

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Visit: Visit 0

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Category

Date

Time

ID

Protocol Version

Was the subject screened? No Yes

Any previous SNs (e.g. 276 01 1234)

Date of first informed consent

Age year s
 month s

Sex Male
 Female

Race, White
select all that apply 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 Non-Hispanic Latino
 Hispanic Latino
 Not reported
 Unknown

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| No | do e | Reason | o do e | Date | Height (cm) | Weight (kg) | Body Mass Index (kg/m ²) | BMI (calculated) (kg/m ²) |
|----|--------------------------|--------|--------|------|----------------|----------------|---|--|
| 1 | <input type="checkbox"/> | | | | | | | |

Months: 1 5 10

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

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Reproductive

Childbearing potential No Yes NA

No childbearing potential Postmenopausal (≥ 12 months)
 Surgically menopause
 Ovarian

Date of Last Menstrual Period

Date of Sterilization

Other, please specify

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| Ca ego y | Spec e | NA | No do e | Reaso o do e | Da e | e | Resu |
|----------|----------------------|----------------------|--------------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Negative
 Positive

Mo e ows: 1 5 10

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

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No dose

Reason for dose

Date

Site

| System/Organs | No. a / Ab o a / ND | Ab o a es/Sy p o s | C ca S g f ca ce | F d g (ca cu a ed) |
|---|--|----------------------|--|----------------------|
| 1 <input type="text" value="Ge e a co d o /psyc e"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 2 <input type="text" value="Sk"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 3 <input type="text" value="Ly p odes"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 4 <input type="text" value="Head (eyes, ea s, ou)"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 5 <input type="text" value="Neck/ y o d g a d"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 6 <input type="text" value="Lu gs"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 7 <input type="text" value="Hea"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 8 <input type="text" value="Abdo e"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 9 <input type="text" value="Muscu oske e a sys e"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 10 <input type="text" value="Neu o og ca sys e"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 11 <input type="text" value="Vascu a sys e"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 12 <input type="text" value="Ca d ovascu a"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 13 <input type="text" value="Gas o es a"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 14 <input type="text" value="O e"/> | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab o a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |

| No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Concomitant Significance | Diastolic Blood Pressure (mmHg) | Concomitant Significance | Pulse Rate (beats/min) | Concomitant Significance | Respiratory Rate (breaths/min) | Concomitant Significance |
|----------------------------|----------------------|----------------------|----------------------|---------------------------|--|--------------------------------|--|---------------------------------|--|------------------------|--|--------------------------------|--|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Right <input type="radio"/> Left | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS |

More rows: 1 5 10

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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| No do e | Reaso o do e | Da e | e | Measu e e s e | O e easu e e s e, spec fy: | Body e pe a u e C ca S g fca ce (°C) | <input type="radio"/> NCS <input type="radio"/> CS |
|---------|--------------------------|----------------------|----------------------|----------------------|----------------------------|--------------------------------------|--|
| 1 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS |

Mo e ows: 1 5 10

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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| No done | Reason no done | Date | Time | Measurement position | Hear Rate (beats/min) | Interpretation | Conductance | Findings select all that apply |
|----------------------------|----------------------|----------------------|----------------------|----------------------|-----------------------|---|--|--|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Normal <input type="radio"/> Abnormal | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |

More rows: 1 5 10

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

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| Category | Specimen | No done | Reason no done | Date | Time | Mephamphetamine | Opiaes | Cocaine | Cannabis | Phencyclidine | Benzodiazepines | Barbiturates | Methadone | Tricyclic antidepressants | Amphetamines |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|--|--|--|--|--|--|--|--|--|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive |

More rows: 1 5 10

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

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| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e | Resu |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Nega ve <input type="radio"/> os ve |

Mo e ows: 1 5 10

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| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

All comments will be entered on comment page!

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

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

| Category | Specimen | No. done | Reasons done | Date | Event | Fasting? |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> No <input type="text"/> Yes |

Months: 1 5 10

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

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No Yes

Subject does
to ?

Date

If No, please select a valid
reason:

Inclusion Criteria:

Exclusion Criteria:

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Visit: Visit 1

| Ca ego y | Spec e | NA | No do e | Reaso o do e | Da e | e | Resu |
|----------|----------------------|----------------------|--------------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Negative
 Positive

Mo e ows: 1 5 10

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

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No do e

Reason do e

Date

Time

Overall judge the subject No Yes

| System/Organ | No / Abnormal / ND | Abnormalities/Symptoms | Classification | Findings (as applicable) |
|---|--|------------------------|--|--------------------------|
| 1 <input type="text" value="Geena code /psyche"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 2 <input type="text" value="Skin"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 3 <input type="text" value="Lymph nodes"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 4 <input type="text" value="Head (eyes, ears, mouth)"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 5 <input type="text" value="Neck/thyroid gland"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 6 <input type="text" value="Lungs"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 7 <input type="text" value="Heart"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 8 <input type="text" value="Abdomen"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 9 <input type="text" value="Musculoskeletal system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 10 <input type="text" value="Neurological system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 11 <input type="text" value="Vascular system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 12 <input type="text" value="Cardiovascular"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 13 <input type="text" value="Genitourinary"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 14 <input type="text" value="Other"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |



| Category | Specimen | No done | Reason no done | Date | Time | Mephamphetamine | Opiaes | Cocaine | Cannabis | Phencyclidine | Benzodiazepines | Barbiturates | Methadone | Tricyclic antidepressants | Amphetamines |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|--|--|--|--|--|--|--|--|--|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive |

