

Subject Case Report Forms

GRAIL3_Version_1.0_PROD_TP_13APR2021 - All

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Screening Date of Visit

Generated On: 14 Apr 2021 02:49:43

Screening visit date

Date of birth _____

Age _____ Fixed Unit: yrs

Sex assigned at birth _____ Male

Female

Ethnicity _____ Hispanic or Latino

Not Hispanic or Latino

Not reported

Unknown

Race

Mark all that apply.

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or other Pacific Islander

White

Unknown/Not reported

Height at admission to ICU _____ Fixed Unit: cm

Weight at admission to ICU _____ Fixed Unit: kg

Net fluid balance at admission to ICU _____ Fixed Unit: mL

Is the participant on ventilator? _____ Yes

If "No", skip to "Is the participant undergoing ECMO?" _____ No

Ventilator start date _____

Ventilator start time _____

Is the participant undergoing ECMO? _____ Yes

If "No", end of form _____ No

ECMO start date _____

ECMO start time _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Inclusion Exclusion Criteria

Generated On: 14 Apr 2021 02:49:43

Did the participant meet all eligibility criteria? Yes

No

Eligibility status Eligible and enrolled

If "Eligible and enrolled", or "Incomplete screening", end of form. Eligible/Not enrolled

Ineligible

Incomplete screening

Ineligible/Enrolled

Date participant was found "Eligible/Not Enrolled" or "Ineligible"

Select reason(s) why participant is "Eligible/Not Enrolled" or "Ineligible".

E1a. HIV+ (i.e. prior positive test or clinical signs of suspicion of HIV/AIDS; a negative HIV test is not required for enrollment)

E1b. Stem cell transplantation

E1c. Solid organ transplantation with receipt of systemic immunosuppression (any time)

E1d. Cytotoxic anti-cancer chemotherapy within the past three months (Note: next-of-kin estimate is acceptable)

E1e. Congenital immunodeficiency requiring antimicrobial prophylaxis (e.g. TMP-SMX, dapsone, antifungal drugs, intravenous immunoglobulin)

E1f. Receipt of one or more of the following in the indicated time period

E2. Expected to survive < 72 hours (in the opinion of the investigator), or not committed to full intensive care support at the time of study enrollment.

E3. Unable to start receiving first dose of study drug within 120 hours after hospitalization (as measured from admission or time of transfer; subjects who are transferred from a chronic care ward, such as a rehabilitation unit, with an acute event are acceptable).

E4. Pregnant or breastfeeding (either currently or expected within one month).

E5. Absolute neutrophil count < 1,000/mm³ (if no ANC value is available, the WBC must be > 2500/mm³)

- E6. Use of anti-CMV drugs (cidofovir, letermovir, foscarnet, valganciclovir, ganciclovir) within seven (7) days of patient randomization.
- E7. Currently enrolled in an interventional trial of an investigational therapeutic agent known or suspected to have anti-CMV activity or to be associated with significant known hematologic toxicity (prior approval required).
- E8. At baseline patients who have both a tracheostomy, and have been on continuous 24-hour chronic mechanical ventilation.
- E9. Patients with Child Class C Cirrhosis.
- E10. Patients with severe (requiring home oxygen) pre-existing interstitial lung disease.
- E11. Allergy to ganciclovir
- E12. Incarcerated
- E13. Other, specify (e.g. clinician refusal)
- I1. Subject/next of kin informed consent
- I2. Age > 18 years
- I3. CMV IgG seropositive by lateral flow assay (LFA) or standard serologic methods
- I4. Intubated and requiring mechanical positive pressure ventilation with positive end-expiratory pressure (PEEP) > 5 cmH2O; PaO2/FiO2 < 300mmHg; and new, or if no prior imaging, presumed new unilateral or bilateral infiltrates on chest radiography occurring in the setting of sepsis from any source.
- I5 Meets criteria for sepsis within a 24-hour time period within the 120-hour screening window after hospitalization Sepsis will be defined according to the recent Sepsis-3 consensus definition
- I6b. Failed SBT
- I6a. Not eligible for SBT (Spontaneous Breathing Trial). Use of sedation and/or vasopressor does not specifically contraindicate SBT.

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Form: Inclusion Exclusion Criteria

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If "Other", specify (max. 200 characters):

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Form: Informed Consent

Generated On: 14 Apr 2021 02:49:43

Informed consent date

Time of first study product administration _____

Will this participant undergo intensive monitoring? Yes
No

Is this a replacement participant? Yes
No

PTID of participant being replaced _____

Rapid CMV Serology (LFA) _____

Was Rapid CMV Serology (LFA) conducted? Yes
No

If 'No', skip to CMV Serology (ELISA) _____

Rapid CMV Serology (LFA) collection date _____

Rapid CMV Serology (LFA) collection time _____

Rapid CMV Serology (LFA) Result Positive
Negative
Indeterminate

CMV Serology (ELISA) _____

Was CMV Serology (ELISA) conducted? Yes
No

If 'No', skip to Date of chest radiograph _____

CMV Serology (ELISA) collection date _____

CMV Serology (ELISA) collection time _____

CMV Serology (ELISA) result Positive
Negative
Indeterminate

FINAL CMV Status CMV Positive
CMV Negative

Date of chest radiograph _____

Chest radiograph infiltrates assessment Unilateral
Bilateral
None
Other (specify)

If "Other", specify _____

Has this person been diagnosed with COVID-19? Yes
No

If "Has this person been diagnosed with COVID-19?" is "Yes",
provide date _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Participant Replacement Assessment
Generated On: 14 Apr 2021 02:49:43

Date of assessment _____

Does this participant meet protocol-specified criteria for replacement? Yes
No

Why is this participant being replaced?

- Randomized after positive LFA results but prior to negative CLIA-approved ELISA test result
- Participant did not start receiving first dose of study product within 120 hours after hospitalization
- Extubated unexpectedly between time of randomization and first study product administration
- Unexpected death between time of randomization and first study product administration
- Early termination between time of randomization and first study product administration
- Other

If "Early termination" or "Other", specify _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Randomization

Generated On: 14 Apr 2021 02:49:43

Is the participant ready to be randomized?

Yes

No

Randomization date and time _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: 28-Day Follow-up Visit Y/N

Generated On: 14 Apr 2021 02:49:43

Did the participant complete this visit?

Yes

No

If Yes, was this a 28-day summary visit conducted via phone?

Yes

No

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Follow-up Visit Summary
Generated On: 14 Apr 2021 02:49:43

Visit date: _____

Was study product permanently discontinued
(scheduled or early) at this visit? Yes
No

Was study product held at this visit? Yes
No

Were any new adverse events (AEs) reported at this visit? Yes
(If yes, complete an Adverse Event form) No

Is the participant taking any concomitant medications that have not
been previously reported? Yes
No

(Refer to list in study manual of procedures)

Were any protocol deviations reported at this visit? Yes
(If yes, complete a Protocol Deviation form) No

Were any additional study procedures or forms completed outside of
the scheduled study visit per protocol? Yes
No

(Note: Pregnancy Test Results CRF required at discharge)

Did the participant exit/terminate the study at this visit? Yes
(If yes, complete the Termination form) No

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: 28-Day Phone Visit Summary
Generated On: 14 Apr 2021 02:49:43

Visit date: _____

Is the participant still alive? Yes
No

Did the participant report a pregnancy? Yes
(If yes, complete a Pregnancy Report form) No

Were any new adverse events (AEs) reported at this visit? Yes
(If yes, complete an Adverse Event form) No

Were any protocol deviations reported at this visit? Yes
(If yes, complete a Protocol Deviation form) No

Were any additional study procedures or forms completed outside of
the scheduled study visit per protocol? Yes
No

(Note: Pregnancy Test Results CRF required at discharge)

Did the participant exit/terminate the study at this visit? Yes
(If yes, complete the Termination form) No

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: 180-Day Follow-up Visit Summary
Generated On: 14 Apr 2021 02:49:43

Visit date: _____

Vital status Alive

Deceased

Were any protocol deviations reported at this visit? Yes

No

If the participant is female, did she become pregnant within 90 days
of the last dose of study drug? Yes

No

Has the participant had any known development of a new malignant
tumor while on study? Yes

No

If "Yes", specify _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Interim Visit Summary
Generated On: 14 Apr 2021 02:49:43

Visit date: _____

Interim visit code _____

Was study product permanently discontinued (scheduled or early) at this visit? Yes
No

Was study product held at this visit? Yes
No

Were any new adverse events (AEs) reported at this visit? Yes
No

Is the participant taking any concomitant medications that have not been previously reported? Yes
No

(Refer to list in study manual of procedures)

Were any protocol deviations reported at this visit? Yes
No

Did the participant exit/terminate the study at this visit? Yes
No

(If yes, complete the Termination form)

Reason(s) for interim visit (select all that apply)

AE report or follow-up

Completion of missed visit procedures

If completion of missed visit procedures, for which visit are procedures being made up? Day 7 (Visit 3)
Day 13-15 (Visit 5)
Day 20-22 (Visit 7)

Other

If "Other", specify _____

What study procedures were completed at this visit?

Safety Labs

Participant Replacement Assessment

Pregnancy Test Results

Specimen Collection and Storage

SOFA

180-day Follow-up Visit Summary

ADL/IADL

HADS

IES-R

EQ-5D-5L

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Additional Study Procedures

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What additional study procedures were completed at this visit?

Pregnancy Test Results

Participant Replacement

180-day Follow-up Visit Summary

ADL/IADL

HADS

IES-R

EQ-5D-5L

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Missed Visit

Generated On: 14 Apr 2021 02:49:43

Target visit date

Reason visit was missed

Unable to contact participant

Unable to schedule visit within window

Participant or LAR refused visit

Participant incarcerated

Participant withdrew from study

Participant deceased

Participant transferred to a different facility

Patient discharged early

Other

If "Other", specify:

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Discontinuation of Study Product
Generated On: 14 Apr 2021 02:49:43

Date that study product use ended _____

Primary reason for ending study product use

- Scheduled study product use period completed
- Death
- Participant refused further participation
- Participant is unwilling or unable to comply with required study procedures
- Hospital discharge
- Investigator decision
- Participant refused further study product use
- Early study closure
- Protocol deviation
- Adverse event
- Pregnancy
- Withdrawal of consent by participant Legal Authorized Representative (LAR)
- Study terminated by sponsor
- Participant unable to adhere to visit schedule
- Recurrent neutropenia of $<1000/\text{mm}^3$
- Transfer to another facility
- Clinician withdrawal
- Ineligible/enrolled
- Other

If "Other", specify (max. 200 characters): _____

If "Adverse event", select applicable adverse event. _____

Date of study exit _____

Primary reason for completion/discontinuation

Scheduled exit visit/end of study	<input type="radio"/>
Death	<input type="radio"/>
Participant is unwilling or unable to comply with required study procedures	<input type="radio"/>
Lost to follow-up	<input type="radio"/>
Investigator decision	<input type="radio"/>
Early study closure	<input type="radio"/>
Protocol deviation	<input type="radio"/>
Adverse event	<input type="radio"/>
Pregnancy	<input type="radio"/>
Withdrawal of consent by participant	<input type="radio"/>
Study terminated by sponsor	<input type="radio"/>
Patient or LAR refuses further participation	<input type="radio"/>
New scientific developments indicate that the treatment is not in the patient's best interest	<input type="radio"/>
Ineligible/enrolled	<input type="radio"/>
Clinician withdrawal	<input type="radio"/>
Other	<input type="radio"/>

If "Other", specify (max. 200 characters): _____

If "Death", enter date of death _____

If "Adverse event", select applicable adverse event. _____

Were Activities of Daily Living (ADL and IADL) surveys done? Yes
No

Date of assessment _____

Was data for this assessment provided via a Legal Authorized Representative (LAR)? Yes
No

Katz Index of Independence in Activities of Daily Living (ADL)

ACTIVITIES:

Independence = NO supervision, direction or personal assistance (1 POINT);

Dependence = WITH supervision, direction, personal assistance or total care (0 POINTS)

1 - Bathing	INDEPENDENCE: Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity (1) DEPENDENCE: Need help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing (0)
2 - Dressing	INDEPENDENCE: Get clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes. (1) DEPENDENCE: Needs help with dressing self or needs to be completely dressed. (0)
3 - Toileting	INDEPENDENCE: Goes to toilet, gets on and off, arranges clothes, cleans genital area without help. (1) DEPENDENCE: Needs help transferring to the toilet, cleaning self or uses bedpan or commode. (0)
4 - Transferring	INDEPENDENCE: Moves in and out of bed or chair unassisted. Mechanical transfer aids are acceptable (1) DEPENDENCE: Needs help in moving from bed to chair or requires a complete transfer. (0)
5 - Continence	INDEPENDENCE: Exercises complete self control over urination and defecation (1) DEPENDENCE: Is partially or totally incontinent of bowel or bladder (0)
6 - Feeding	INDEPENDENCE: Gets food from plate into mouth without help. Preparation of food may be done by another person (1)

DEPENDENCE: Needs partial or total help with feeding or requires parenteral feeding (0)

ADL TOTAL SCORE

¹ Source: Try This: Best Practices in Nursing Care to Older Adults, The Hartford Institute for Geriatric Nursing, New York University, College of Nursing, www.hartfordign.org.

