	[]	[] NCS [] CS

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

[]

Row	Tools	Not done	Reason not done	Date	Time	Methamphetamines	Opiates	Cocaine	Cannabinoids	Phencyclidine	Benzodiazepines	Barbiturates	Methodone	Tricyclic antidepressants	Amphetamines
1	[]			11/08/2020 11-Aug-2020	09 22	[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

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[]

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

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

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[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			11/08/2020 11-Aug-2020	09:22

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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 Bood essu e (Hg)	C ca Sg fca ce	Das o c Bood essu e (Hg)	C ca Sg fca ce	use Ra e (bea s/)	C ca Sg fca ce	Resp a o y Ra e (b ea s/)	C ca Sg fca ce
1	[]			11/08/2020	09:35	[x] R g [] Lef	125	[] NCS [] CS	69	[] NCS [] CS	69	[] NCS [] CS	16	[] NCS [] CS

11 Aug 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	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	[]			01/09/2020 01 Sep 2020	07:12	52	[x] No a [] Ab o a	[] NCS [] CS	

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Not done

Reason not done

Other, specify

Date
01-Sep-2020

Time

Medication Number

Planned dose ug

Other, specify ug

Total Dose (Volume of Injection) mL

Total Dose given? No Yes

If No, rest volume mL

Application site right left upper arm

Administration according to protocol? No Yes

If No, please specify

Epi/Pandemic related adjustment No Yes

Epi/Pandemic related interruption No Yes

[]

Row	Tools	Not done	Reason not done	Date	Time	Result
1		[]		01/09/2020 01-Sep-2020	07:01	[x] Negative [] Positive

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Date
01-Sep-2020

Time

Subject is allocated to
 Cohort 1
 Cohort 2
 Cohort 3
 Cohort 4
 Cohort 5
 Cohort 6
 Cohort 7
 Cohort 8
 Cohort 9
 Cohort 10
 Cohort 11
 Cohort 12
 Cohort 13

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

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			01/09/2020 01-Sep-2020	08:05

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	[]			01/09/2020 01-Sep-2020	08:05

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"/>		01/09/2020 01-Sep-2020	08:05	<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"/>		01/09/2020 01-Sep-2020	07:04	Oral		35,7	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		01/09/2020 01-Sep-2020	09:24	Oral		35,5	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		01/09/2020 01-Sep-2020	11:26	Oral		35,5	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		01/09/2020 01-Sep-2020	14:18	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")!

[] No [x] Yes

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

Date
01-Sep-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	[]			01/09/2020 01 Sep 2020	09:32	[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
2		3 ou s	[]			01/09/2020 01 Sep 2020	11:32	[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	[]			01/09/2020 01 Sep 2020	14:31	[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")!

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[]

Row	Tools	Not done	Reason not done	Date	Time	Test name	Result
1	[]			31/08/2020 31-Aug-2020	08:57	On site: Qiagen	[x] Negative [] Positive

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[]

Not done

Reason not done

Date

01-Sep-2020

Time

Overall health judgement - No Yes
subject healthy?

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

[]

Row	ools	Scheduled time	Not done	Reason not done	Date	Time	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Fatigue/ redness	
		hour	[]		0 /09/2020 0 Sep 2020	09:32	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening
2		3 hours	[]		0 /09/2020 0 Sep 2020	:32	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening
3		5 hours	[]		0 /09/2020 0 Sep 2020	:3	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening	[x] None [] Mid [] Moderate [] Severe [] Potentially life threatening

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

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[]

Row	Tools	Not done	Reason not done	Date	Time	Methamphetamines	Opiates	Cocaine	Cannabinoids	Phencyclidine	Benzodiazepines	Barbiturates	Methodone	Tricyclic antidepressants	Amphetamines
1	[]			01/09/2020 01-Sep-2020	06 59	[x] Negative [] Positive	[x] Negative [] Positive	[x] Negative [] Positive	[x] Negative [] Positive	[x] Negative [] Positive	[x] Negative [] Positive	[x] Negative [] Positive	[x] Negative [] Positive	[x] Negative [] Positive	[x] Negative [] Positive

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

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[]

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

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

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[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			01/09/2020 01-Sep-2020	06:59

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All comments will be entered on comment page!