More rows: 1 5 10

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

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| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e | Resu |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Negative <input type="radio"/> Positive |

Mo e ows: 1 5 10

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

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| Scheduled time | No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Concomitant Significance | Diastolic Blood Pressure (mmHg) | Concomitant Significance | Pulse Rate (beats/min) | Concomitant Significance | Respiratory Rate (breaths/min) | Concomitant Significance |
|----------------|--------------------------|----------------|------|------|---------------------------|------------------------|--------------------------------|--------------------------|---------------------------------|--------------------------|------------------------|--------------------------|--------------------------------|--------------------------|
| 1 | <input type="checkbox"/> | | | | | R L | | NCS CS | | NCS CS | | NCS CS | | NCS CS |

More rows: 1 5 10

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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| Scheduled time | No. of observations | Reason for observation | Date | Time | Measurement site | Observation site, specify | Body temperature (°C) | Case category |
|----------------|--------------------------|------------------------|------|------|------------------|---------------------------|-----------------------|--|
| 1 | <input type="checkbox"/> | | | | | | | <input type="radio"/> NCS <input type="radio"/> CS |

Months: 1 5 10

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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| No done | Reason no done | Date | Time | Measurement position | Hear Rate (beats/min) | Interpretation | Conductance | Findings select all that apply |
|----------------------------|----------------------|----------------------|----------------------|----------------------|-----------------------|---|--|--------------------------------|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Normal <input type="radio"/> Abnormal | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |

More rows: 1 5 10

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| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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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

| Category | Specimen | No. done | Reasons done | Date | Event | Fasting? |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> No <input type="text"/> Yes |

Months: 1 5 10

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| Ca ego y | Spec e | No do e | Reaso o do e | Da e | e | es a e | Resu |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Negative
 Positive

Mo e ows: 1 5 10

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

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No Yes

Subject does
to ?

Date

If No, please select a valid
reason:

Reason:

Reason:

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Ca ego y

Da e

e

- Subjec s a oca ed o
- Co o 1
 - Co o 2
 - Co o 3
 - Co o 4
 - Co o 5
 - Co o 6
 - Co o 7
 - Co o 8
 - Co o 9
 - Co o 10

- G oup
- A (BN 162a1)
 - B (BN 162b1)
 - C (BN 162b2)
 - D (BN 162c2)
 - E (BN 162c2 /B)

| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Sc edue e

No do e

Reaso o do e

O e , spec fy

Da e

e

Rou e of Ad s a o

ea e

Med ca o Nu be

Dose Fo

a ed dose ug

O e , spec fy ug

U

o a Dose (Vo u e of I jec o) L

U

o a Dose g ve ? No Yes

L

If No, es vo u e

App ca o s e g ef uppe a

Ad s a o acco d g o p o o c o ? No Yes

If No, please specify

Ep/ a de c e a ed adjus e No Yes

Ep/ a de c e a ed e up o No Yes

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| Category | Scheduled time | No done | Reason no done | Date | Time | Test Name | Value or | Intensity of Pain | Intensity of Tenderness | Intensity of erythema/Redness | Intensity of Swelling |
|----------|----------------------|--------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|--|--|--|--|
| 1 | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Proximal <input type="radio"/> Distal | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Proximal <input type="radio"/> Distal | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Proximal <input type="radio"/> Distal | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Proximal <input type="radio"/> Distal |

More rows: 1 5 10

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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| Category | Scheduled time | Not done | Reason not done | Date | Time | Test Name | Evaluator | Fever | Intensity of Headache | New or worsened muscle pain | New or worsened joint pain | Intensity of Nausea | Intensity of Vomiting | Intensity of Diarrhea | Intensity of Chills | Intensity of Loss of appetite | Intensity of Malaise | Fatigue/Tiredness | |
|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|--|--|--|--|--|--|--|--|--|--|--|--|
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |

More rows 5 0

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

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Visit: Visit 2

090177e194f39051Approved\Approved On: 18-Sep-2020 07:16 (GMT)

No do e

Reason do e

Date

Time

Overall judge the subject No Yes

| System/Organ | No | a | Ab | o | a | ND | Ab | o | a | es/Sy | p | o | s | C | ca | S | g | f | ca | ce | F | d | g | (ca | cu | a | e | d) |
|--------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 1 Ge e a co d o /psyc e | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2 Sk | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3 Ly p odes | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4 Head (eyes, ea s, ou) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5 Neck/ y o d g a d | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6 Lu gs | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7 Hea | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8 Abdo e | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9 Muscu oske e a sys e | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10 Neu o og ca sys e | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 11 Vasca sys e | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 12 Ca d ovasca | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 13 Gas o es a | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 14 O e | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

| No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Pulse Rate (beats/min) | Respiratory Rate (breaths/min) |
|----------------------------|----------------------|----------------------|----------------------|---------------------------|---|--------------------------------|---------------------------------|------------------------|--------------------------------|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> R <input type="text"/> L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

More rows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| No do e | Reaso o do e | Da e | e | Measu e e s e | O e easu e e s e, spec fy: | Body e pe a u e C ca S g fca ce (°C) | <input type="radio"/> NCS <input type="radio"/> CS |
|---------|--------------------------|----------------------|----------------------|----------------------|----------------------------|--------------------------------------|--|
| 1 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| | Category | Specimen | Node | Reason | Date | |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Months: 1 5 10

All comments will be entered on comment page!

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)



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

| Category | Specimen | No. done | Reason for not done | Date | Event | Fasting? |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> No <input type="text"/> Yes |

Months: 1 5 10

All comments will be entered on comment page!