Lawton-Brody Instrumental Activities of Daily Living Scale (IADL)

Select the item description that most clearly resembles the patient's highest functional level

1 - Ability to use the telephone Operates telephone on own initiative-looks up and dials numbers, etc. (1).
Dials a few well-known numbers (1).
Answers telephone but does not dial (1)
Does not use telephone at all (0).

2 - Shopping Takes care of all shopping needs independently (1).
Shops independently for small purchases (0).
Needs to be accompanied on any shopping trip (0)
Completely unable to shop (0).

3 - Food preparation Plans, prepares and serves adequate meals independently (1).
Prepares adequate meals if supplied with ingredients (0).
Heats, serves and prepares meals, or prepares meals, or prepares meals but does not maintain adequate diet (0)
Needs to have meals prepared and served (0).

4 - Housekeeping Maintains house alone or with occasional assistance (e.g. "heavy work domestic help") (1).
Performs light daily tasks such as dish washing, bed making (1).
Performs light daily tasks but cannot maintain acceptable level of cleanliness (1)
Needs help with all home maintenance tasks (1)
Does not participate in any housekeeping tasks (0)

5 - Laundry Does personal laundry completely (1).
Launders small items-rinses stockings, etc. (1).
All laundry must be done by others (0)

6 - Mode of transportation

	Travels independently on public transportation or drives own car (1). <input type="radio"/>
	Arranges own travel via taxi, but does not otherwise use public transportation (1) <input type="radio"/>
	Travels on public transportation when accompanied by another (1) <input type="radio"/>
	Travel limited to taxi or automobile with assistance of another (0) <input type="radio"/>
	Does not travel at all (0) <input type="radio"/>
<hr/>	
7 - Responsibility for own medications	Is responsible for taking medication in correct dosages at correct time (1). <input type="radio"/>
	Takes responsibility if medication is prepared in advance in separate dosage (0) <input type="radio"/>
	Is not capable of dispensing own medication (0) <input type="radio"/>
<hr/>	
8 - Ability to handle finances	Manages financial matters independently (budgets, writes checks, pays rent, bills, goes to bank), collects and keeps track of income (1). <input type="radio"/>
	Manages day-to-day purchases, but needs help with banking, major purchases, etc. (1) <input type="radio"/>
	Incapable of handling money (0) <input type="radio"/>

IADL TOTAL SCORE _____

² Source: Try This: Best Practices in Nursing Care to Older Adults, The Hartford Institute for Geriatric Nursing, New York University, College of Nursing, www.hartfordign.org

Was Hospital Anxiety and Depression Scale (HADS) Survey done? Yes
No

Date of assessment _____

Select the item description that is closest to how you have been feeling in the past week. Don't take too long over your replies; your immediate is best.

1 - I feel tense or 'wound up' Most of the time
A lot of the time
From time to time, occasionally
Not at all

2 - I still enjoy the things I used to enjoy Definitely as much
Not quite so much
Only a little
Hardly at all

3 - I get a sort of frightened feeling as if something awful is about to happen Very definitely and quite badly
Yes, but not too badly
A little, but it doesn't worry me
Not at all

4 - I can laugh and see the funny side of things As much as I always could
Not quite so much now
Definitely not so much now
Not at all

5 - Worrying thoughts go through my mind A great deal of the time
A lot of the time
From time to time, but not too often
Only occasionally

6 - I feel cheerful Not at all
Not often
Sometimes
Most of the time

7 - I can sit and feel relaxed Definitely
Usually
Not often
Not at all

8 - I feel as if I am slowed down Nearly all the time
Very often
Sometimes
Not at all

9 - I get a sort of frightened feeling like 'butterflies' in the stomach

Not at all

Occasionally

Quite often

Not at all

10 - I have lost interest in my appearance

Definitely

I don't take as much care as I should

I may not take quite as much care

I take just as much care as ever

11 - I feel restless as I have to be on the move

Very much indeed

Quite a lot

Not very much

Not at all

12 - I look forward with enjoyment to things

As much as I ever did

Rather less than I used to

Definitely less than I used to

Hardly at all

13 - I get sudden feelings of panic

Very often indeed

Quite often

Not very often

Not at all

14 - I can enjoy a good book or radio or TV program

Often

Sometimes

Not often

Very seldom

HADS TOTAL SCORE: Depression _____

HADS TOTAL SCORE: Anxiety _____

¹ Source: Hospital Anxiety and Depression Scale (HADS)

Was IES-R Survey done? Yes
No

Date of assessment _____

Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you during the past seven days with respect to the event you experienced. How much were you distressed or bothered by these difficulties?

Select the answer that best describes the difficulties you have had.

1 - Any reminder brought back feelings about it
Not at all
A little bit
Moderately
Quite a bit
Extremely

2 - I had trouble staying asleep
Not at all
A little bit
Moderately
Quite a bit
Extremely

3 - Other things kept making me think about it
Not at all
A little bit
Moderately
Quite a bit
Extremely

4 - I felt irritable and angry
Not at all
A little bit
Moderately
Quite a bit
Extremely

5 - I avoided letting myself get upset when I thought about it or was reminded of it
Not at all
A little bit
Moderately
Quite a bit
Extremely

6 - I thought about it when I didn't mean to
Not at all
A little bit
Moderately
Quite a bit

	Extremely <input type="radio"/>
7 - I felt as if it hadn't happened or wasn't real	Not at all <input type="radio"/>
	A little bit <input type="radio"/>
	Moderately <input type="radio"/>
	Quite a bit <input type="radio"/>
	Extremely <input type="radio"/>
8 - I stayed away from reminders about it	Not at all <input type="radio"/>
	A little bit <input type="radio"/>
	Moderately <input type="radio"/>
	Quite a bit <input type="radio"/>
	Extremely <input type="radio"/>
9 - Images of it popped into my mind	Not at all <input type="radio"/>
	A little bit <input type="radio"/>
	Moderately <input type="radio"/>
	Quite a bit <input type="radio"/>
	Extremely <input type="radio"/>
10 - I was jumpy and easily startled	Not at all <input type="radio"/>
	A little bit <input type="radio"/>
	Moderately <input type="radio"/>
	Quite a bit <input type="radio"/>
	Extremely <input type="radio"/>
11 - I tried not to think about it	Not at all <input type="radio"/>
	A little bit <input type="radio"/>
	Moderately <input type="radio"/>
	Quite a bit <input type="radio"/>
	Extremely <input type="radio"/>
12 - I was aware that I still had a lot of feelings about it, but I didn't deal with them	Not at all <input type="radio"/>
	A little bit <input type="radio"/>
	Moderately <input type="radio"/>
	Quite a bit <input type="radio"/>
	Extremely <input type="radio"/>
13 - My feelings about it were kind of numb	Not at all <input type="radio"/>
	A little bit <input type="radio"/>
	Moderately <input type="radio"/>
	Quite a bit <input type="radio"/>
	Extremely <input type="radio"/>

14 - I found myself acting or feeling as though I was back at that time

Not at all

A little bit

Moderately

Quite a bit

Extremely

15 - I had trouble falling asleep

Not at all

A little bit

Moderately

Quite a bit

Extremely

16 - I had waves of strong feelings about it

Not at all

A little bit

Moderately

Quite a bit

Extremely

17 - I tried to remove it from my memory

Not at all

A little bit

Moderately

Quite a bit

Extremely

18 - I had trouble concentrating

Not at all

A little bit

Moderately

Quite a bit

Extremely

19 - Reminders of the event caused physical reactions such as sweating, difficulty in breathing, nausea or palpitations

Not at all

A little bit

Moderately

Quite a bit

Extremely

20 - I had dreams about it

Not at all

A little bit

Moderately

Quite a bit

Extremely

21 - I felt watchful or on-guard

Not at all

	A little bit	<input type="radio"/>
	Moderately	<input type="radio"/>
	Quite a bit	<input type="radio"/>
	Extremely	<input type="radio"/>

22 - I tried not to talk about it	Not at all	<input type="radio"/>
	A little bit	<input type="radio"/>
	Moderately	<input type="radio"/>
	Quite a bit	<input type="radio"/>
	Extremely	<input type="radio"/>

IES-R TOTAL SCORE _____

¹ Source: Weiss, D. S., & Marmar, C. R. (1996). The Impact of Event Scale - Revised. In J. Wilson & T. M. Keane (Eds.), *Assessing psychological trauma and PTSD* (pp. 399-411). New York: Guilford.

Was the EQ-5D-5L Survey done? Yes
No

Date of assessment _____

Under each heading, please select one answer that best describes your health TODAY.

1 - Mobility I have no problems in walking about
I have slight problems in walking about
I have moderate problems in walking about
I have severe problems in walking about
I am unable to walk about

2 - Self-Care I have no problems washing or dressing myself
I have slight problems washing or dressing myself
I have moderate problems washing or dressing myself
I have severe problems washing or dressing myself
I am unable to wash or dress myself

3 - Usual Activities (e.g. work, study, housework, family or leisure activities) I have no problems doing my usual activities
I have slight problems doing my usual activities
I have moderate problems doing my usual activities
I have severe problems doing my usual activities
I am unable to do my usual activities

4 - Pain/Discomfort I have no pain or discomfort
I have slight pain or discomfort
I have moderate pain or discomfort
I have severe pain or discomfort
I have extreme pain or discomfort

5 - Anxiety/Depression I am not anxious or depressed
I am slightly anxious or depressed
I am moderately anxious or depressed
I am severely anxious or depressed
I am extremely anxious or depressed

We would like to know how good or bad your health is TODAY. This scale is numbered from 0 to 100, where 100 means the best health you can imagine and 0 means the worst health you can imagine.

6 - Your health TODAY _____

EQ-5D-5L TOTAL SCORE _____

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¹ Source: 2009 EuroQol Research Foundation. EQ-5D™ is a trade mark of the EuroQol Research Foundation. UK (English) v1.2

Was APACHE III Chronic Health done? Yes
No

Date of assessment _____

Hospital admission date _____

Hospital admission time _____

Hospital admission type Medical
Surgical, scheduled
Surgical, unscheduled
Other

If "Other", specify _____

Date of ICU admission _____

Time of ICU admission _____

Participant admitted directly from: OR
Recovery room
ER
Floor
Another special care unit
Another hospital
Direct admit
Stepdown unit
Other

If "Another special care unit" or "Other", specify _____

Primary admission diagnosis Cardiac (MI, cardiac arrest, arrhythmia, etc.)

Select the first one in the list that applies to the participant GI (GI bleeding, bowel obstruction, etc. – not to include abdominal sources of sepsis)

Neurologic (stroke, seizure, overdose with coma, mental status changes, myasthenia gravis, Guillain Barre, etc. – not to include traumatic brain injury)

Trauma

Respiratory failure

Sepsis/Septic shock

Shock, non-septic

When did symptoms for "Primary admission diagnosis" start? _____

Is Participant Immediately post-operative from elective surgery? Yes
No

ICU re-admit? Yes
No

ICU re-admit within 24 hours? Yes
No

Chronic Health Items present on admission
If more than one is present, apply the one with highest point value.