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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"/>		01/09/2020 01-Sep-2020	07 13	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	181	<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CS	78	<input type="checkbox"/> NCS <input type="checkbox"/> CS	51	<input type="checkbox"/> NCS <input type="checkbox"/> CS	14	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		01/09/2020 01-Sep-2020	09 30	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	137	<input type="checkbox"/> NCS <input type="checkbox"/> CS	60	<input type="checkbox"/> NCS <input type="checkbox"/> CS	56	<input type="checkbox"/> NCS <input type="checkbox"/> CS	10	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		01/09/2020 01-Sep-2020	11 32	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	144	<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CS	83	<input type="checkbox"/> NCS <input type="checkbox"/> CS	63	<input type="checkbox"/> NCS <input type="checkbox"/> CS	15	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		01/09/2020 01-Sep-2020	14 27	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	157	<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CS	68	<input type="checkbox"/> NCS <input type="checkbox"/> CS	64	<input type="checkbox"/> NCS <input type="checkbox"/> CS	17	<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"/>		02/09/2020 02-Sep-2020	08:44	<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!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		02/09/2020 02-Sep-2020	08:35	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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Not Too s done	Reason not done	Date	T me	Intens ty of Pa n	Intens ty of Tenderness	Intens ty of Erythema/Redness	Intens ty of Indurat on/Swe ng
[]			02/09/2020 02 Sep 2020	08:30	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng

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

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090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Not done

Reason not done

Date

02-Sep-2020

Time

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

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

14

[] Normal [] Abnormal [] ND

[] NCS [] CS

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Fatigue/ Irritability	
[]				02/09/2020	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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			02/09/2020 02-Sep-2020	08:50

All comments will be entered on comment page!

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	No oo s do 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 (bea s/)	C ca Sg fca ce
1	[]			02/09/2020	08:41	[x] R g [] Lef	135	[] NCS [] CS	66	[] NCS [] CS	52	[] NCS [] CS	14	[] NCS [] CS

02 Sep 2020

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

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

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

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

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			07/09/2020 07-Sep-2020	08:25

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

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

[]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		<input type="text" value="07/09/2020"/> 07-Sep-2020	<input type="text" value="08:25"/>	<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!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		07/09/2020 07-Sep-2020	08:22	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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Not Too s done	Reason not done	Date	T me	Intens ty of Pa n	Intens ty of Tenderness	Intens ty of Erythema/Redness	Intens ty of Indurat on/Swe ng
[]			07/09/2020 07 Sep 2020	08:29	<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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Not done

Reason not done

Date

07-Sep-2020

Time

Overall health judgement - No Yes
subject healthy?

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

14

[] Normal [] Abnormal [] ND

[] NCS [] CS

[]

Row	Tools	Not done	Reason not done	Date	Time	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Fatigue/ Irritability	
[]				07/09/2020	08:29	<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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			07/09/2020 07-Sep-2020	08:10

All comments will be entered on comment page!

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	No oos do 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 (bea s/)	C ca Sg fca ce
1	[]			07/09/2020 07 Sep 2020	08:23	[x] R g [] Lef	132	[] NCS [] CS	66	[] NCS [] CS	58	[] NCS [] CS	16	[] NCS [] CS

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Not done

Reason not done

Other, specify

Date
22-Sep-2020

Time

Medication Number

Planned dose ug

Other, specify ug

Total Dose (Volume of Injection) mL

Total Dose given? No Yes

If No, rest volume mL

Application site right left upper arm

Administration according to protocol? No Yes

If No, please specify

Epi/Pandemic related adjustment No Yes

Epi/Pandemic related interruption No Yes

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

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

Adverse Event term

AE no.