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

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| Category | No do e | Reason o do e | Date | Time | Event Name | Evaluation | Intensity of a | Intensity of e de ess | Intensity of Eye a/Red ess | Intensity of I du a o /Swe g |
|----------|--------------------------|------------------|------|------|------------|------------|--|--|--|--|
| 1 | <input type="checkbox"/> | | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe |

Months: 1 5 10

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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| Category | Not done | Reason not done | Date | Time | Test Name | Evaluator | Fever | Intensity of Headache | New or worsened muscle pain | New or worsened joint pain | Intensity of Nausea | Intensity of Vomiting | Intensity of Diarrhea | Intensity of Chills | Intensity of Loss of appetite | Intensity of Malaise | Fatigue/Tiredness | |
|----------|--------------------------|-----------------|------|------|-----------|-----------|--|--|--|--|--|--|--|--|--|--|--|--|
| | <input type="checkbox"/> | | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |

More rows 5 0

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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090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Visit: Phone Call at 48h

Phone call only valid for the first 6 subjects per cohort. For the last 6 subjects please tick NA.

| | NA | No do e | Reaso o do e | Da e | e | Ou co e of e ca (e g No f d gs o ew AEs/CMS epo ed) |
|---|--------------------------|--------------------------|----------------------|----------------------|----------------------|---|
| 1 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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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Visit: Visit 3

090177e194f39051Approved\Approved On: 18-Sep-2020 07:16 (GMT)

No do e

Reason do e

Date

Time

Overall judge the subject No Yes

| System/Organs | No / Abnormal / ND | Abnormalities/Symptoms | Classification | Findings (as applicable) |
|---|--|------------------------|--|--------------------------|
| 1 <input type="text" value="Geena code /psyche"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 2 <input type="text" value="Sk"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 3 <input type="text" value="Lymph nodes"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 4 <input type="text" value="Head (eyes, ears, mouth)"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 5 <input type="text" value="Neck/thyroid gland"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 6 <input type="text" value="Lungs"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 7 <input type="text" value="Heart"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 8 <input type="text" value="Abdomen"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 9 <input type="text" value="Musculoskeletal system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 10 <input type="text" value="Neurological system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 11 <input type="text" value="Vascular system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 12 <input type="text" value="Cardiovascular"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 13 <input type="text" value="Genitourinary"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 14 <input type="text" value="Other"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |

| No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Pulse Rate (beats/min) | Respiratory Rate (breaths/min) |
|----------------------------|----------------------|----------------------|----------------------|---------------------------|---|--------------------------------|---------------------------------|------------------------|--------------------------------|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> R <input type="text"/> L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

More rows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| No do e | Reaso o do e | Da e | e | Measu e e s e | O e easu e e s e, spec fy: | Body e pe a u e C ca S g fca ce (°C) | <input type="radio"/> NCS <input type="radio"/> CS |
|---------|--------------------------|----------------------|----------------------|----------------------|----------------------------|--------------------------------------|--|
| 1 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

All comments will be entered on comment page!

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

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

| Category | Specimen | No. done | Reasons done | Date | Event | Fasting? | |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |

Months: 1 5 10

All comments will be entered on comment page!

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| Category | No do e | Reason o do e | Date | Time | Event Name | Evaluation | Intensity of a | Intensity of e de ess | Intensity of Eye a/Red ess | Intensity of I du a o /Swe g |
|----------|--------------------------|------------------|------|------|------------|------------|--|--|--|--|
| 1 | <input type="checkbox"/> | | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe |

Months: 1 5 10

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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| Category | Not done | Reason not done | Date | Time | Test Name | Evaluator | Fever | Intensity of Headache | New or worsened muscle pain | New or worsened joint pain | Intensity of Nausea | Intensity of Vomiting | Intensity of Diarrhea | Intensity of Chills | Intensity of Loss of appetite | Intensity of Malaise | Fatigue/Tiredness | |
|----------|--------------------------|-----------------|------|------|-----------|-----------|--|--|--|--|--|--|--|--|--|--|--|--|
| | <input type="checkbox"/> | | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |

More rows 5 0

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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Visit: Visit 4

| Case ID | Specimen | NA | No. of Tests | Reason for No. of Tests | Date | Result |
|---------|----------------------|--------------------------|--------------------------|-------------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Months: 1 5 10

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

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No do e

Reason do e

Date

Time

Overall judge the subject No Yes

| System/Organs | No / Abnormal / ND | Abnormalities/Symptoms | Classification | Findings (as applicable) |
|---|--|------------------------|--|--------------------------|
| 1 <input type="text" value="Geena code /psyche"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 2 <input type="text" value="Sk"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 3 <input type="text" value="Lymph nodes"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 4 <input type="text" value="Head (eyes, ears, mouth)"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 5 <input type="text" value="Neck/thyroid gland"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 6 <input type="text" value="Lungs"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 7 <input type="text" value="Heart"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 8 <input type="text" value="Abdomen"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 9 <input type="text" value="Musculoskeletal system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 10 <input type="text" value="Neurological system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 11 <input type="text" value="Vascular system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 12 <input type="text" value="Cardiovascular"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 13 <input type="text" value="Genitourinary"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 14 <input type="text" value="Other"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |

| Scheduled time | No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Concomitant Significance | Concomitant Significance | Pulse Rate (beats/min) | Concomitant Significance | Respiratory Rate (breaths/min) | Concomitant Significance |
|----------------|--------------------------|----------------|------|------|---------------------------|------------------------|--------------------------------|---------------------------------|--------------------------|--------------------------|------------------------|--------------------------|--------------------------------|--------------------------|
| 1 | <input type="checkbox"/> | | | | | R L | | | NCS CS | | | NCS CS | | NCS CS |