- AIDS (does not include HIV positive without AIDS criteria) [23 points]
- Hepatic failure with coma or encephalopathy [16 points]
- Non-Hodgkin's Lymphoma [13 points]
- Solid tumor with metastasis [11 points]
- Leukemia (AML, CML, all lymphocytic leukemia, multiple melanoma [10 points]
- Significant immunocompromise (e.g. chemotherapy, radiation, high dose steroids, other immunosuppressive medications, etc) [10 points]
- Cirrhosis [4 points]
- None/not available

APACHE III PHYSIOLOGY

Instructions: Use values from 24 hours preceding randomization. If no values were obtained for clinical purposes during the 24 hours preceding randomization, the lab tests must be obtained (after obtaining participant/surrogate consent) before initializing study procedures)

Was APACHE III Acute Physiology done? Yes
 No

Date of assessment _____

Pulse: highest _____ Fixed Unit: beats/min

Pulse: lowest _____ Fixed Unit: beats/min

Mean Blood Pressure (MAP): highest _____ Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest _____ Fixed Unit: mmHg

Body temperature: highest _____ Fixed Unit: C

Body temperature: lowest _____ Fixed Unit: C

Respiratory rate: highest _____ Fixed Unit: breaths/min

Respiratory rate: lowest _____ Fixed Unit: breaths/min

PaO2: lowest _____ Fixed Unit: mmHg

If PaO2 not done, check this box AND record SpO2 below

SpO2: lowest _____ Fixed Unit: %

FiO2: closest to lowest PaO2 (or SpO2 if PaO2 not done) _____

PaCO2: on same ABG as lowest PaO2 _____ Fixed Unit: %

If PaCO2 not done, check this box

Venous PCO2: closest to lowest SpO2 _____ Fixed Unit: %

If Venous PCO2 not done, check this box

End tidal CO2: closest to lowest SpO2 _____ Fixed Unit: %

If End tidal CO2 not done, check this box

ACID-BASE ABNORMALITIES

Blood pH: Source _____ Arterial blood gases (ABG)

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Venus blood gases (VBG)

pH: highest

pH: lowest

pCO2: highest

Fixed Unit: mmHg

pCO2: lowest

Fixed Unit: mmHg

Total urine output over 24 hours prior to randomization

Fixed Unit: cc/day

Is the participant on chronic dialysis or peritoneal dialysis?

Yes

No

HEMATOLOGY AND CHEMISTRY

Hematocrit: highest

Fixed Unit: %

Hematocrit: lowest

Fixed Unit: %

WBC: highest

Fixed Unit: cells/mm3

WBC: lowest

Fixed Unit: cells/mm3

Creatinine: highest

Fixed Unit: mg/dL

Creatinine: lowest

Fixed Unit: mg/dL

Serum BUN: highest

Fixed Unit: mg/dL

Serum Sodium: highest

Fixed Unit: meq/L

Serum Sodium: lowest

Fixed Unit: meq/L

Serum Albumin: highest

Fixed Unit: g/dL

Serum Albumin: lowest

Fixed Unit: g/dL

Total Bilirubin: highest

Fixed Unit: mg/dL

Serum Glucose: highest

Fixed Unit: mg/dL

Serum Glucose: lowest

Fixed Unit: mg/dL

NEUROLOGICAL ABNORMALITIES: lowest

Eye response

No eye opening

	Eyes open to pain	<input type="radio"/>
	Eyes open to verbal command	<input type="radio"/>
	Eyes open spontaneously	<input type="radio"/>
<hr/>		
Verbal response	No response	<input type="radio"/>
	Inappropriate words & Incomprehensible sounds	<input type="radio"/>
	Confused conversation	<input type="radio"/>
	Oriented, converses	<input type="radio"/>
<hr/>		
Motor response	Decerebrate rigidity/no response	<input type="radio"/>
	Flexion withdrawal/decorticate rigidity	<input type="radio"/>
	Localizes pain	<input type="radio"/>
	Obeys commands	<input type="radio"/>
<hr/>		
Neurological Abnormalities Score		<hr/>

Interim visit?

If Interim visit, check this box and save form to add row for interim visit

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

SOFA assessment time point

Day 1 (Visit 1)

Day 2 (Visit 1)

Day 3 (Visit 2)

Day 4 (Visit 2)

Day 5 (Visit 2)

Day 6 (Visit 3)

Day 7 (Visit 3)

Day 10-12 (Visit 4)

Day 13-15 (Visit 5)

Day 17-19 (Visit 6)

Day 20-22 (Visit 7)

Day 24-26 (Visit 8)

Day 27-28 (Visit 9)

Interim Visit

If "Interim visit", specify interim visit code.

Date of assessment

SOFA Score components Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor Yes

No

If Vasopressor is Yes, Select applicable concomitant medication

SpO2: lowest Fixed Unit: %

PaO2: lowest Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2

Platelets: lowest Fixed Unit: 10³/mm³

Total Bilirubin: highest Fixed Unit: mg/dL

Creatinine: highest Fixed Unit: mg/dL

Total urine output over 24 hours Fixed Unit: mL

GLASGOW COMA SCORE:lowest Spontaneous--open with blinking at baseline

Eye response To verbal stimuli, command, speech

To pain only (not applied to face)

No response

Verbal response Oriented

Confused conversation, but able to answer questions

Inappropriate words

Incomprehensible speech

No response

Motor response Obeys commands for movement

Purposeful movement to painful stimulus

Withdraws in response to pain

Flexion in response to pain (decorticate posturing)

Extension response in response to pain (decerebrate posturing)

No response

Glasgow Coma Score (calculated)

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

SOFA assessment time point Day 1 (Visit 1)

Day 2 (Visit 1)

Day 3 (Visit 2)

Day 4 (Visit 2)

Day 5 (Visit 2)

Day 6 (Visit 3)

Day 7 (Visit 3)

Day 10-12 (Visit 4)

Day 13-15 (Visit 5)

Day 17-19 (Visit 6)

Day 20-22 (Visit 7)

Day 24-26 (Visit 8)

Day 27-28 (Visit 9)

Interim Visit

If "Interim visit", specify interim visit code.

Date of assessment

SOFA Score components

Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor

Yes

No

If Vasopressor is Yes, Select applicable concomitant medication

SpO2: lowest

Fixed Unit: %

PaO2: lowest

Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2

Platelets: lowest

Fixed Unit: 10³/mm³

Total Bilirubin: highest

Fixed Unit: mg/dL

Creatinine: highest

Fixed Unit: mg/dL

Total urine output over 24 hours

Fixed Unit: mL

GLASGOW COMA SCORE:lowest

Spontaneous--open with blinking
at baseline

To verbal stimuli, command,
speech

Eye response

To pain only (not applied to
face)

No response

Verbal response

Oriented

Confused conversation, but able
to answer questions

Inappropriate words

Incomprehensible speech

No response

Motor response

Obeys commands for movement

Purposeful movement to painful
stimulus

Withdraws in response to pain

Flexion in response to pain
(decorticate posturing)

Extension response in response to pain (decerebrate posturing)
No response

Glasgow Coma Score (calculated) _____

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

SOFA assessment time point

Day 1 (Visit 1)
Day 2 (Visit 1)
Day 3 (Visit 2)
Day 4 (Visit 2)
Day 5 (Visit 2)
Day 6 (Visit 3)
Day 7 (Visit 3)
Day 10-12 (Visit 4)
Day 13-15 (Visit 5)
Day 17-19 (Visit 6)
Day 20-22 (Visit 7)
Day 24-26 (Visit 8)
Day 27-28 (Visit 9)
Interim Visit

If "Interim visit", specify interim visit code. _____

Date of assessment _____

SOFA Score components Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest _____

Vasopressor Yes
No

If Vasopressor is Yes, Select applicable concomitant medication _____

SpO2: lowest Fixed Unit: %

PaO2: lowest Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2 _____

Platelets: lowest Fixed Unit: 10³/mm³

Total Bilirubin: highest Fixed Unit: mg/dL

Creatinine: highest Fixed Unit: mg/dL

Total urine output over 24 hours Fixed Unit: mL

GLASGOW COMA SCORE:lowest

Spontaneous--open with blinking at baseline

To verbal stimuli, command, speech

Eye response To pain only (not applied to face)

No response

Verbal response Oriented

Confused conversation, but able to answer questions

Inappropriate words

Incomprehensible speech

No response

Motor response Obeys commands for movement

Purposeful movement to painful stimulus

Withdraws in response to pain

Flexion in response to pain (decorticate posturing)

Extension response in response to pain (decerebrate posturing)

No response

Glasgow Coma Score (calculated)

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

SOFA assessment time point

Day 1 (Visit 1)

Day 2 (Visit 1)

Day 3 (Visit 2)

Day 4 (Visit 2)

Day 5 (Visit 2)

Day 6 (Visit 3)

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Day 13-15 (Visit 5)

Day 17-19 (Visit 6)

Day 20-22 (Visit 7)

Day 24-26 (Visit 8)

Day 27-28 (Visit 9)

Interim Visit

If "Interim visit", specify interim visit code.

Date of assessment

SOFA Score components

Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor

Yes

No

If Vasopressor is Yes, Select applicable concomitant medication

SpO2: lowest

Fixed Unit: %

PaO2: lowest

Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2

Platelets: lowest

Fixed Unit: 10³/mm³

Total Bilirubin: highest

Fixed Unit: mg/dL

Creatinine: highest

Fixed Unit: mg/dL

Total urine output over 24 hours

Fixed Unit: mL

GLASGOW COMA SCORE:lowest

Spontaneous--open with blinking
at baseline

To verbal stimuli, command,
speech

Eye response

To pain only (not applied to
face)

No response

Verbal response

Oriented

Confused conversation, but able
to answer questions

Inappropriate words

Incomprehensible speech

No response

Motor response

Obeys commands for movement

Purposeful movement to painful
stimulus

Withdraws in response to pain

Flexion in response to pain
(decorticate posturing)

Extension response in response to pain (decerebrate posturing)
No response

Glasgow Coma Score (calculated) _____

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

SOFA assessment time point

Day 1 (Visit 1)
Day 2 (Visit 1)
Day 3 (Visit 2)
Day 4 (Visit 2)
Day 5 (Visit 2)
Day 6 (Visit 3)
Day 7 (Visit 3)
Day 10-12 (Visit 4)
Day 13-15 (Visit 5)
Day 17-19 (Visit 6)
Day 20-22 (Visit 7)
Day 24-26 (Visit 8)
Day 27-28 (Visit 9)
Interim Visit

If "Interim visit", specify interim visit code. _____

Date of assessment _____

SOFA Score components Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor Yes
No

If Vasopressor is Yes, Select applicable concomitant medication _____

SpO2: lowest Fixed Unit: %

PaO2: lowest Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2 _____

Platelets: lowest Fixed Unit: 10³/mm³

Total Bilirubin: highest Fixed Unit: mg/dL

Creatinine: highest Fixed Unit: mg/dL

Total urine output over 24 hours Fixed Unit: mL

GLASGOW COMA SCORE:lowest Spontaneous--open with blinking at baseline

To verbal stimuli, command, speech

Eye response To pain only (not applied to face)

No response

Verbal response Oriented

Confused conversation, but able to answer questions

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Motor response Obeys commands for movement

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Withdraws in response to pain

Flexion in response to pain (decorticate posturing)

Extension response in response to pain (decerebrate posturing)

No response

Glasgow Coma Score (calculated)

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

SOFA assessment time point Day 1 (Visit 1)

Day 2 (Visit 1)

Day 3 (Visit 2)

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Day 5 (Visit 2)

Day 6 (Visit 3)

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Day 17-19 (Visit 6)

Day 20-22 (Visit 7)

Day 24-26 (Visit 8)

Day 27-28 (Visit 9)

Interim Visit

If "Interim visit", specify interim visit code.

Date of assessment

SOFA Score components

Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor

Yes

No

If Vasopressor is Yes, Select applicable concomitant medication

SpO2: lowest

Fixed Unit: %

PaO2: lowest

Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2

Platelets: lowest

Fixed Unit: 10³/mm³

Total Bilirubin: highest

Fixed Unit: mg/dL

Creatinine: highest

Fixed Unit: mg/dL

Total urine output over 24 hours

Fixed Unit: mL

GLASGOW COMA SCORE:lowest

Spontaneous--open with blinking
at baseline

To verbal stimuli, command,
speech

Eye response

To pain only (not applied to
face)

No response

Verbal response

Oriented

Confused conversation, but able
to answer questions

Inappropriate words

Incomprehensible speech

No response

Motor response

Obeys commands for movement

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stimulus

Withdraws in response to pain

Flexion in response to pain
(decorticate posturing)

Extension response in response to pain (decerebrate posturing)
No response

Glasgow Coma Score (calculated) _____

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

SOFA assessment time point

Day 1 (Visit 1)
Day 2 (Visit 1)
Day 3 (Visit 2)
Day 4 (Visit 2)
Day 5 (Visit 2)
Day 6 (Visit 3)
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Day 13-15 (Visit 5)
Day 17-19 (Visit 6)
Day 20-22 (Visit 7)
Day 24-26 (Visit 8)
Day 27-28 (Visit 9)
Interim Visit

If "Interim visit", specify interim visit code. _____

Date of assessment _____

SOFA Score components Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor Yes
No

If Vasopressor is Yes, Select applicable concomitant medication _____

SpO2: lowest Fixed Unit: %

PaO2: lowest Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2 _____

Platelets: lowest Fixed Unit: 10³/mm³

Total Bilirubin: highest Fixed Unit: mg/dL

Creatinine: highest Fixed Unit: mg/dL

Total urine output over 24 hours Fixed Unit: mL

GLASGOW COMA SCORE:lowest Spontaneous--open with blinking at baseline

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Extension response in response to pain (decerebrate posturing)

No response

Glasgow Coma Score (calculated)

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

SOFA assessment time point Day 1 (Visit 1)

Day 2 (Visit 1)

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Day 4 (Visit 2)

Day 5 (Visit 2)

Day 6 (Visit 3)

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Day 17-19 (Visit 6)

Day 20-22 (Visit 7)

Day 24-26 (Visit 8)

Day 27-28 (Visit 9)

Interim Visit

If "Interim visit", specify interim visit code.