Medical History term

Other, specification

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			22/09/2020 22-Sep-2020	09:37

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Scheduled time	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		Predose	<input type="checkbox"/>		22/09/2020 22-Sep-2020	09:30	Oral		36,1	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		22/09/2020 22-Sep-2020	10:55	Oral		35,9	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		22/09/2020 22-Sep-2020	12:55	Oral		36	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		22/09/2020 22-Sep-2020	15:51	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	oos	Scheduled e	No do e	Reason do e	o	Date	Time	Issues of a	Issues of e de ess	Issues of Eye a/Red ess	Issues of I du a o /Swe g
1		edose	[]			22/09/2020 22 Sep 2020	09:40	[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		1 ou	[]			22/09/2020 22 Sep 2020	10:56	[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		3 ou s	[]			22/09/2020 22 Sep 2020	12:58	[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
4		6 ou s	[]			22/09/2020 22 Sep 2020	16:02	[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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Not done

Reason not done

Date

22-Sep-2020

Time

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

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

14

Normal Abnormal ND

NCS CS

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{ }

Row	tools	Scheduled time	Not done	Reason not done	Date	Time	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Fatigue/ redness		
1		Predose	<input type="checkbox"/>		22/09/2020 22 Sep 2020	09: 2	<input checked="" type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input checked="" type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	
							<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate
							<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe
							<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening
2		hour	<input type="checkbox"/>		22/09/2020 22 Sep 2020	0:57	<input checked="" type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input checked="" type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	
							<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	
							<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	
							<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	
3		3 hours	<input type="checkbox"/>		22/09/2020 22 Sep 2020	2:58	<input checked="" type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input checked="" type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	
							<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	
							<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	
							<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	
		6 hours	<input type="checkbox"/>		22/09/2020 22 Sep 2020	6:03	<input checked="" type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input checked="" type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> None	
							<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Mild	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	
							<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	<input type="checkbox"/> Severe	
							<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<input type="checkbox"/> Potentially life threatening	<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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

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

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Scheduled time	Not done	Reason not done	Date	Time	Measurement side (Arm)	Systolic Blood Pressure (mmHg)	Clinical Significance	Diastolic Blood Pressure (mmHg)	Clinical Significance	Pulse Rate (beats/min)	Clinical Significance	Respiratory Rate (breaths/min)	Clinical Significance
1		Predose	<input type="checkbox"/>		22/09/2020 22-Sep-2020	09 35	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	111	<input type="checkbox"/> NCS <input type="checkbox"/> CS	55	<input type="checkbox"/> NCS <input type="checkbox"/> CS	53	<input type="checkbox"/> NCS <input type="checkbox"/> CS	14	<input type="checkbox"/> NCS <input type="checkbox"/> CS
2		1 hour	<input type="checkbox"/>		22/09/2020 22-Sep-2020	11 01	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	138	<input type="checkbox"/> NCS <input type="checkbox"/> CS	69	<input type="checkbox"/> NCS <input type="checkbox"/> CS	54	<input type="checkbox"/> NCS <input type="checkbox"/> CS	17	<input type="checkbox"/> NCS <input type="checkbox"/> CS
3		3 hours	<input type="checkbox"/>		22/09/2020 22-Sep-2020	13 04	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	145	<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CS	74	<input type="checkbox"/> NCS <input type="checkbox"/> CS	58	<input type="checkbox"/> NCS <input type="checkbox"/> CS	18	<input type="checkbox"/> NCS <input type="checkbox"/> CS
4		6 hours	<input type="checkbox"/>		22/09/2020 22-Sep-2020	15 56	<input checked="" type="checkbox"/> Right <input type="checkbox"/> Left	149	<input checked="" type="checkbox"/> NCS <input type="checkbox"/> CS	76	<input type="checkbox"/> NCS <input type="checkbox"/> CS	63	<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")!

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

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

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

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			29/09/2020 29-Sep-2020	08:40

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			29/09/2020 29-Sep-2020	08:40

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

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

Row	Tools	Not done	Reason not done	Date	Time	Fasting?
1		<input type="checkbox"/>		29/09/2020 29-Sep-2020	08:40	<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!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		29/09/2020 29-Sep-2020	08:14	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")!