More rows: 1 5 10

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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| Scheduled time | Reason for dose | Date | Measurement | Measurement site, specify: | Body temperature (°C) | Case |
|------------------------|--------------------------|----------------------|----------------------|----------------------------|-----------------------|--|
| 1 <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS |

Months: 1 5 10

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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090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Sc edue e

No do e

Reaso o do e

O e , spec fy

Da e

e

Rou e of Ad s a o

ea e

Med ca o Nu be

Dose Fo

a ed dose ug

O e , spec fy ug

U

o a Dose (Vo u e of I jec o) L

U

o a Dose g ve ? No Yes

L

If No, es vo u e

App ca o s e g ef uppe a

Ad s a o acco d g o p o o c o ? No Yes

If No, please specify

Ep / a de c e a ed ad jus e No Yes

Ep / a de c e a ed e up o No Yes

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| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

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| Category | Scheduled time | No done | Reason no done | Date | Time | Test Name | Value or | Intensity of Pain | Intensity of Tenderness | Intensity of erythema/Redness | Intensity of Swelling |
|----------|----------------------|--------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|--|--|--|--|
| 1 | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Proximal <input type="radio"/> Distal | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Proximal <input type="radio"/> Distal | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Proximal <input type="radio"/> Distal | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Proximal <input type="radio"/> Distal |

More rows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| Category | Scheduled time | Not done | Reason not done | Date | Time | Test Name | Evaluator | Fever | Intensity of Headache | New or worsened muscle pain | New or worsened joint pain | Intensity of Nausea | Intensity of Vomiting | Intensity of Diarrhea | Intensity of Chills | Intensity of Loss of appetite | Intensity of Malaise | Fatigue/Tiredness | |
|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|--|--|--|--|--|--|--|--|--|--|--|--|
| <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |

More rows 5 0

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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090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Visit:
Phone Call at 48h (a1, b1, b2, c2P/B)

Phone call only valid for the first 6 subjects per cohort. For the last 6 subjects please tick NA.

| | NA | No do e | Reaso o do e | Da e | e | Ou co e of e ca (e g No f d gs o ew AEs/CMs epo ed) |
|---|--------------------------|--------------------------|----------------------|----------------------|----------------------|---|
| 1 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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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Visit: Visit 5

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No do e

Reason do e

Date

Time

Overall judge the subject No Yes

| System/Organ | No / Abnormal / ND | Abnormalities/Symptoms | Classification | Findings (as applicable) |
|---|--|------------------------|--|--------------------------|
| 1 <input type="text" value="Geena code /psych e"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 2 <input type="text" value="Sk"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 3 <input type="text" value="Lymph nodes"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 4 <input type="text" value="Head (eyes, ears, mouth)"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 5 <input type="text" value="Neck/thyroid gland"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 6 <input type="text" value="Lungs"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 7 <input type="text" value="Heart"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 8 <input type="text" value="Abdomen"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 9 <input type="text" value="Musculoskeletal system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 10 <input type="text" value="Neurological system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 11 <input type="text" value="Vascular system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 12 <input type="text" value="Cardiovascular"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 13 <input type="text" value="Genitourinary"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 14 <input type="text" value="Other"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |

| No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Concomitant Significance | Diastolic Blood Pressure (mmHg) | Concomitant Significance | Pulse Rate (beats/min) | Concomitant Significance | Respiratory Rate (breaths/min) | Concomitant Significance |
|----------------------------|----------------------|----------------------|----------------------|---------------------------|--|--------------------------------|--|---------------------------------|--|------------------------|--|--------------------------------|--|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Right <input type="radio"/> Left | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS |

More rows: 1 5 10

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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| No do e | Reaso o do e | Da e | e | Measu e e s e | O e easu e e s e, spec fy: | Body e pe a u e C ca S g fca ce (°C) | <input type="radio"/> NCS <input type="radio"/> CS |
|---------|--------------------------|----------------------|----------------------|----------------------|----------------------------|--------------------------------------|--|
| 1 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | |

Mo e ows: 1 5 10

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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| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

All comments will be entered on comment page!

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

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

| Category | Specimen | No. done | Reasons done | Date | Event | Fasting? |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> No <input type="text"/> Yes |

Months: 1 5 10

All comments will be entered on comment page!

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

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| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

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| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

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| Category | No do e | Reason | Date | Event Name | Evaluation | Intensity of Pain | Intensity of Redness | Intensity of Swelling |
|----------|--------------------------|--------|------|------------|------------|---|---|---|
| 1 | <input type="checkbox"/> | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> More than 7 days (feeling) | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> More than 7 days (feeling) | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> More than 7 days (feeling) |

Months: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)



| Category | Not done | Reason not done | Date | Time | Test Name | Evaluator | Fever | Intensity of Headache | New or worsened muscle pain | New or worsened joint pain | Intensity of Nausea | Intensity of Vomiting | Intensity of Diarrhea | Intensity of Chills | Intensity of Loss of appetite | Intensity of Malaise | Fatigue/Tiredness | |
|----------|--------------------------|-----------------|------|------|-----------|-----------|--|--|--|--|--|--|--|--|--|--|--|--|
| | <input type="checkbox"/> | | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |

More rows 5 0

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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Visit:
Visit 6 (a1, b1, b2, c2P/B) / (c2) (EoT)