Date of assessment

SOFA Score components

Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor

Yes

No

If Vasopressor is Yes, Select applicable concomitant medication

SpO2: lowest

Fixed Unit: %

PaO2: lowest

Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2

Platelets: lowest

Fixed Unit: 10³/mm³

Total Bilirubin: highest

Fixed Unit: mg/dL

Creatinine: highest

Fixed Unit: mg/dL

Total urine output over 24 hours

Fixed Unit: mL

GLASGOW COMA SCORE:lowest

Spontaneous--open with blinking at baseline

To verbal stimuli, command, speech

Eye response

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Purposeful movement to painful stimulus

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Flexion in response to pain (decorticate posturing)

Extension response in response to pain (decerebrate posturing)
No response

Glasgow Coma Score (calculated) _____

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

SOFA assessment time point

Day 1 (Visit 1)
Day 2 (Visit 1)
Day 3 (Visit 2)
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Day 5 (Visit 2)
Day 6 (Visit 3)
Day 7 (Visit 3)
Day 10-12 (Visit 4)
Day 13-15 (Visit 5)
Day 17-19 (Visit 6)
Day 20-22 (Visit 7)
Day 24-26 (Visit 8)
Day 27-28 (Visit 9)
Interim Visit

If "Interim visit", specify interim visit code. _____

Date of assessment _____

SOFA Score components Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor Yes
No

If Vasopressor is Yes, Select applicable concomitant medication _____

SpO2: lowest Fixed Unit: %

PaO2: lowest Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2 _____

Platelets: lowest Fixed Unit: 10³/mm³

Total Bilirubin: highest Fixed Unit: mg/dL

Creatinine: highest Fixed Unit: mg/dL

Total urine output over 24 hours Fixed Unit: mL

GLASGOW COMA SCORE:lowest Spontaneous--open with blinking at baseline

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Extension response in response to pain (decerebrate posturing)

No response

Glasgow Coma Score (calculated)

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

SOFA assessment time point Day 1 (Visit 1)

Day 2 (Visit 1)

Day 3 (Visit 2)

Day 4 (Visit 2)

Day 5 (Visit 2)

Day 6 (Visit 3)

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Day 17-19 (Visit 6)

Day 20-22 (Visit 7)

Day 24-26 (Visit 8)

Day 27-28 (Visit 9)

Interim Visit

If "Interim visit", specify interim visit code.

Date of assessment

SOFA Score components

Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor

Yes

No

If Vasopressor is Yes, Select applicable concomitant medication

SpO2: lowest

Fixed Unit: %

PaO2: lowest

Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2

Platelets: lowest

Fixed Unit: 10³/mm³

Total Bilirubin: highest

Fixed Unit: mg/dL

Creatinine: highest

Fixed Unit: mg/dL

Total urine output over 24 hours

Fixed Unit: mL

GLASGOW COMA SCORE:lowest

Spontaneous--open with blinking
at baseline

To verbal stimuli, command,
speech

Eye response

To pain only (not applied to
face)

No response

Verbal response

Oriented

Confused conversation, but able
to answer questions

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Incomprehensible speech

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Motor response

Obeys commands for movement

Purposeful movement to painful
stimulus

Withdraws in response to pain

Flexion in response to pain
(decorticate posturing)

Extension response in response to pain (decerebrate posturing)
No response

Glasgow Coma Score (calculated) _____

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

SOFA assessment time point

Day 1 (Visit 1)
Day 2 (Visit 1)
Day 3 (Visit 2)
Day 4 (Visit 2)
Day 5 (Visit 2)
Day 6 (Visit 3)
Day 7 (Visit 3)
Day 10-12 (Visit 4)
Day 13-15 (Visit 5)
Day 17-19 (Visit 6)
Day 20-22 (Visit 7)
Day 24-26 (Visit 8)
Day 27-28 (Visit 9)
Interim Visit

If "Interim visit", specify interim visit code. _____

Date of assessment _____

SOFA Score components Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor Yes
No

If Vasopressor is Yes, Select applicable concomitant medication _____

SpO2: lowest Fixed Unit: %

PaO2: lowest Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2 _____

Platelets: lowest Fixed Unit: 10³/mm³

Total Bilirubin: highest Fixed Unit: mg/dL

Creatinine: highest Fixed Unit: mg/dL

Total urine output over 24 hours Fixed Unit: mL

GLASGOW COMA SCORE:lowest Spontaneous--open with blinking at baseline

Eye response To verbal stimuli, command, speech

To pain only (not applied to face)

No response

Verbal response Oriented

Confused conversation, but able to answer questions

Inappropriate words

Incomprehensible speech

No response

Motor response Obeys commands for movement

Purposeful movement to painful stimulus

Withdraws in response to pain

Flexion in response to pain (decorticate posturing)

Extension response in response to pain (decerebrate posturing)

No response

Glasgow Coma Score (calculated)

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

SOFA assessment time point Day 1 (Visit 1)

Day 2 (Visit 1)

Day 3 (Visit 2)

Day 4 (Visit 2)

Day 5 (Visit 2)

Day 6 (Visit 3)

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Day 10-12 (Visit 4)

Day 13-15 (Visit 5)

Day 17-19 (Visit 6)

Day 20-22 (Visit 7)

Day 24-26 (Visit 8)

Day 27-28 (Visit 9)

Interim Visit

If "Interim visit", specify interim visit code.

Date of assessment

SOFA Score components

Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor

Yes

No

If Vasopressor is Yes, Select applicable concomitant medication

SpO2: lowest

Fixed Unit: %

PaO2: lowest

Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2

Platelets: lowest

Fixed Unit: 10³/mm³

Total Bilirubin: highest

Fixed Unit: mg/dL

Creatinine: highest

Fixed Unit: mg/dL

Total urine output over 24 hours

Fixed Unit: mL

GLASGOW COMA SCORE:lowest

Spontaneous--open with blinking
at baseline

To verbal stimuli, command,
speech

Eye response

To pain only (not applied to
face)

No response

Verbal response

Oriented

Confused conversation, but able
to answer questions

Inappropriate words

Incomprehensible speech

No response

Motor response

Obeys commands for movement

Purposeful movement to painful
stimulus

Withdraws in response to pain

Flexion in response to pain
(decorticate posturing)

Extension response in response to pain (decerebrate posturing)
No response

Glasgow Coma Score (calculated) _____

Was SOFA assessment done? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

SOFA assessment time point

Day 1 (Visit 1)
Day 2 (Visit 1)
Day 3 (Visit 2)
Day 4 (Visit 2)
Day 5 (Visit 2)
Day 6 (Visit 3)
Day 7 (Visit 3)
Day 10-12 (Visit 4)
Day 13-15 (Visit 5)
Day 17-19 (Visit 6)
Day 20-22 (Visit 7)
Day 24-26 (Visit 8)
Day 27-28 (Visit 9)
Interim Visit

If "Interim visit", specify interim visit code. _____

Date of assessment _____

SOFA Score components Fixed Unit: mmHg

Mean Blood Pressure (MAP): lowest

Vasopressor Yes
No

If Vasopressor is Yes, Select applicable concomitant medication _____

SpO2: lowest Fixed Unit: %

PaO2: lowest Fixed Unit: mmHg

If PaO2 not done, check this box

FiO2: closest to lowest SpO2 _____

Platelets: lowest Fixed Unit: 10³/mm³

Total Bilirubin: highest Fixed Unit: mg/dL

Creatinine: highest Fixed Unit: mg/dL

Total urine output over 24 hours Fixed Unit: mL

GLASGOW COMA SCORE:lowest	Spontaneous--open with blinking at baseline <input type="radio"/>
Eye response	To verbal stimuli, command, speech <input type="radio"/>
	To pain only (not applied to face) <input type="radio"/>
	No response <input type="radio"/>
	<hr/>
Verbal response	Oriented <input type="radio"/>
	Confused conversation, but able to answer questions <input type="radio"/>
	Inappropriate words <input type="radio"/>
	Incomprehensible speech <input type="radio"/>
	No response <input type="radio"/>
<hr/>	
Motor response	Obeys commands for movement <input type="radio"/>
	Purposeful movement to painful stimulus <input type="radio"/>
	Withdraws in response to pain <input type="radio"/>
	Flexion in response to pain (decorticate posturing) <input type="radio"/>
	Extension response in response to pain (decerebrate posturing) <input type="radio"/>
	No response <input type="radio"/>

Glasgow Coma Score (calculated)

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Study Product Administration (Daily)
Generated On: 14 Apr 2021 02:49:43

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point

Day 1: Dose 1

Day 1: Dose 2

Day 2: Dose 1

Day 2: Dose 2

Day 3: Dose 1

Day 3: Dose 2

Day 4: Dose 1

Day 4: Dose 2

Day 5: Dose 1

Day 5: Dose 2

Day 6: Dose 1

Day 6: Dose 2

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18

Day 19

Day 20

Day 21

Day 22

Day 23

Day 24

Day 25

Day 26

Day 27

Day 28

Date study product administered _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Study Product Administration (Daily)
Generated On: 14 Apr 2021 02:49:43

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

Product administration time point

Day 1: Dose 1	<input type="radio"/>
Day 1: Dose 2	<input checked="" type="radio"/>
Day 2: Dose 1	<input type="radio"/>
Day 2: Dose 2	<input type="radio"/>
Day 3: Dose 1	<input type="radio"/>
Day 3: Dose 2	<input type="radio"/>
Day 4: Dose 1	<input type="radio"/>
Day 4: Dose 2	<input type="radio"/>
Day 5: Dose 1	<input type="radio"/>
Day 5: Dose 2	<input type="radio"/>
Day 6: Dose 1	<input type="radio"/>
Day 6: Dose 2	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>

Day 26
Day 27
Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point

Day 1: Dose 1
Day 1: Dose 2
Day 2: Dose 1
Day 2: Dose 2
Day 3: Dose 1
Day 3: Dose 2
Day 4: Dose 1
Day 4: Dose 2
Day 5: Dose 1
Day 5: Dose 2
Day 6: Dose 1
Day 6: Dose 2
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19
Day 20
Day 21

- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
 - Day 1: Dose 2
 - Day 2: Dose 1
 - Day 2: Dose 2
 - Day 3: Dose 1
 - Day 3: Dose 2
 - Day 4: Dose 1
 - Day 4: Dose 2
 - Day 5: Dose 1
 - Day 5: Dose 2
 - Day 6: Dose 1
 - Day 6: Dose 2
 - Day 7
 - Day 8
 - Day 9
 - Day 10
 - Day 11
 - Day 12
 - Day 13
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- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date study product administered _____

Renal adjusted dose? Yes No

If yes, specify dose _____

If Renal adjusted dose, specify dose _____ Fixed Unit: mg/kg

Was study drug administered? Yes No

If "No", specify reason. _____

Reason not done (max. 200 characters) _____

Product administration time point

- Day 1: Dose 1
- Day 1: Dose 2
- Day 2: Dose 1
- Day 2: Dose 2
- Day 3: Dose 1
- Day 3: Dose 2
- Day 4: Dose 1
- Day 4: Dose 2
- Day 5: Dose 1
- Day 5: Dose 2
- Day 6: Dose 1
- Day 6: Dose 2
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- Day 27
- Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
 - Day 1: Dose 2
 - Day 2: Dose 1
 - Day 2: Dose 2
 - Day 3: Dose 1
 - Day 3: Dose 2
 - Day 4: Dose 1
 - Day 4: Dose 2
 - Day 5: Dose 1
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 - Day 6: Dose 1
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Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

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Was study drug administered? Yes

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Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
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 - Day 2: Dose 1
 - Day 2: Dose 2
 - Day 3: Dose 1
 - Day 3: Dose 2
 - Day 4: Dose 1
 - Day 4: Dose 2
 - Day 5: Dose 1
 - Day 5: Dose 2
 - Day 6: Dose 1

- Day 6: Dose 2
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Date study product administered _____

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Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
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 - Day 3: Dose 2
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- Day 4: Dose 2
- Day 5: Dose 1
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Date study product administered _____

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If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point Day 1: Dose 1

Day 1: Dose 2

Day 2: Dose 1

- Day 2: Dose 2
- Day 3: Dose 1
- Day 3: Dose 2
- Day 4: Dose 1
- Day 4: Dose 2
- Day 5: Dose 1
- Day 5: Dose 2
- Day 6: Dose 1
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- Day 26
- Day 27
- Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Study Product Administration (Daily)
Generated On: 14 Apr 2021 02:49:43

Reason not done (max. 200 characters) _____

Product administration time point

Day 1: Dose 1	<input type="checkbox"/>
Day 1: Dose 2	<input type="checkbox"/>
Day 2: Dose 1	<input type="checkbox"/>
Day 2: Dose 2	<input type="checkbox"/>
Day 3: Dose 1	<input type="checkbox"/>
Day 3: Dose 2	<input type="checkbox"/>
Day 4: Dose 1	<input type="checkbox"/>
Day 4: Dose 2	<input type="checkbox"/>
Day 5: Dose 1	<input type="checkbox"/>
Day 5: Dose 2	<input checked="" type="checkbox"/>
Day 6: Dose 1	<input type="checkbox"/>
Day 6: Dose 2	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose

Fixed Unit: mg/kg

Was study drug administered?