[]

Row	Not Too s done	Reason not done	Date	T me	Intens ty of Pa n	Intens ty of Tenderness	Intens ty of Erythema/Redness	Intens ty of Indurat on/Swe ng
[]			29/09/2020 29 Sep 2020	08:02	<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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Not done

Reason not done

Date

29-Sep-2020

Time

Overall health judgement - No Yes
subject healthy?

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

14

[] Normal [] Abnormal [] ND

[] NCS [] CS

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Fatigue/ Irritability	
[]				29/09/2020	08:03	<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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			29/09/2020 29-Sep-2020	07:50

All comments will be entered on comment page!

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	No o o s d o e	Reaso do e	o	Da e	e	Measu e e s de (A)	Sys o c Bood essu e (Hg)	C ca Sg fca ce	Das o c Bood essu e (Hg)	C ca Sg fca ce	u se Ra e (bea s/)	C ca Sg fca ce	Resp a o y Ra e	C ca Sg fca ce
1	[]			29/09/2020 29 Sep 2020	08:13	[x] R g [] Lef	146	[x] NCS [] CS	63	[] NCS [] CS	49	[x] NCS [] CS	11	[] NCS [] CS

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			14/10/2020 14-Oct-2020	07:47

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		14/10/2020 14-Oct-2020	07:41	Oral		36,1	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Not Too s done	Reason not done	Date	T me	Intens ty of Pa n	Intens ty of Tenderness	Intens ty of Erythema/Redness	Intens ty of Indurat on/Swe ng
[]			4/ 0/2020 4 Oct 2020	08:08	<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")!

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]
Not done

Reason not done

Date

14-Oct-2020

Time

Overall health judgement - No Yes
subject healthy?

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

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U' ab & (A^} caa HGI ECECFI

Ua^ KOUUO^i|a
Xa aKa a^ A^Ea Ee G&GUBDA^GDQ| VD

Ö: [^] KÜa dCE
Ø : { KÜ@ • a^ Oca a a^ } A^ED

14

[] Normal [] Abnormal [] ND

[] NCS [] CS

U' ab & (a^} caa HKI ECECFI

Xa aKa aA qe Fa Fa G&G UDDA GDCI VD

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

[]

Row	Tools	Not done	Reason not done	Date	Time	Fever	Intensity of Headache	New or worsened muscle pain	New or worsened joint pain	Intensity of Nausea	Intensity of Vomiting	Intensity of Diarrhea	Intensity of Chills	Intensity of Loss of appetite	Intensity of Malaise	Fatigue/ Irritability	
[]				/ 0/2020	08:09	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially life threatening

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

Row	No oos do e	Reaso do e	o	Da e	e	Measu e e s de (A)	Sys o c B ood essu e (Hg)	C ca Sg f ca ce	Das o c B ood essu e (Hg)	C ca Sg f ca ce	u se Ra e (bea s/)	C ca Sg f ca ce	Resp a o y Ra e (b ea s/)	C ca Sg f ca ce
1	[]			14/10/2020	07:42	[] R g [x] Lef	126	[] NCS [] CS	65	[] NCS [] CS	78	[] NCS [] CS	15	[] NCS [] CS

14 Oc 2020

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

[]

Row	Tools	Not done	Reason not done	Date	Time
1	[]			24/11/2020 24-Nov-2020	10:20

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

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Tools	Not done	Reason not done	Date	Time	Measurement site	Other measurement site, specify:	Body Temperature (°C)	Clinical Significance
1		<input type="checkbox"/>		24/11/2020 24-Nov-2020	09:53	Oral		36,6	<input type="checkbox"/> NCS <input type="checkbox"/> CS