090177e194f39051Approved\Approved On: 18-Sep-2020 07:16 (GMT)

No do e

Reason do e

Date

Time

Overall judge the subject No Yes

| System/Organ | No / Abnormal / ND | Abnormalities/Symptoms | Classification | Findings (as applicable) |
|---|--|------------------------|--|--------------------------|
| 1 <input type="text" value="Geena code /psyche"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 2 <input type="text" value="Skin"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 3 <input type="text" value="Lymph nodes"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 4 <input type="text" value="Head (eyes, ears, mouth)"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 5 <input type="text" value="Neck/thyroid gland"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 6 <input type="text" value="Lungs"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 7 <input type="text" value="Heart"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 8 <input type="text" value="Abdomen"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 9 <input type="text" value="Musculoskeletal system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 10 <input type="text" value="Neurological system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 11 <input type="text" value="Vascular system"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 12 <input type="text" value="Cardiovascular"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 13 <input type="text" value="Genitourinary"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 14 <input type="text" value="Other"/> | <input type="radio"/> No <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |

| No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Pulse Rate (beats/min) | Respiratory Rate (breaths/min) |
|----------------------------|----------------------|----------------------|----------------------|---------------------------|---|--------------------------------|---------------------------------|------------------------|--------------------------------|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

More rows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| No do e | Reaso o do e | Da e | e | Measu e e s e | O e easu e e s e, spec fy: | Body e pe a u e C ca S g fca ce (°C) | <input type="radio"/> NCS <input type="radio"/> CS |
|---------|--------------------------|----------------------|----------------------|----------------------|----------------------------|--------------------------------------|--|
| 1 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

All comments will be entered on comment page!

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

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

| Category | Specimen | No. done | Reason for not done | Date | Event | Fasting? |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> No <input type="text"/> Yes |

Months: 1 5 10

All comments will be entered on comment page!

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| Category | No do e | Reason do e | Date | Time | Event Name | Evaluation | Intensity of Pain | Intensity of Redness | Intensity of Swelling |
|----------|--------------------------|----------------|------|------|------------|------------|--|--|--|
| 1 | <input type="checkbox"/> | | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> More than 7 days before healing | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> More than 7 days before healing | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> More than 7 days before healing |

Months: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)



| Category | Not done | Reason not done | Date | Time | Test Name | Evaluator | Fever | Intensity of Headache | New or worsened muscle pain | New or worsened joint pain | Intensity of Nausea | Intensity of Vomiting | Intensity of Diarrhea | Intensity of Chills | Intensity of Loss of appetite | Intensity of Malaise | Fatigue/Tiredness | |
|----------|--------------------------|-----------------|------|------|-----------|-----------|--|--|--|--|--|--|--|--|--|--|--|--|
| | <input type="checkbox"/> | | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |

More rows 5 0

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Visit:
Visit 7 (a1, b1, b2, c2P/B) (EoT)

090177e194f39051Approved\Approved On: 18-Sep-2020 07:16 (GMT)

No do e

Reason do e

Date

Time

Overall judge the subject No Yes

| System/Organ | No / a / Ab / o / a / ND | Ab / o / a / es / Sy / po / s | Classification | Findings (as applicable) |
|---|--|-------------------------------|--|--------------------------|
| 1 Ge / e / a / co / d / o / /psyc / e | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 2 Sk | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 3 Ly / p / odes | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 4 Head (eyes, ears, mouth) | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 5 Neck / y / o / d / g / a / d | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 6 Lu / gs | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 7 Hea | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 8 Abdo / e | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 9 Muscu / oske / e / a / sys / e | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 10 Neu / o / g / ca / sys / e | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 11 Vascu / a / sys / e | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 12 Ca / d / ovascu / a | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 13 Gas / o / es / a | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 14 O / e | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Ab <input type="radio"/> o <input type="radio"/> a <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |

| No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Pulse Rate (beats/mn) | Respiratory Rate (breaths/mn) |
|----------------------------|----------------------|----------------------|----------------------|---------------------------|---|--------------------------------|---------------------------------|-----------------------|-------------------------------|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> R <input type="text"/> L | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

More rows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| No do e | Reaso o do e | Da e | e | Measu e e s e | O e easu e e s e, spec fy: | Body e pe a u e C ca S g fca ce (°C) | <input type="radio"/> NCS <input type="radio"/> CS |
|---------|--------------------------|----------------------|----------------------|----------------------|----------------------------|--------------------------------------|--|
| 1 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

All comments will be entered on comment page!

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)



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

| Category | Specimen | No. done | Reason for not done | Date | Event | Fasting? |
|----------|----------------------|----------------------|--------------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> No <input type="text"/> Yes |

Months: 1 5 10

All comments will be entered on comment page!