Yes

If "No", specify reason.

No

Reason not done (max. 200 characters)

Product administration time point

Day 1: Dose 1

Day 1: Dose 2

Day 2: Dose 1

Day 2: Dose 2

Day 3: Dose 1

Day 3: Dose 2

Day 4: Dose 1

Day 4: Dose 2

Day 5: Dose 1

Day 5: Dose 2

Day 6: Dose 1

Day 6: Dose 2

Day 7

Day 8

Day 9

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Day 11

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Day 13

Day 14

Day 15

Day 16

Day 17

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Day 22

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Day 25

Day 26

Day 27

Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point Day 1: Dose 1

Day 1: Dose 2

Day 2: Dose 1

Day 2: Dose 2

Day 3: Dose 1

Day 3: Dose 2

Day 4: Dose 1

Day 4: Dose 2

Day 5: Dose 1

Day 5: Dose 2

Day 6: Dose 1

Day 6: Dose 2

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Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point

Day 1: Dose 1
Day 1: Dose 2
Day 2: Dose 1
Day 2: Dose 2
Day 3: Dose 1
Day 3: Dose 2
Day 4: Dose 1
Day 4: Dose 2
Day 5: Dose 1
Day 5: Dose 2
Day 6: Dose 1
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Date study product administered _____

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If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
 - Day 1: Dose 2
 - Day 2: Dose 1
 - Day 2: Dose 2
 - Day 3: Dose 1
 - Day 3: Dose 2
 - Day 4: Dose 1
 - Day 4: Dose 2
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 - Day 6: Dose 1
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Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
 - Day 1: Dose 2
 - Day 2: Dose 1
 - Day 2: Dose 2
 - Day 3: Dose 1
 - Day 3: Dose 2
 - Day 4: Dose 1
 - Day 4: Dose 2
 - Day 5: Dose 1
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Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point

- Day 1: Dose 1
- Day 1: Dose 2
- Day 2: Dose 1
- Day 2: Dose 2
- Day 3: Dose 1
- Day 3: Dose 2
- Day 4: Dose 1
- Day 4: Dose 2
- Day 5: Dose 1
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- Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
 - Day 1: Dose 2
 - Day 2: Dose 1
 - Day 2: Dose 2
 - Day 3: Dose 1
 - Day 3: Dose 2
 - Day 4: Dose 1
 - Day 4: Dose 2
 - Day 5: Dose 1

- Day 5: Dose 2
- Day 6: Dose 1
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Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
 - Day 1: Dose 2
 - Day 2: Dose 1
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 - Day 3: Dose 1

- Day 3: Dose 2
- Day 4: Dose 1
- Day 4: Dose 2
- Day 5: Dose 1
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- Day 27
- Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point Day 1: Dose 1

- Day 1: Dose 2
- Day 2: Dose 1
- Day 2: Dose 2
- Day 3: Dose 1
- Day 3: Dose 2
- Day 4: Dose 1
- Day 4: Dose 2
- Day 5: Dose 1
- Day 5: Dose 2
- Day 6: Dose 1
- Day 6: Dose 2
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- Day 19
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- Day 25
- Day 26
- Day 27
- Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose _____ Fixed Unit: mg/kg

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Study Product Administration (Daily)
Generated On: 14 Apr 2021 02:49:43

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

Product administration time point	Day 1: Dose 1	<input type="radio"/>
	Day 1: Dose 2	<input type="radio"/>
	Day 2: Dose 1	<input type="radio"/>
	Day 2: Dose 2	<input type="radio"/>
	Day 3: Dose 1	<input type="radio"/>
	Day 3: Dose 2	<input type="radio"/>
	Day 4: Dose 1	<input type="radio"/>
	Day 4: Dose 2	<input type="radio"/>
	Day 5: Dose 1	<input type="radio"/>
	Day 5: Dose 2	<input type="radio"/>
	Day 6: Dose 1	<input type="radio"/>
	Day 6: Dose 2	<input type="radio"/>
	Day 7	<input type="radio"/>
	Day 8	<input type="radio"/>
	Day 9	<input type="radio"/>
	Day 10	<input type="radio"/>
	Day 11	<input type="radio"/>
	Day 12	<input type="radio"/>
	Day 13	<input type="radio"/>
	Day 14	<input checked="" type="radio"/>
	Day 15	<input type="radio"/>
	Day 16	<input type="radio"/>
	Day 17	<input type="radio"/>
	Day 18	<input type="radio"/>
	Day 19	<input type="radio"/>
	Day 20	<input type="radio"/>
	Day 21	<input type="radio"/>
	Day 22	<input type="radio"/>
	Day 23	<input type="radio"/>
	Day 24	<input type="radio"/>
	Day 25	<input type="radio"/>
	Day 26	<input type="radio"/>
	Day 27	<input type="radio"/>
	Day 28	<input type="radio"/>

Date study product administered _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Study Product Administration (Daily)
Generated On: 14 Apr 2021 02:49:43

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters)

Product administration time point

Day 1: Dose 1	<input type="radio"/>
Day 1: Dose 2	<input type="radio"/>
Day 2: Dose 1	<input type="radio"/>
Day 2: Dose 2	<input type="radio"/>
Day 3: Dose 1	<input type="radio"/>
Day 3: Dose 2	<input type="radio"/>
Day 4: Dose 1	<input type="radio"/>
Day 4: Dose 2	<input type="radio"/>
Day 5: Dose 1	<input type="radio"/>
Day 5: Dose 2	<input type="radio"/>
Day 6: Dose 1	<input type="radio"/>
Day 6: Dose 2	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input checked="" type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>

Day 26
Day 27
Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point

Day 1: Dose 1
Day 1: Dose 2
Day 2: Dose 1
Day 2: Dose 2
Day 3: Dose 1
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Day 4: Dose 1
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Day 5: Dose 1
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Date study product administered _____

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Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
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 - Day 4: Dose 1
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Date study product administered _____

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If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point

- Day 1: Dose 1
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- Day 3: Dose 2
- Day 4: Dose 1
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Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
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 - Day 2: Dose 1
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 - Day 3: Dose 1
 - Day 3: Dose 2
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Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
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- Product administration time point
- Day 1: Dose 1
 - Day 1: Dose 2
 - Day 2: Dose 1
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Reason not done (max. 200 characters) _____

Product administration time point Day 1: Dose 1

Day 1: Dose 2

Day 2: Dose 1

- Day 2: Dose 2
- Day 3: Dose 1
- Day 3: Dose 2
- Day 4: Dose 1
- Day 4: Dose 2
- Day 5: Dose 1
- Day 5: Dose 2
- Day 6: Dose 1
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Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

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GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Study Product Administration (Daily)
Generated On: 14 Apr 2021 02:49:43

Reason not done (max. 200 characters) _____

Product administration time point

Day 1: Dose 1	<input type="checkbox"/>
Day 1: Dose 2	<input type="checkbox"/>
Day 2: Dose 1	<input type="checkbox"/>
Day 2: Dose 2	<input type="checkbox"/>
Day 3: Dose 1	<input type="checkbox"/>
Day 3: Dose 2	<input type="checkbox"/>
Day 4: Dose 1	<input type="checkbox"/>
Day 4: Dose 2	<input type="checkbox"/>
Day 5: Dose 1	<input type="checkbox"/>
Day 5: Dose 2	<input type="checkbox"/>
Day 6: Dose 1	<input type="checkbox"/>
Day 6: Dose 2	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose

Fixed Unit: mg/kg

Was study drug administered?

Yes

If "No", specify reason.

No

Reason not done (max. 200 characters)

Product administration time point

Day 1: Dose 1

Day 1: Dose 2

Day 2: Dose 1

Day 2: Dose 2

Day 3: Dose 1

Day 3: Dose 2

Day 4: Dose 1

Day 4: Dose 2

Day 5: Dose 1

Day 5: Dose 2

Day 6: Dose 1

Day 6: Dose 2

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18

Day 19

Day 20

Day 21

Day 22

Day 23

Day 24

Day 25

Day 26

Day 27

Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point Day 1: Dose 1

Day 1: Dose 2

Day 2: Dose 1

Day 2: Dose 2

Day 3: Dose 1

Day 3: Dose 2

Day 4: Dose 1

Day 4: Dose 2

Day 5: Dose 1

Day 5: Dose 2

Day 6: Dose 1

Day 6: Dose 2

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18

Day 19

Day 20

Day 21

Day 22

Day 23

Day 24
Day 25
Day 26
Day 27
Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

Product administration time point

Day 1: Dose 1
Day 1: Dose 2
Day 2: Dose 1
Day 2: Dose 2
Day 3: Dose 1
Day 3: Dose 2
Day 4: Dose 1
Day 4: Dose 2
Day 5: Dose 1
Day 5: Dose 2
Day 6: Dose 1
Day 6: Dose 2
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13
Day 14
Day 15
Day 16
Day 17
Day 18
Day 19

- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
 - Day 1: Dose 2
 - Day 2: Dose 1
 - Day 2: Dose 2
 - Day 3: Dose 1
 - Day 3: Dose 2
 - Day 4: Dose 1
 - Day 4: Dose 2
 - Day 5: Dose 1
 - Day 5: Dose 2
 - Day 6: Dose 1
 - Day 6: Dose 2
 - Day 7
 - Day 8
 - Day 9
 - Day 10
 - Day 11
 - Day 12
 - Day 13
 - Day 14
 - Day 15

- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose Fixed Unit: mg/kg

Was study drug administered? Yes

If "No", specify reason. No

Reason not done (max. 200 characters) _____

- Product administration time point
- Day 1: Dose 1
 - Day 1: Dose 2
 - Day 2: Dose 1
 - Day 2: Dose 2
 - Day 3: Dose 1
 - Day 3: Dose 2
 - Day 4: Dose 1
 - Day 4: Dose 2
 - Day 5: Dose 1
 - Day 5: Dose 2
 - Day 6: Dose 1
 - Day 6: Dose 2
 - Day 7
 - Day 8
 - Day 9
 - Day 10
 - Day 11

- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date study product administered _____

Renal adjusted dose? Yes

If yes, specify dose No

If Renal adjusted dose, specify dose _____ Fixed Unit: mg/kg

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Collect data at or near 8:00am each day.

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18

Day 19

Day 20

Day 21

Day 22

Day 23

Day 24

Day 25

Day 26

Day 27

Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____
or ICU continued from previous day?

ICU discharge time _____
If discharged on previous date, leave empty _____
or ICU Continued to next day?

3 - Is the participant on ventilator? Yes
If "No", skip to "Ventilator stop time" No

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC
PC with set pressure level (specify)
APRV
IMV
PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting _____
If "PS", specify iPAP _____ Fixed Unit: cmH2O

If "PS", specify ePAP _____ Fixed Unit: cmH2O

Cumulative fluid balance _____ Fixed Unit: mL

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Participant Status (Daily)

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4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP

BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes No

If "No", skip to "ECMO stop time"

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes No

If "No", specify reason.

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10

- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital
Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____
2 - Is the participant in the ICU? Yes
No

If "No", skip to "ICU discharge time"

ICU admission time _____
or ICU continued from previous day?

ICU discharge time _____
If discharged on previous date, leave empty _____
or ICU Continued to next day?