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

Row	No oos do e	Reason do e	Date	Time	Measure (A)	Side	Systolic Blood Pressure (Hg)	Diastolic Blood Pressure (Hg)	Respiratory Rate (beats/)	SpO2	Temperature	Heart Rate	ECG
1	[]		24/11/2020 24 Nov 2020	10:10	[] Rg [x] Lef		145	64	63	[] NCS [] CS	[] NCS [] CS	[] NCS [] CS	[] 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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E reporting according to 62 reporting of E and reactions 03 July 2020

Any Adverse Events? No Yes *

Row	ools	E No	diverse E ent	Serious	Reason select all that apply	E of special rterest	Epi./Pandemic related	Start Date	Start me	Start me unkn	End Date	End ime	End me unkn	Ongoing	Se erity/Intens ty	Intens ty (toxic ty grading scale)	reatment emergent E	Relationship to BMP treatment	DL (Dose limiting toxic ty)	ction taken with IMP reatment	Concomitant medication or therapy	Outcome of E	E Group ID
			fracture leg ankle	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Congenital anomaly or Birth Defect <input type="checkbox"/> Persistent or Significant Disability/Incapacity <input type="checkbox"/> Results in Death <input checked="" type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life threatening <input type="checkbox"/> Other Medically Important Serious Event	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	1/0/2020 Oct 2020	:20					<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially Life threatening	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> Not related <input type="checkbox"/> Related	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Dose not changed <input type="checkbox"/> Dose reduced <input type="checkbox"/> Drug interrupted <input type="checkbox"/> Drug withdrawn <input checked="" 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 checked="" type="checkbox"/> Recovering/resolving <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown	

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Any Comments? [] No [x] Yes *

Row	Tools Visit	Modul	Timepoint	Comment	Date of Comment
1	Visit 6 (a1, b1, b2) / (c2) (EoT)	Phone Call		fracture left ankle: surgery left ankle on 20 Oct 2020 performed, subject reported no dizziness or drowsiness as cause of accident. Slipped on the stairs when entered to Train. CM will be reported when medical report is available	21/10/2020 21-Oct-2020
2	Visit 6 (a1, b1, b2) / (c2) (EoT)	Phone Call		update SAE: Demission from Hospital today (30 Oct 2020). Subject agreed to send medical report.	30/10/2020 30-Oct-2020

090177e195ec8249\Final\Final On: 04-Jan-2021 03:10 (GMT)

Row	Study Day	Not done	Date	Time	Intensity of Pain	Intensity of Tenderness	Intensity of Erythema/Redness	Intensity of Induration/Swelling
		<input type="checkbox"/>	0 /09/2020 0 Sep 2020	20:00	<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 checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
2	2	<input type="checkbox"/>	02/09/2020 02 Sep 2020	20:00	<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 checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
3	3	<input type="checkbox"/>	03/09/2020 03 Sep 2020	20:00	<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
4	4	<input type="checkbox"/>	04/09/2020 04 Sep 2020	20:00	<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
5	5	<input type="checkbox"/>	05/09/2020 05 Sep 2020	20:00	<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
6	6	<input type="checkbox"/>	06/09/2020 06 Sep 2020	20:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
7	7	<input type="checkbox"/>	07/09/2020 07 Sep 2020	08:22	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
8	22	<input type="checkbox"/>	22/09/2020 22 Sep 2020	20:00	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening
9	23	<input type="checkbox"/>	23/09/2020 23 Sep 2020	20:00	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input type="checkbox"/> None <input checked="" type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening	<input checked="" type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potentially threatening

0	24	[]	24/09/2020 24 Sep 2020	20:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng
	25	[]	25/09/2020 25 Sep 2020	20:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng
2	26	[]	26/09/2020 26 Sep 2020	20:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng
3	27	[]	27/09/2020 27 Sep 2020	20:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng
4	28	[]	28/09/2020 28 Sep 2020	20:00	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng	<input checked="" type="checkbox"/> None <input type="checkbox"/> M d <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Potent a y fe threaten ng
5	29	[]	29/09/2020 29 Sep 2020	08: 4	<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

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Any Medical History?