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| Category | No do e | Reason | Date | Time | Event Name | Evaluation | Intensity of Pain | Intensity of Redness | Intensity of Swelling | Intensity of Itching |
|----------|--------------------------|--------|------|------|------------|------------|--|--|--|--|
| 1 | <input type="checkbox"/> | | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe |

Months: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)



| Category | Not done | Reason not done | Date | Time | Test Name | Evaluator | Fever | Intensity of Headache | New or worsened muscle pain | New or worsened joint pain | Intensity of Nausea | Intensity of Vomiting | Intensity of Diarrhea | Intensity of Chills | Intensity of Loss of appetite | Intensity of Malaise | Fatigue/Tiredness | |
|----------|--------------------------|-----------------|------|------|-----------|-----------|--|--|--|--|--|--|--|--|--|--|--|--|
| | <input type="checkbox"/> | | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |

More rows 5 0

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Visit:
Visit 7 (c2) (FU) / V 8 (a1, b1, b2, c2P/B) (FU)

| No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Pulse Rate (beats/min) | Respiratory Rate (breaths/min) |
|----------------------------|----------------------|----------------------|----------------------|---------------------------|---|--------------------------------|---------------------------------|------------------------|--------------------------------|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

More rows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| No do e | Reaso o do e | Da e | e | Measu e e s e | O e easu e e s e, spec fy: | Body e pe a u e C ca S g fca ce (°C) | <input type="radio"/> NCS <input type="radio"/> CS |
|---------|--------------------------|----------------------|----------------------|----------------------|----------------------------|--------------------------------------|--|
| 1 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| | Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|---|----------------------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Visit:
Visit 8 (c2) (FU) / V 9 (a1, b1, b2, c2P/B) (FU)

| No done | Reason no done | Date | Time | Measurement position (BP) | Measurement side (Arm) | Systolic Blood Pressure (mmHg) | Concomitant Significance | Diastolic Blood Pressure (mmHg) | Concomitant Significance | Pulse Rate (beats/min) | Concomitant Significance | Respiratory Rate (breaths/min) | Concomitant Significance |
|----------------------------|----------------------|----------------------|----------------------|---------------------------|--|--------------------------------|--|---------------------------------|--|------------------------|--|--------------------------------|--|
| 1 <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Right <input type="radio"/> Left | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS |

More rows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| No do e | Reaso o do e | Da e | e | Measu e e s e | O e easu e e s e, spec fy: | Body e pe a u e C ca S g fca ce (°C) | <input type="radio"/> NCS <input type="radio"/> CS |
|---------|--------------------------|----------------------|----------------------|----------------------|----------------------------|--------------------------------------|--|
| 1 | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | |

Mo e ows: 1 5 10

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

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

| Ca ego y | Spec e | No do e | Reaso o do e | Da e | e |
|----------|----------------------|--------------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

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090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Visit: End of Trial

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Ca ego y

a fu y co pe ed? No Yes

Da e of Co pe o o Ea y W d awa

- Ma Reaso fo pe a ue e a o
- Adve se Eve
 - Dea
 - Los o Fo ow up
 - y sca Dec so
 - eg a cy
 - o oco Dev a o
 - Sc ee Fa ue
 - S e e a ed by Spo so
 - S udy e a ed by Spo so
 - ec ca obe s
 - W d awa by Subjec
 - O e

Da e of Dea

O e , spec fy:

Ep / a de c e a ed No Yes

Da e of as vs /co ac

090177e194f39051\Approved\Approved On: 18-Sep-2020 07:16 (GMT)

Ca ego y

Fo ow up fu y co pe ed? No Yes

Da e of Co pe o o Ea y W d awa

- Ma Reaso fo pe a ue e a o
- Adve se Eve
 - Dea
 - Los o Fo ow up
 - y sca Dec so
 - eg a cy
 - o oco Dev a o
 - Sc ee Fa ue
 - S e e a ed by Spo so
 - S udy e a ed by Spo so
 - ec ca obe s
 - W d awa by Subjec
 - O e

Da e of Dea

O e , spec fy:

Ep / a de c e a ed No Yes

Da e of as vs /co ac

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Visit: Unrelated Forms

No Yes
Any Medical History?

If Ongoing, please specify intensity (toxicity grading scale)

| | Ab o a y/D sease | S a Da e | E d Da e | O go g |
|----|----------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |
| 2 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |
| 3 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |
| 4 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |
| 5 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |
| 6 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |
| 7 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |
| 8 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |
| 9 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |
| 10 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |

Mo e ows: 1 5 10

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| Vacc a o V s | a ed obse va o pe od | O e pa ed obse va o pe od (e g 8 ou s) | Ad e e ce o pa ed obse va o pe od? | If No, ac ua obse va o pe od (ou s) | Reaso |
|--------------|----------------------|--|--|--------------------------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

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

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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.

| Case ID | Study Day | No doe | Date | Event Name | Evaluation | Intensity of Local Reaction | Intensity of Systemic Reaction | Intensity of Eye/Redness | Intensity of Sweating |
|---------|-----------|--------------------------|------|------------|------------|--|--|--|--|
| 1 | | <input type="checkbox"/> | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life threatening |
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Mo e ows: 1 5 10

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

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| Category | Study Day | Not done | Date | Time | Test Name | Evaluator | 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 |
|----------|----------------------|--------------------------|----------------------|----------------------|----------------------|----------------------|-----------------------|--|--|--|--|--|--|--|--|--|--|
| 1 | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |
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| 6 | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |
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More rows 1 5 10

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No Yes

Any local/systemic reactions **NO RELATED**

| Category | Study Day | Date | Event Name | Local/systemic reactions |
|----------|-----------|------|------------|--------------------------|
| 1 | | | | |

Months: 1 5 10

Please insert as many new rows as needed.