3 - Is the participant on ventilator? Yes
No

If "No", skip to "Ventilator stop time"

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

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Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH2O

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation

AC

PC with set pressure level (specify)

APRV

IMV

PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18

Day 19

Day 20

Day 21

Day 22

Day 23

Day 24

Day 25

Day 26

Day 27

Day 28

Date of assessment _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Participant Status (Daily)

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1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) Fixed Unit: mL

Plateau pressure (Pplat) Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH2O

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC

PC with set pressure level
(specify)

APRV

IMV

PS (specify iPAP and ePAP
levels)

If "PC (with set pressure level)", specify pressure setting _____

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes
No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP
BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes
No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes
No

If "No", skip to "ECMO stop time"

ECMO start time

or ECMO continued from previous day?

ECMO stop time

or ECMO continued to next day?

Was assessment done? Yes
No

If "No", specify reason.

If "No", reason not done (max. 200 characters)

Participant status assessment time point Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8

- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital
Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes
No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes
No

If "No", skip to "Ventilator stop time"

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

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Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH2O
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
SpO2	Fixed Unit: %
PaO2	Fixed Unit: mmHG
If PaO2 not done, check this box	<input type="checkbox"/>
FiO2	
Mode of mechanical ventilation	AC <input type="radio"/> PC with set pressure level (specify) <input type="radio"/> APRV <input type="radio"/> IMV <input type="radio"/> PS (specify iPAP and ePAP levels) <input type="radio"/>
If "PC (with set pressure level)", specify pressure setting	
If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
Cumulative fluid balance	Fixed Unit: mL
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?	Yes <input type="radio"/> No <input type="radio"/>
If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	
5 - Is the participant on non-invasive ventilation?	Yes <input type="radio"/> No <input type="radio"/>
If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	
If yes, CPAP or BiPAP?	CPAP <input type="radio"/> BiPAP <input type="radio"/>
If CPAP, what is the pressure level?	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

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6 - Is the participant on high flow nasal cannula oxygen? Yes

If "No", skip to item 7 "Is participant undergoing ECMO?" No

If yes, what is the FiO2? _____

If yes, what is the flow rate? _____ Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18

Day 19

Day 20

Day 21

Day 22

Day 23

Day 24

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Form: Participant Status (Daily)
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Day 25

Day 26

Day 27

Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

No

If "No", skip to "Ventilator stop time"

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC

PC with set pressure level

(specify)

APRV

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	IMV <input type="checkbox"/>
	PS (specify iPAP and ePAP levels) <input type="checkbox"/>
If "PC (with set pressure level)", specify pressure setting	
If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
Cumulative fluid balance	Fixed Unit: mL
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	
5 - Is the participant on non-invasive ventilation?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	
If yes, CPAP or BiPAP?	CPAP <input type="checkbox"/>
	BiPAP <input type="checkbox"/>
If CPAP, what is the pressure level?	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Is the participant on high flow nasal cannula oxygen?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 7 "Is participant undergoing ECMO?"	
If yes, what is the FiO2?	
If yes, what is the flow rate?	Fixed Unit: L/min
7 - Is the participant undergoing ECMO?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to "ECMO stop time"	
ECMO start time	
or ECMO continued from previous day?	<input type="checkbox"/>
ECMO stop time	
or ECMO continued to next day?	<input type="checkbox"/>
Was assessment done?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", specify reason.	
If "No", reason not done (max. 200 characters)	
Participant status assessment time point	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>

- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Participant Status (Daily)

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3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC
PC with set pressure level (specify)
APRV
IMV
PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting _____
If "PS", specify iPAP _____ Fixed Unit: cmH2O

If "PS", specify ePAP _____ Fixed Unit: cmH2O

Cumulative fluid balance _____ Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?" No

If yes, CPAP or BiPAP? CPAP

BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2? Fixed Unit: L/min

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

No

If "No", skip to "ECMO stop time"

ECMO start time _____

or ECMO continued from previous day?

ECMO stop time _____

or ECMO continued to next day?

Was assessment done? Yes

No

If "No", specify reason. _____

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital
Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes
No

If "No", skip to "ICU discharge time"

ICU admission time _____
or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____
or ICU Continued to next day?

3 - Is the participant on ventilator? Yes
No

If "No", skip to "Ventilator stop time"

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

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If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation

AC

PC with set pressure level (specify)

APRV

IMV

PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes

No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP

BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

No

If "No", skip to "ECMO stop time"

ECMO start time

or ECMO continued from previous day?

ECMO stop time

or ECMO continued to next day?

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Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters)

Participant status assessment time point

Day 1	<input type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input checked="" type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>

Date of assessment

1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time

or ICU continued from previous day?

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next day?

3 - Is the participant on ventilator?

Yes

If "No", skip to "Ventilator stop time"

No

Ventilator start time

or Ventilator continued from previous day?

Ventilator stop time

or Ventilator continued to next day?

Tidal volume (Vt)

Fixed Unit: mL

Plateau pressure (Pplat)

Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP)

Fixed Unit: cmH2O

Static Compliance (Cstat)

Fixed Unit: mL/cmH2O

SpO2

Fixed Unit: %

PaO2

Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation

AC

PC with set pressure level
(specify)

APRV

IMV

PS (specify iPAP and ePAP
levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP

Fixed Unit: cmH2O

If "PS", specify ePAP

Fixed Unit: cmH2O

Cumulative fluid balance

Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?

Yes

No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?" No

If yes, CPAP or BiPAP? CPAP
BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

If "No", skip to item 7 "Is participant undergoing ECMO?" No

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1	<input type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input checked="" type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>

- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital
Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes
No

If "No", skip to "ICU discharge time"

ICU admission time _____
or ICU continued from previous day?

ICU discharge time _____
If discharged on previous date, leave empty _____
or ICU Continued to next day?

3 - Is the participant on ventilator? Yes
No

If "No", skip to "Ventilator stop time"

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation AC
PC with set pressure level (specify)
APRV
IMV
PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes
No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP
BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes
No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1	<input type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input checked="" type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>

Date of assessment _____

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1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) Fixed Unit: mL

Plateau pressure (Pplat) Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH2O

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation

AC

PC with set pressure level (specify)

APRV

IMV

PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting _____

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes
No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP
BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes
No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes
No

If "No", skip to "ECMO stop time"

ECMO start time

or ECMO continued from previous day?

ECMO stop time

or ECMO continued to next day?

Was assessment done? Yes
No

If "No", specify reason.

If "No", reason not done (max. 200 characters)

Participant status assessment time point Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8

- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____
or ICU continued from previous day?

ICU discharge time _____
If discharged on previous date, leave empty _____
or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

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Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH2O
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
SpO2	Fixed Unit: %
PaO2	Fixed Unit: mmHG
If PaO2 not done, check this box	<input type="checkbox"/>
FiO2	
Mode of mechanical ventilation	AC <input type="radio"/> PC with set pressure level (specify) <input type="radio"/> APRV <input type="radio"/> IMV <input type="radio"/> PS (specify iPAP and ePAP levels) <input type="radio"/>
If "PC (with set pressure level)", specify pressure setting	
If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
Cumulative fluid balance	Fixed Unit: mL
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?	Yes <input type="radio"/> No <input type="radio"/>
If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	
5 - Is the participant on non-invasive ventilation?	Yes <input type="radio"/> No <input type="radio"/>
If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	
If yes, CPAP or BiPAP?	CPAP <input type="radio"/> BiPAP <input type="radio"/>
If CPAP, what is the pressure level?	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O

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6 - Is the participant on high flow nasal cannula oxygen? Yes

If "No", skip to item 7 "Is participant undergoing ECMO?" No

If yes, what is the FiO2? _____

If yes, what is the flow rate? _____ Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18

Day 19

Day 20

Day 21

Day 22

Day 23

Day 24

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Form: Participant Status (Daily)
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Day 25

Day 26

Day 27

Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

No

If "No", skip to "Ventilator stop time"

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC

PC with set pressure level

(specify)

APRV

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	IMV <input type="checkbox"/>
	PS (specify iPAP and ePAP levels) <input type="checkbox"/>
If "PC (with set pressure level)", specify pressure setting	
If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
Cumulative fluid balance	Fixed Unit: mL
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	
5 - Is the participant on non-invasive ventilation?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	
If yes, CPAP or BiPAP?	CPAP <input type="checkbox"/>
	BiPAP <input type="checkbox"/>
If CPAP, what is the pressure level?	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Is the participant on high flow nasal cannula oxygen?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 7 "Is participant undergoing ECMO?"	
If yes, what is the FiO2?	
If yes, what is the flow rate?	Fixed Unit: L/min
7 - Is the participant undergoing ECMO?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to "ECMO stop time"	
ECMO start time	
or ECMO continued from previous day?	<input type="checkbox"/>
ECMO stop time	
or ECMO continued to next day?	<input type="checkbox"/>
Was assessment done?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", specify reason.	
If "No", reason not done (max. 200 characters)	
Participant status assessment time point	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>

- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Participant Status (Daily)

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3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC
PC with set pressure level (specify)
APRV
IMV
PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting _____
If "PS", specify iPAP _____ Fixed Unit: cmH2O

If "PS", specify ePAP _____ Fixed Unit: cmH2O

Cumulative fluid balance _____ Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?" No

If yes, CPAP or BiPAP? CPAP

BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2? _____

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

No

If "No", skip to "ECMO stop time"

ECMO start time _____

or ECMO continued from previous day?

ECMO stop time _____

or ECMO continued to next day?

Was assessment done? Yes

No

If "No", specify reason. _____

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18
Day 19
Day 20
Day 21
Day 22
Day 23
Day 24
Day 25
Day 26
Day 27
Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital
Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes
No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes
No

If "No", skip to "Ventilator stop time"

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

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If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation

AC

PC with set pressure level (specify)

APRV

IMV

PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes

No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP

BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

No

If "No", skip to "ECMO stop time"

ECMO start time

or ECMO continued from previous day?

ECMO stop time

or ECMO continued to next day?

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Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1	<input type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input checked="" type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____

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or ICU continued from previous day?

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next day?

3 - Is the participant on ventilator?

Yes

If "No", skip to "Ventilator stop time"

No

Ventilator start time

or Ventilator continued from previous day?

Ventilator stop time

or Ventilator continued to next day?

Tidal volume (Vt)

Fixed Unit: mL

Plateau pressure (Pplat)

Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP)

Fixed Unit: cmH2O

Static Compliance (Cstat)

Fixed Unit: mL/cmH2O

SpO2

Fixed Unit: %

PaO2

Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation

AC

PC with set pressure level
(specify)

APRV

IMV

PS (specify iPAP and ePAP
levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP

Fixed Unit: cmH2O

If "PS", specify ePAP

Fixed Unit: cmH2O

Cumulative fluid balance

Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?

Yes

No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

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5 - Is the participant on non-invasive ventilation? Yes

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?" No

If yes, CPAP or BiPAP? CPAP
BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

If "No", skip to item 7 "Is participant undergoing ECMO?" No

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Day 11
Day 12
Day 13

- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital
If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____
2 - Is the participant in the ICU? Yes
If "No", skip to "ICU discharge time" No

ICU admission time _____
or ICU continued from previous day?

ICU discharge time _____
If discharged on previous date, leave empty _____
or ICU Continued to next day?

3 - Is the participant on ventilator? Yes
If "No", skip to "Ventilator stop time" No

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation AC
PC with set pressure level (specify)
APRV
IMV
PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?" No

If yes, CPAP or BiPAP? CPAP
BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

If "No", skip to item 7 "Is participant undergoing ECMO?" No

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1	<input type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input checked="" type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>

Date of assessment _____

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1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) Fixed Unit: mL

Plateau pressure (Pplat) Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH2O

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC

PC with set pressure level
(specify)

APRV

IMV

PS (specify iPAP and ePAP
levels)

If "PC (with set pressure level)", specify pressure setting _____

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

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Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?" No

If yes, CPAP or BiPAP? CPAP
BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

If "No", skip to item 7 "Is participant undergoing ECMO?" No

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time

or ECMO continued from previous day?

ECMO stop time

or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters)

Participant status assessment time point Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____
or ICU continued from previous day?