[] No [x] Yes *

Row Tools Abnormality/Disease

Start Date

End Date

Ongoing

1

Menopause

UN/UN/199
3

UN-UNK-1993

UN/UN/199
3

UN-UNK-1993

[x] No [] Yes

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Row	Tools Vaccination Visit	Planned observation period	Other planned observation period (e.g. 8 hours)	Adherence to planned observation period?	If No, actual observation period (hours)	Reason
1	Visit 1	6 hours		[] No [x] Yes		
2	Visit 4	6 hours		[] No [x] Yes		

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

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
	Valeron N retard	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	20/ 0/2020 20 Oct 2020		<input checked="" type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	ORAL		50/4	mg		BID		fracture leg ankle	
2	Pantozol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	20/ 0/2020 20 Oct 2020		<input checked="" type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	ORAL		40	mg		QD		fracture leg ankle	
3	Ibuprofen	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	20/ 0/2020 20 Oct 2020		<input checked="" type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	ORAL		600	mg		TID		fracture leg ankle	
4	Clexane	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	4/ 0/2020 4 Oct 2020		<input checked="" type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	SUBCUTANEOUS		4	mg		QD		fracture leg ankle	
5	Ibuprofen	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	4/ 0/2020 4 Oct 2020		<input checked="" type="checkbox"/>	24/ 0/2020 24 Oct 2020		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		600	mg		Q3D		fracture leg ankle	
6	Ibuprofen	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	25/ 0/2020 25 Oct 2020		<input checked="" type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	ORAL		600	mg		QD		fracture leg ankle	
7	Clexane	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	4/ 0/2020 4 Oct 2020		<input checked="" type="checkbox"/>	2 / /2020 2 Nov 2020		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	SUBCUTANEOUS		40	mg		QD		fracture leg ankle	
8	Tiilidin	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	20/ 0/2020 20 Oct 2020		<input checked="" type="checkbox"/>	30/ 0/2020 30 Oct 2020		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	ORAL		50/4	mg		TWICE		fracture leg ankle	
9	Pantozol	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	20/ 0/2020 20 Oct 2020		<input checked="" type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	ORAL		40	mg		QD		fracture leg ankle	

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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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Row	Tools	Informed Consent for Blood sampling for research purposes?	Visit	Date		Time	Date of Blood sampling	Time of Blood sampling
1		<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Visit 6	14/10/2020 14-Oct-2020	*	07:29	14/10/2020 14-Oct-2020	07:47
2		<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Visit 8	24/11/2020 24-Nov-2020	*	09:13	24/11/2020 24-Nov-2020	10:20

Please insert as many new rows as needed.

Row	Tools Date	Time	Protocol Version
1	22/09/2020 22-Sep-2020	07:35	8.0, 21 JUL 2020
2	24/11/2020 24-Nov-2020	09:13	10.0, 28 OCT 2020

Please insert as many new rows as needed.

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

Row	Tools Date	Time	Outcome of the call (e.g. No findings or new AEs/CMs reported)
1	21/10/2020 21-Oct-2020	10:50	findings or new AEs/CMs reported)
2	30/10/2020 30-Oct-2020	15:20	other: see comment

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 Date

Time

2

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All comments will be entered on comment page!

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

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Q i { K a a U a } • a & X U V U V A C E D

Row	o o s D a e	e	Measu e e s de (A)	Sys o c B ood essu e (Hg)	C ca Sg fca ce	Das o c B ood essu e (Hg)	C ca Sg fca ce	use Ra e (bea s/)	C ca Sg fca ce	Resp a o y Ra e (b ea s/)	C ca Sg fca ce
1	01/09/2020 01 Sep 2020	07:55	[x] R g [] Lef	143	[x] NCS [] CS	70	[] NCS [] CS	50	[] NCS [] CS	14	[] NCS [] CS
2	01/09/2020 01 Sep 2020	14:30	[x] R g [] Lef	152	[x] NCS [] CS	68	[] NCS [] CS	66	[] NCS [] CS	15	[] NCS [] CS

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