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AE epo g acco d g BN 162 epo g of AE a d eac o s 03Ju y2020

Any Adverse Events? No Yes

| AE No. | Adverse Event | Serious | Reason, select all that apply | AE of special interest | Epi /Pandemic related | Start Date | Start Time | Start Time unkn. | End Date | End Time | End Time unkn. | Ongoing | Severity/Intensity | Intensity (toxicity grading scale) | Treatment emergent AE | Relationship to IMP Treatment | DLT (Dose limiting toxicity) | Action taken with IMP Treatment | Concomitant medication or therapy | Outcome of AE | AE Group ID |
|--------|---------------|--|---|--|--|------------|------------|------------------|----------|----------|----------------|--|--|--|--|--|--|---|--|--|-------------|
| 1 | | No <input type="radio"/> Yes <input type="radio"/> | <input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life Threatening <input type="checkbox"/> Other Medically Important Serious Event | No <input type="radio"/> Yes <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | | | | | | | No <input type="radio"/> Yes <input type="radio"/> | Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> | Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially Life Threatening <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Not related <input type="radio"/> Related <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Not recovered/not resolved <input type="radio"/> Recovered/resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Recovering/resolving <input type="radio"/> Fatal <input type="radio"/> Unknown <input type="radio"/> | |
| 2 | | No <input type="radio"/> Yes <input type="radio"/> | <input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life Threatening <input type="checkbox"/> Other Medically Important Serious Event | No <input type="radio"/> Yes <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | | | | | | | No <input type="radio"/> Yes <input type="radio"/> | Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> | Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially Life Threatening <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Not related <input type="radio"/> Related <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Not recovered/not resolved <input type="radio"/> Recovered/resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Recovering/resolving <input type="radio"/> Fatal <input type="radio"/> Unknown <input type="radio"/> | |
| 3 | | No <input type="radio"/> Yes <input type="radio"/> | <input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life Threatening <input type="checkbox"/> Other Medically Important Serious Event | No <input type="radio"/> Yes <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | | | | | | | No <input type="radio"/> Yes <input type="radio"/> | Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> | Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially Life Threatening <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Not related <input type="radio"/> Related <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Not recovered/not resolved <input type="radio"/> Recovered/resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Recovering/resolving <input type="radio"/> Fatal <input type="radio"/> Unknown <input type="radio"/> | |
| 4 | | No <input type="radio"/> Yes <input type="radio"/> | <input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Persist or Signif Disability/Incapacity <input type="checkbox"/> Results in Death <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Is Life Threatening <input type="checkbox"/> Other Medically Important Serious Event | No <input type="radio"/> Yes <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | | | | | | | No <input type="radio"/> Yes <input type="radio"/> | Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> | Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially Life Threatening <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Not related <input type="radio"/> Related <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Drug interrupted <input type="radio"/> Drug withdrawn <input type="radio"/> Not applicable <input type="radio"/> Unknown <input type="radio"/> | No <input type="radio"/> Yes <input type="radio"/> | Not recovered/not resolved <input type="radio"/> Recovered/resolved <input type="radio"/> Recovered/resolved with sequelae <input type="radio"/> Recovering/resolving <input type="radio"/> Fatal <input type="radio"/> Unknown <input type="radio"/> | |

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07/08/2020

Blank eCRF (CIP 8.0)

114/139

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------|------------------------------|---|-----------------------------|------------------------------|--|-----------------------------|------------------------------|---|-----------------------------|------------------------------|---|-----------------------------|------------------------------|--|-----------------------------|------------------------------|--|-------------------------------|-----------------------------------|---------------------------------|-------------------------------|-----------------------------------|---------------------------------|---|--------------------------------------|----------------------------------|-----------------------------|------------------------------|---|---------------------------------------|---|---|---|----------------------------------|---|---|---|---|--------------------------------|----------------------------------|
| <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Congenital Anomaly or Birth Defect | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Persist or Signif Disability/Incapacity | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Results in Death | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Requires or Prolongs Hospitalization | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Is Life Threatening | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Other Medically Important Serious Event | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe | <input type="checkbox"/> Potentially Life Threatening | <input type="checkbox"/> Not related | <input type="checkbox"/> Related | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Dose not changed | <input type="checkbox"/> Dose reduced | <input type="checkbox"/> Drug interrupted | <input type="checkbox"/> Drug withdrawn | <input type="checkbox"/> Not applicable | <input type="checkbox"/> Unknown | <input type="checkbox"/> Not recovered/not resolved | <input type="checkbox"/> Recovered/resolved | <input type="checkbox"/> Recovered/resolved with sequelae | <input type="checkbox"/> Recovering/resolving | <input type="checkbox"/> Fatal | <input type="checkbox"/> Unknown |
|-----------------------------|------------------------------|---|-----------------------------|------------------------------|--|-----------------------------|------------------------------|---|-----------------------------|------------------------------|---|-----------------------------|------------------------------|--|-----------------------------|------------------------------|--|-------------------------------|-----------------------------------|---------------------------------|-------------------------------|-----------------------------------|---------------------------------|---|--------------------------------------|----------------------------------|-----------------------------|------------------------------|---|---------------------------------------|---|---|---|----------------------------------|---|---|---|---|--------------------------------|----------------------------------|

More rows 5 0

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Are you currently taking any other medications/therapies? No Yes

| 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. |
|------------------------|--|----------------------|----------------------|--------------------------|----------------------|----------------------|--------------------------|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|--------------------------|----------------------|----------------------|
| <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 2 <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 3 <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 4 <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 5 <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | <input type="checkbox"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

More rows 5 0

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No Yes
Any Cores?

| | Vs | Modu | epo | Core | Date of Core |
|---|----------------------|----------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 2 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 3 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 4 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 5 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Months: 1 5 10

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Any protocol Deviations? No Yes

| Vs | Modu | epo | Desc p o of Dev a o | Reaso fo Dev a o | Ca ego y | Da e of Occu e ce |
|----|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 2 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 3 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 4 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 5 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

More rows: 1 5 10

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Category

Specimen

Is informed consent for participant collection necessary? No Yes

Date of IC for participant collection

Time of IC for participant collection

Alliquot taken from previous CMI sampling

Date of previous CMI sampling for analysis Date of previous CMI sampling for analysis

1

Months: 1 5 10

Please insert as many new rows as needed.