ICU discharge time _____
If discharged on previous date, leave empty _____
or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

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Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH2O
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
SpO2	Fixed Unit: %
PaO2	Fixed Unit: mmHG
If PaO2 not done, check this box	<input type="checkbox"/>
FiO2	
Mode of mechanical ventilation	AC <input type="radio"/> PC with set pressure level (specify) <input type="radio"/> APRV <input type="radio"/> IMV <input type="radio"/> PS (specify iPAP and ePAP levels) <input type="radio"/>
If "PC (with set pressure level)", specify pressure setting	
If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
Cumulative fluid balance	Fixed Unit: mL
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?	Yes <input type="radio"/> No <input type="radio"/>
If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	
5 - Is the participant on non-invasive ventilation?	Yes <input type="radio"/> No <input type="radio"/>
If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	
If yes, CPAP or BiPAP?	CPAP <input type="radio"/> BiPAP <input type="radio"/>
If CPAP, what is the pressure level?	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O

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6 - Is the participant on high flow nasal cannula oxygen? Yes

If "No", skip to item 7 "Is participant undergoing ECMO?" No

If yes, what is the FiO2? _____

If yes, what is the flow rate? _____ Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18

Day 19

Day 20

Day 21

Day 22

Day 23

Day 24

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Day 25

Day 26

Day 27

Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

No

If "No", skip to "Ventilator stop time"

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC

PC with set pressure level

(specify)

APRV

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	IMV <input type="checkbox"/>
	PS (specify iPAP and ePAP levels) <input type="checkbox"/>
If "PC (with set pressure level)", specify pressure setting	
If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
Cumulative fluid balance	Fixed Unit: mL
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	
5 - Is the participant on non-invasive ventilation?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	
If yes, CPAP or BiPAP?	CPAP <input type="checkbox"/>
	BiPAP <input type="checkbox"/>
If CPAP, what is the pressure level?	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Is the participant on high flow nasal cannula oxygen?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 7 "Is participant undergoing ECMO?"	
If yes, what is the FiO2?	
If yes, what is the flow rate?	Fixed Unit: L/min
7 - Is the participant undergoing ECMO?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to "ECMO stop time"	
ECMO start time	
or ECMO continued from previous day?	<input type="checkbox"/>
ECMO stop time	
or ECMO continued to next day?	<input type="checkbox"/>
Was assessment done?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", specify reason.	
If "No", reason not done (max. 200 characters)	
Participant status assessment time point	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>

- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

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3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC
PC with set pressure level (specify)
APRV
IMV
PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting _____
If "PS", specify iPAP _____ Fixed Unit: cmH2O

If "PS", specify ePAP _____ Fixed Unit: cmH2O

Cumulative fluid balance _____ Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?" No

If yes, CPAP or BiPAP? CPAP

BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2? Fixed Unit: L/min

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

No

If "No", skip to "ECMO stop time"

ECMO start time _____

or ECMO continued from previous day?

ECMO stop time _____

or ECMO continued to next day?

Was assessment done? Yes

No

If "No", specify reason. _____

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital
Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes
No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes
No

If "No", skip to "Ventilator stop time"

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

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If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation

AC

PC with set pressure level (specify)

APRV

IMV

PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes

No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP

BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

No

If "No", skip to "ECMO stop time"

ECMO start time

or ECMO continued from previous day?

ECMO stop time

or ECMO continued to next day?

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Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1	<input type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input checked="" type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____

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or ICU continued from previous day?

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next day?

3 - Is the participant on ventilator?

Yes

If "No", skip to "Ventilator stop time"

No

Ventilator start time

or Ventilator continued from previous day?

Ventilator stop time

or Ventilator continued to next day?

Tidal volume (Vt)

Fixed Unit: mL

Plateau pressure (Pplat)

Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP)

Fixed Unit: cmH2O

Static Compliance (Cstat)

Fixed Unit: mL/cmH2O

SpO2

Fixed Unit: %

PaO2

Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation

AC

PC with set pressure level
(specify)

APRV

IMV

PS (specify iPAP and ePAP
levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP

Fixed Unit: cmH2O

If "PS", specify ePAP

Fixed Unit: cmH2O

Cumulative fluid balance

Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?

Yes

No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

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5 - Is the participant on non-invasive ventilation? Yes

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?" No

If yes, CPAP or BiPAP? CPAP
BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

If "No", skip to item 7 "Is participant undergoing ECMO?" No

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point Day 1
Day 2
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Day 4
Day 5
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Day 8
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Day 13

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- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

No

If "No", skip to "Ventilator stop time"

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

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Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
SpO2	Fixed Unit: %
PaO2	Fixed Unit: mmHG
If PaO2 not done, check this box	<input type="checkbox"/>
FiO2	
Mode of mechanical ventilation	AC <input type="radio"/>
	PC with set pressure level (specify) <input type="radio"/>
	APRV <input type="radio"/>
	IMV <input type="radio"/>
	PS (specify iPAP and ePAP levels) <input type="radio"/>
If "PC (with set pressure level)", specify pressure setting	
If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
Cumulative fluid balance	Fixed Unit: mL
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?	Yes <input type="radio"/>
	No <input type="radio"/>
If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	
5 - Is the participant on non-invasive ventilation?	Yes <input type="radio"/>
	No <input type="radio"/>
If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	
If yes, CPAP or BiPAP?	CPAP <input type="radio"/>
	BiPAP <input type="radio"/>
If CPAP, what is the pressure level?	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Is the participant on high flow nasal cannula oxygen?	Yes <input type="radio"/>
	No <input type="radio"/>
If "No", skip to item 7 "Is participant undergoing ECMO?"	
If yes, what is the FiO2?	
If yes, what is the flow rate?	Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1	<input type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input checked="" type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>

Date of assessment _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Participant Status (Daily)

Generated On: 14 Apr 2021 02:49:43

1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) Fixed Unit: mL

Plateau pressure (Pplat) Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH2O

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation

- AC
- PC with set pressure level
- (specify)
- APRV
- IMV
- PS (specify iPAP and ePAP
- levels)

If "PC (with set pressure level)", specify pressure setting _____

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes
No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP
BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes
No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes
No

If "No", skip to "ECMO stop time"

ECMO start time

or ECMO continued from previous day?

ECMO stop time

or ECMO continued to next day?

Was assessment done? Yes
No

If "No", specify reason.

If "No", reason not done (max. 200 characters)

Participant status assessment time point Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8

- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____
or ICU continued from previous day?

ICU discharge time _____
If discharged on previous date, leave empty _____
or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Participant Status (Daily)
Generated On: 14 Apr 2021 02:49:43

Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH2O
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
SpO2	Fixed Unit: %
PaO2	Fixed Unit: mmHG
If PaO2 not done, check this box	<input type="checkbox"/>
FiO2	
Mode of mechanical ventilation	AC <input type="radio"/> PC with set pressure level (specify) <input type="radio"/> APRV <input type="radio"/> IMV <input type="radio"/> PS (specify iPAP and ePAP levels) <input type="radio"/>
If "PC (with set pressure level)", specify pressure setting	
If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
Cumulative fluid balance	Fixed Unit: mL
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?	Yes <input type="radio"/> No <input type="radio"/>
If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	
5 - Is the participant on non-invasive ventilation?	Yes <input type="radio"/> No <input type="radio"/>
If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	
If yes, CPAP or BiPAP?	CPAP <input type="radio"/> BiPAP <input type="radio"/>
If CPAP, what is the pressure level?	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Participant Status (Daily)

Generated On: 14 Apr 2021 02:49:43

6 - Is the participant on high flow nasal cannula oxygen? Yes

If "No", skip to item 7 "Is participant undergoing ECMO?" No

If yes, what is the FiO2? _____

If yes, what is the flow rate? _____ Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

If "No", skip to "ECMO stop time" No

ECMO start time _____
or ECMO continued from previous day?

ECMO stop time _____
or ECMO continued to next day?

Was assessment done? Yes

If "No", specify reason. No

If "No", reason not done (max. 200 characters) _____

Participant status assessment time point

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

Day 18

Day 19

Day 20

Day 21

Day 22

Day 23

Day 24

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Participant Status (Daily)
Generated On: 14 Apr 2021 02:49:43

Day 25
Day 26
Day 27
Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

If "Discharged", skip to item 2 "Is the participant in the ICU?" Discharged

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

If "No", skip to "ICU discharge time" No

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC

PC with set pressure level
(specify)

APRV

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Participant Status (Daily)
Generated On: 14 Apr 2021 02:49:43

	IMV <input type="checkbox"/>
	PS (specify iPAP and ePAP levels) <input type="checkbox"/>
If "PC (with set pressure level)", specify pressure setting	
If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
Cumulative fluid balance	Fixed Unit: mL
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	
5 - Is the participant on non-invasive ventilation?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	
If yes, CPAP or BiPAP?	CPAP <input type="checkbox"/>
	BiPAP <input type="checkbox"/>
If CPAP, what is the pressure level?	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Is the participant on high flow nasal cannula oxygen?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to item 7 "Is participant undergoing ECMO?"	
If yes, what is the FiO2?	
If yes, what is the flow rate?	Fixed Unit: L/min
7 - Is the participant undergoing ECMO?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", skip to "ECMO stop time"	
ECMO start time	
or ECMO continued from previous day?	<input type="checkbox"/>
ECMO stop time	
or ECMO continued to next day?	<input type="checkbox"/>
Was assessment done?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If "No", specify reason.	
If "No", reason not done (max. 200 characters)	
Participant status assessment time point	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>

- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital

Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes

No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Participant Status (Daily)

Generated On: 14 Apr 2021 02:49:43

3 - Is the participant on ventilator? Yes

If "No", skip to "Ventilator stop time" No

Ventilator start time _____
or Ventilator continued from previous day?

Ventilator stop time _____
or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

If PaO2 not done, check this box

FiO2 _____

Mode of mechanical ventilation AC
PC with set pressure level (specify)
APRV
IMV
PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting _____
If "PS", specify iPAP _____ Fixed Unit: cmH2O

If "PS", specify ePAP _____ Fixed Unit: cmH2O

Cumulative fluid balance _____ Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes
No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?" No

If yes, CPAP or BiPAP? CPAP

BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2? Fixed Unit: L/min

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

No

If "No", skip to "ECMO stop time"

ECMO start time

or ECMO continued from previous day?

ECMO stop time

or ECMO continued to next day?

Was assessment done? Yes

No

If "No", specify reason.

If "No", reason not done (max. 200 characters)

Participant status assessment time point

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 7

Day 8

Day 9

Day 10

Day 11

Day 12

Day 13

Day 14

Day 15

Day 16

Day 17

- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28

Date of assessment _____

1 - Is the participant in hospital or discharged? In Hospital
Discharged

If "Discharged", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? Yes
No

If "No", skip to "ICU discharge time"

ICU admission time _____

or ICU continued from previous day?

ICU discharge time _____

If discharged on previous date, leave empty _____

or ICU Continued to next day?

3 - Is the participant on ventilator? Yes
No

If "No", skip to "Ventilator stop time"

Ventilator start time _____

or Ventilator continued from previous day?

Ventilator stop time _____

or Ventilator continued to next day?

Tidal volume (Vt) _____ Fixed Unit: mL

Plateau pressure (Pplat) _____ Fixed Unit: cmH2O

Positive End-expiratory Pressure (PEEP) _____ Fixed Unit: cmH2O

Static Compliance (Cstat) _____ Fixed Unit: mL/cmH2O

SpO2 _____ Fixed Unit: %

PaO2 _____ Fixed Unit: mmHG

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Participant Status (Daily)

Generated On: 14 Apr 2021 02:49:43

If PaO2 not done, check this box

FiO2

Mode of mechanical ventilation

AC

PC with set pressure level (specify)

APRV

IMV

PS (specify iPAP and ePAP levels)

If "PC (with set pressure level)", specify pressure setting

If "PS", specify iPAP Fixed Unit: cmH2O

If "PS", specify ePAP Fixed Unit: cmH2O

Cumulative fluid balance Fixed Unit: mL

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? Yes

No

If "No", skip to item 5 "Is the participant on non-invasive ventilation?"

5 - Is the participant on non-invasive ventilation? Yes

No

If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"

If yes, CPAP or BiPAP? CPAP

BiPAP

If CPAP, what is the pressure level? Fixed Unit: cmH2O

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Is the participant on high flow nasal cannula oxygen? Yes

No

If "No", skip to item 7 "Is participant undergoing ECMO?"

If yes, what is the FiO2?

If yes, what is the flow rate? Fixed Unit: L/min

7 - Is the participant undergoing ECMO? Yes

No

If "No", skip to "ECMO stop time"

ECMO start time

or ECMO continued from previous day?

ECMO stop time

or ECMO continued to next day?

Lab Name: _____

CBC

Was CBC with differential collected? Yes
No

CBC with differential collection date _____

Hemoglobin

Hemoglobin severity grade Not gradable
Update Adverse Event log as applicable. Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Hemoglobin adverse event, if applicable _____

Hemoglobin not reportable as an adverse event

Hematocrit

MCV

Platelets

Platelets severity grade Not gradable
Update Adverse Event log as applicable. Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Platelets adverse event, if applicable _____

Platelets not reportable as an adverse event

WBC

WBC severity grade Not gradable
Update Adverse Event log as applicable. Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

WBC adverse event, if applicable _____

WBC not reportable as an adverse event

DIFFERENTIAL

Neutrophils

Neutrophils severity grade Not gradable
Update Adverse Event log as applicable. Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Safety Labs

Generated On: 14 Apr 2021 02:49:43

Lab Name: _____

Neutrophils adverse event, if applicable _____

Neutrophils not reportable as an adverse event

Lymphocytes _____

Lymphocytes severity grade _____

Not gradable

Update Adverse Event log as applicable.