Is informed consent for separate HLA typing necessary? No Yes

Date

Time

Separate Blood Sampling for HLA typing taken

Date of HLA typing sample

Time of HLA typing sample

HLA typing Blood Sampling aliquot taken from CMI sampling

Date of collected CMI sample Date of collected CMI sample

1

Months: 1 5 10

Please insert as many new rows as needed.

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Visit: Unscheduled Forms

| | Ca ego y | Da e | e | o oco Ve s o |
|---|----------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

Please insert as many new rows as needed.

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Date

Time

Overall judge the subject healthy? No Yes

| System/Organ | No / a / Abnormal / ND | Abnormalities/Symptoms | Classification | Finding (as dictated) |
|------------------------------|--|------------------------|--|-----------------------|
| 1 Geena code /psyche | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 2 Sk | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 3 Lymph nodes | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 4 Head (eyes, ears, mouth) | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 5 Neck/thyroid gland | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 6 Lungs | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 7 Heart | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 8 Abdomen | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 9 Musculoskeletal system | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 10 Neurological system | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 11 Vascular system | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 12 Cardiovascular | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 13 Gastrointestinal | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |
| 14 Other | <input type="radio"/> No <input type="radio"/> a <input type="radio"/> Abnormal <input type="radio"/> ND | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |

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| Date | Time | Measurement position (B) | Measurement side (A) | System Blood pressure (Hg) | Clinical Significance | Diastolic Blood pressure (Hg) | Clinical Significance | Heart Rate (beats/min) | Clinical Significance | Respiratory Rate (beats/min) | Clinical Significance |
|------|----------------------|--------------------------|----------------------|----------------------------|--|-------------------------------|--|------------------------|--|------------------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Rg <input type="radio"/> Lef | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS |

Measurements: 1 5 10

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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| Date | Time | Measurement Site | Other Measurement Site, specify: | Body Temperature Category | Scale |
|------|----------------------|----------------------|----------------------------------|---------------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> NCS <input type="radio"/> CS |

Months: 1 5 10

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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| | Date | Weight (kg) |
|---|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> |

Measurements: 1 5 10

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

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| Date | Time | Measurement Position | Heart Rate (beats/min) | Interpretation | Classification | Findings |
|------|----------------------|----------------------|------------------------|---|--|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Normal <input type="radio"/> Abnormal | <input type="radio"/> NCS <input type="radio"/> CS | <input type="text"/> |

Measurements: 1 5 10

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

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| Category | Specimen | Date | Time | Mephamphetamine | Opiates | Cocaine | Cannabinoids | Phencyclidine | Benzodiazepines | Barbiturates | Methadone | Tricyclic antidepressants | Amphetamines |
|----------|----------------------|----------------------|----------------------|--|--|--|--|--|--|--|--|--|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive | <input type="radio"/> Negative <input type="radio"/> Positive |

More rows: 1 5 10

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

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| | Ca ego y | Spec e | Da e | e | Resu |
|---|----------------------|----------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Nega ve <input type="radio"/> os ve |

Mo e ows: 1 5 10

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

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Ca ego y Spec e Da e e Resu

1 Negative
 Positive

Mo e ows: 1 5 10

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

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| | Ca ego y | Spec e | Da e | e |
|---|----------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Mo e ows: 1 5 10

All comments will be entered on comment page!

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

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

| Category | Specimen | Date | Time | Fasting? | |
|----------|----------------------|----------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes |

Months: 1 5 10

All comments will be entered on comment page!

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

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| | Category | Specimen | Date | Time | Assessment | Result |
|---|----------------------|----------------------|----------------------|----------------------|----------------------|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> Negative <input type="radio"/> Positive |

Months: 1 5 10

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

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| | Category | Specimen | Date | Time |
|---|----------------------|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Months: 1 5 10

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

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Ca ego y Spec e Da e e

1

Mo e ows: 1 5 10

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

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| Category | Date | Event | Event Name | Evaluation | Intensity of Pain | Intensity of Edema | Intensity of Eye Redness | Intensity of Itching |
|----------|----------------------|----------------------|----------------------|----------------------|--|--|--|--|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Moderate to Severe |

Months: 1 5 10

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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No Yes

Subject: Does the subject meet the exclusion criteria?

Date:

If No, please select a reason for exclusion:

Inclusion Criteria:

Exclusion Criteria:

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| Category | Date | Time | Test Name | Evaluator | Fever | Intensity of Headache | New or worsened muscle pain | New or worsened joint pain | Intensity of Nausea | Intensity of Vomiting | Intensity of Diarrhea | Intensity of Chills | Intensity of Loss of appetite | Intensity of Malaise | Fatigue/Tiredness |
|----------|------|------|-----------|-----------|--|--|--|--|--|--|--|--|--|--|--|
| 1 | | | | | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening | <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Potentially life threatening |

More rows 1 5 10

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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| Category | Specimen | Indicated | Consent for Blood Sampling for Research Purposes? | Visit | Date | Event | Date of Blood Sampling | Event of Blood Sampling |
|----------|----------------------|----------------------|--|----------------------|----------------------|----------------------|------------------------|-------------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="radio"/> No <input type="radio"/> Yes | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Months: 1 5 10

Please insert as many new rows as needed.

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