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Lymphocytes adverse event, if applicable _____

Lymphocytes not reportable as an adverse event

CHEMISTRY

Was Chemistry collected? _____

Yes

No

Creatinine _____

Creatinine severity grade _____

Not gradable

Update Adverse Event log as applicable.

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Creatinine adverse event _____

Creatinine not reportable as an adverse event

Creatinine Clearance _____

Creatinine Clearance severity grade _____

Not gradable

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Creatinine Clearance adverse event _____

Creatinine Clearance not reportable as an adverse event

Comments (max. 200 characters): _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Specimen Collection and Storage
Generated On: 14 Apr 2021 02:49:43

Specimen type

Blood for genomic analysis

Blood for T cell immunity samples

Sputum (ETA) for CMV PCR

Plasma or serum for CMV PCR

BAL Fluid for CMV PCR

Was specimen collected? Yes
No

If "No", record reason why sample was not collected

Not required

Participant refused

Not intubated (ETA only)

Other

If "Other", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters).

Specimen type

Blood for genomic analysis

Blood for T cell immunity samples

Sputum (ETA) for CMV PCR

Plasma or serum for CMV PCR

BAL Fluid for CMV PCR

Was specimen collected? Yes
No

If "No", record reason why sample was not collected

Not required

Participant refused

Not intubated (ETA only)

Other

If "Other", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters).

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Specimen Collection and Storage
Generated On: 14 Apr 2021 02:49:43

Specimen type

Blood for genomic analysis

Blood for T cell immunity samples

Sputum (ETA) for CMV PCR

Plasma or serum for CMV PCR

BAL Fluid for CMV PCR

Was specimen collected? Yes

No

If "No", record reason why sample was not collected

Not required

Participant refused

Not intubated (ETA only)

Other

If "Other", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters).

Specimen type

Blood for genomic analysis

Blood for T cell immunity samples

Sputum (ETA) for CMV PCR

Plasma or serum for CMV PCR

BAL Fluid for CMV PCR

Was specimen collected? Yes

No

If "No", record reason why sample was not collected

Not required

Participant refused

Not intubated (ETA only)

Other

If "Other", record reason why sample was not collected (max. 200 characters).

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters).

GRAIL3_Version_1.0_PROD_TP_13APR2021: All
Form: Specimen Collection and Storage
Generated On: 14 Apr 2021 02:49:43

Specimen type

Blood for genomic analysis

Blood for T cell immunity samples

Sputum (ETA) for CMV PCR

Plasma or serum for CMV PCR

BAL Fluid for CMV PCR

Was specimen collected? Yes

No

If "No", record reason why sample was not collected

Not required

Participant refused

Not intubated (ETA only)

Other

If "Other", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored

Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters). _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Adverse Event

Generated On: 14 Apr 2021 02:49:43

Only limited AEs and SAEs should be collected and reported. Refer to protocol and Study Manual for further instructions.

Date AE reported to site _____

Adverse event (AE) _____

Onset date _____

At which visit was this adverse event first reported?

Screening

Visit 1

Visit 2

Visit 3

Visit 4

Visit 5

Visit 6

Visit 7

Visit 8

Visit 9

Visit 10 - 180 Day Follow-up

Interim Visit

If "Interim visit", specify interim visit code. _____

Is the AE still ongoing? Yes

No

If "No", outcome date _____

Severity grade

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Grade 5 (Death)

Relationship to study product

Definitely related

Probably related

Record pertinent details for relationship assessment in "Comments".

Possibly related

Not related

Action taken with study product

Dose not changed

Dose reduced

Drug withdrawn

Drug interrupted

Not applicable

Other actions

Mark "None" or all that apply.

None

Medication(s)

Therapeutic procedure/surgery

Diagnostic procedure

Other

If "Other", specify (max. 200 characters): _____

Status/Outcome Recovered/Resolved

If "Severity/Frequency increased" is selected, report as a new Recovering/Resolving

adverse event. Recovered/Resolved with

sequelae

Not recovered/Not resolved

Fatal

Severity/Frequency increased

If status or outcome is "Severity/Frequency increased", select adverse event. _____

Is this a serious adverse event according to protocol guidelines? Yes

If "No", go to "Has or will this AE be reported as an SAE?". No

If "Yes", check all that apply.

Results in death

Is life-threatening

Requires prolongation of existing hospitalization

Results in persistent or significant disability/incapacity

Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

Has or will this AE be reported as a SAE? If "No", go to "Does this AE meet criteria for an Unanticipated Problem (UP)?" Yes

No

SAE onset date _____

Does this AE meet criteria for an Unanticipated Problem (UP)?

Was this AE a worsening of a baseline medical condition? Yes

No

Comments (max. 450 characters): _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Medical History

Generated On: 14 Apr 2021 02:49:43

Refer to Study Manual for instructions on which conditions should be recorded in Medical History.

Date medical history collected _____

Description of medical history condition/event _____

Is condition/event gradable?

Yes

No

Severity grade

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Start date of medical history condition/event _____

Is the condition ongoing?

Yes

No

Date medical history/condition ended/resolved _____

Comments (max. 200 characters): _____

Form: Concomitant Medications

Generated On: 14 Apr 2021 02:49:43

Only limited Concomitant Medications should be collected and reported. Refer to Study Manual for complete coded list of concomitant medications to be recorded.

Medication name _____

Medication code _____

Indication _____

Date started _____

Start time (required for vasopressors and neuromuscular blockers) _____

Date stopped _____

Stop time (required for vasopressors and neuromuscular blockers) _____

OR

Ongoing

Dose _____

Dose units _____

Gram

Microgram

Milligram

Milliliters

Milligrams per kilogram

Micrograms per kilogram per minute

Micrograms per minute

Units

Units per minute

Unknown

Other

If "Other", specify: _____

Frequency _____

As needed

Daily

Twice daily

Three times daily

Four times daily

Monthly

Every hour

Once

Continuous infusion

Other

If "Other", specify: _____

Route _____

Oral

Intramuscular

Intravenous

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Form: Concomitant Medications

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Subcutaneous

Other

If "Other", specify: _____

Taken for a reported AE?

Yes

No

If "Yes", select adverse event. _____

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Form: Product Hold

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Date when study product hold was initiated _____

Visit when study product hold was initiated _____

Visit 2 - Day 4

Visit 3 - Day 7

Visit 4 - Day 11

Visit 5 - Day 14

Visit 6 - Day 18

Visit 7 - Day 21

Visit 8 - Day 25

Interim Visit

If 'Interim visit' is chosen, provide interim visit code: _____

Why is study product being held? _____

Adverse Event

Participant unable/unwilling to comply with required study procedures, or o/w might be put at undue risk to their safety and well-being by continuing product use according to judgment of IoR/designee

Patient or next of kin refuses further participation

ANC dropped below 1000/mm³

Other

If "Other", specify: _____

Adverse Event: _____

Will the study product resume? _____

Yes

No - hold continuing for another reason

No - early termination

No - hold continuing at scheduled product use end visit

No - permanently discontinued

If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled product use end visit', complete the Product Discontinuation form.

Date study product resumed _____

Date study product hold continuing for another reason _____

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Protocol Deviations

Generated On: 14 Apr 2021 02:49:43

Site awareness date _____

Deviation date _____

Has or will this deviation be reported to local IRB/EC? Yes
No

Type of deviation

- Inappropriate enrollment
- Failure to follow randomization or blinding procedures
- Study product management deviation
- Study product dispensing error
- Study product use/non-use deviation
- Conduct of non-protocol procedure
- Improper AE
- Unreported AE
- Unreported SAE
- Breach of confidentiality
- Lab assessment deviation
- Mishandled lab specimen
- Staff performing duties that they are not qualified to perform
- Questionnaire administration deviation
- Use of non-IRB/EC-approved materials
- Use of excluded concomitant medications, devices, or non-study products
- Informed consent process deviation
- Visit completed outside of window
- Other

Description of deviation _____

Plans and/or action taken to address the deviation _____

Plans and/or action taken to prevent future occurrences of the deviation _____

Deviation reported by _____

Is the outcome of this pregnancy obtainable? Yes

If "No", end of form. No

How many pregnancy outcomes resulted from this reported pregnancy? _____

Outcome Date _____

Place of delivery/outcome Home
Hospital
Clinic
Unknown
Other

If "Other", specify: _____

Specify outcome Full term live birth (greater than or equal to 37 weeks)
If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:". If "Full term live birth", go to "Were there any complications related to the pregnancy outcome?". Premature live birth (less than 37 weeks)
Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks)
Spontaneous abortion (less than 20 weeks)
Ectopic pregnancy
Therapeutic/elective abortion
Other

If "Other", specify: _____

Method C-section
Standard vaginal
Operative vaginal
Vaginal

Provide a brief narrative of the circumstances (max. 400 characters). _____

Were there any complications related to the pregnancy outcome? Yes

If "No", go to "Were any fetal/infant congenital anomalies identified?". No

Delivery-related complications. Mark "None" or all that apply.

- None
- Intrapartum hemorrhage
- Postpartum hemorrhage
- Non-reassuring fetal status
- Chorioamnionitis
- Other

If "Other", specify: _____

Non-delivery related complications. Mark "None" or all that apply.

None

Hypertensive disorders of pregnancy

Gestational diabetes

Other

If "Other", specify: _____

Were any fetal/infant congenital anomalies identified? Mark all that apply. Yes

No

If "No" or "Unknown", go to "Complete the infant items below for live births only." Not assessed

Unknown

Central nervous system, cranio-facial

Central nervous system, spinal

Cardiovascular

Renal

Gastrointestinal

Pulmonary

Musculoskeletal/extremities

Physical defect

Skin

Genitourinary

Chromosomal

Cranio-facial (structural)

Hematologic

Infectious

Endocrine/metabolic

Other

Describe congenital anomaly/defect (max. 200 characters). _____

Complete the infant items below for live births only. Otherwise, end of form. Male

Female

Infant sex _____

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Form: Pregnancy Outcome
Generated On: 14 Apr 2021 02:49:43

Infant birth weight Fixed Unit: kg

Or

Infant birth weight unavailable

Infant birth length Fixed Unit: cm

Or

Infant birth length unavailable

Infant birth head circumference Fixed Unit: cm

Or

Infant birth head circumference unavailable

Infant birth abdominal circumference Fixed Unit: cm

Or

Infant birth abdominal circumference unavailable

Infant gestational age by examination in weeks Fixed Unit: Weeks

Infant gestational age by examination in days Fixed Unit: Days

Or

Infant gestational age by examination unavailable

If unavailable, end of form.

Method used to determine gestational age Ballard
Dubowitz
Other

If "Other", specify (max. 200 characters):

Date pregnancy reported to site _____

Visit at which this pregnancy was reported _____

Screening

Visit 1

Visit 2

Visit 3

Visit 4

Visit 5

Visit 6

Visit 7

Visit 8

Visit 9

Visit 10 - 180 Day Follow-up

Interim Visit

If "Interim visit", specify visit code. _____

Date of onset of last menstrual period _____

Or _____

Amenorrheic for past 6 months

Estimated date of delivery _____

What primary information was used to estimate the date of delivery?

Last menstrual period

Initial ultrasound <20 weeks

Initial ultrasound >= 20 weeks

Physical examination

Conception date by assisted reproduction

Other

If "Other", specify: _____

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Form: Pregnancy Test Results

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Was a pregnancy test performed? Yes

No

If no, specify reason not done:

Male

Not of reproductive potential

Participant pregnant

Other

If Other, specify: _____

Specimen date _____

Specimen type

Serum

Urine

Collection time _____

Pregnancy test result

Positive

Negative

GRAIL3_Version_1.0_PROD_TP_13APR2021: All

Form: Microbiology

Generated On: 14 Apr 2021 02:49:43

Date Sample Collected _____

Sample Type _____

Blood

Sputum (ETA)

BAL Fluid

Other

If "Other", specify sample type (max. 200 characters). _____

Organism identified (NOTE: multiple organisms in a single sample
require unique log entries) _____

Does this patient have VAP or nosocomial pneumonia by protocol
definition? _____

Yes

No

Select adverse event, if applicable _____
