Form: Participant Identifier

Participant ID:

Form: Screening Date of Visit

Screening visit date	

Form: Demographics

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	☐
Rapid CMV Serology (LFA)	
Was Rapid CMV Serology (LFA) conducted?	Yes ☐
	No ☐
If 'No', skip to CMV Serology (ELISA)	
Rapid CMV Serology (LFA) sample type	Serum ☐
	Plasma ☐
	Other ☐
If "Other", specify	_____
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 ☐
CMV Serology (ELISA) sample type	Serum ☐
	Plasma ☐
	Other ☐
If "Other", specify	_____

Form: Demographics

CMV Serology (ELISA) CLIA lab name	
CMV Serology (ELISA) kit manufacturer	
CMV Serology (ELISA) collection date	
CMV Serology (ELISA) collection time	
CMV Serology (ELISA) result	Positive ☐ Negative ☐ Indeterminate ☐
Final CMV Status	CMV Positive ☐ CMV Negative ☐
IF THE PARTICIPANT WAS NOT CONSENTED, DO NOT ENTER DATA BELOW THIS LINE	
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
Screening Blood Gasses	
PaO2 (intubated)	Fixed Unit: mmHg
If PaO2 not done, check this box AND record SpO2 below	☐
SpO2 (intubated)	Fixed Unit: %
FiO2: closest to PaO2 (or SpO2 if PaO2 not done)	
Assess the following questions from the time the participant was admitted to the hospital (up to 5-days prior to study enrollment). This may include time admitted to another hospital.	
Is or was the participant on non-invasive ventilation?	Yes ☐ No ☐
If "No", skip to "Is or was the participant on high-flow nasal canula?"	
NIV start date	
NIV start time	
NIV stop date (if applicable)	
Is or was the participant on high-flow nasal cannula?	Yes ☐ No ☐
If "No", skip to "Is or was the participant on ventilator?"	
HFNC start date	
HFNC start time	
HFNC stop date (if applicable)	
Is or was the participant on ventilator?	Yes ☐
If "No", skip to "Is the participant undergoing ECMO?"	No ☐
Ventilator start date	
Ventilator start time	
Ventilator stop date (if applicable)	

Form: Demographics

Is or was the participant undergoing ECMO?	Yes ☐
If "No", end of form	No ☐
ECMO start date	_____
ECMO start time	_____
ECMO stop date (if applicable)	_____

Form: Inclusion Exclusion Criteria

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Eligibility status If "Eligible and enrolled", or "Incomplete screening", end of form.	Eligible and enrolled ☐ Eligible/Not enrolled ☐ Ineligible ☐ Incomplete screening ☐ Ineligible/Enrolled ☐
Date participant was found "Eligible/Not Enrolled" or "Ineligible"	_____
Select reason(s) why participant is "Ineligible/Enrolled" or "Ineligible".	Subject/next of kin informed consent ☐ CMV IgG seropositive by lateral flow assay (LFA) or standard serologic methods ☐ HIV+ (i.e. prior positive test or clinical signs of suspicion of HIV/AIDS; a negative HIV test is not required for enrollment) ☐ Stem cell transplantation ☐ Solid organ transplantation with receipt of systemic immunosuppression (any time) ☐ Cytotoxic anti-cancer chemotherapy within the past three months (Note: next-of-kin estimate is acceptable) ☐ Congenital immunodeficiency requiring antimicrobial prophylaxis (e.g. TMP-SMX, dapsone, antifungal drugs, intravenous immunoglobulin) ☐ Receipt of one or more of the following in the indicated time period ☐ 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. ☐ 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). ☐ Pregnant or breastfeeding (either currently or expected within one month). ☐ Absolute neutrophil count < 1,000/mm3 (if no ANC value is available, the WBC must be > 2500/mm3) ☐

Form: Inclusion Exclusion Criteria

	☐ Use of anti-CMV drugs (cidofovir, letermovir, foscarnet, valganciclovir, ganciclovir) within seven (7) days of patient randomization.
	☐ Use if IVIG within four (4) weeks of patient randomization.
	☐ Intubated for airway protection only.
	☐ 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).
	☐ At baseline patients who have a tracheostomy, and have been receiving any positive pressure ventilation through it during the 30-day period prior to ICU admission.
	☐ Patients with Child Class C Cirrhosis.
	☐ Patients with severe (requiring home oxygen) pre-existing interstitial lung disease.
	☐ Allergy to ganciclovir
	☐ Incarcerated
	☐ Other, specify (e.g. clinician refusal)
If "Other", specify (max. 200 characters):	_____

Form: Informed Consent

Informed consent date	

Form: Randomization

Is the participant ready to be randomized?	Yes ☐ No ☐
Randomization date and time	_____

Form: Enrollment

Randomzation Date/Time	_____
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	_____
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 ☐
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	_____

Form: Participant Replacement Assessment

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	

Form: Follow-up Visit Y/N

Did the participant complete this visit?	Yes ☐ No ☐

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

Did the participant complete this visit?	Yes ☐ No ☐
If Yes, was this a 28-day summary visit conducted via phone?	Yes ☐ No ☐

Form: Follow-up Visit Summary

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? (If yes, complete an Adverse Event form)	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported? (Refer to list in study manual of procedures)	Yes ☐ No ☐
Were any protocol deviations reported at this visit? (If yes, complete a Protocol Deviation form)	Yes ☐ No ☐
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol? (Note: Pregnancy Test Results CRF required at discharge)	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit? (If yes, complete the Termination form)	Yes ☐ No ☐

Form: 28-Day Phone Visit Summary

Visit date:	_____
Is the participant still alive?	Yes ☐ No ☐
Did the participant report a pregnancy? (If yes, complete a Pregnancy Report form)	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit? (If yes, complete an Adverse Event form)	Yes ☐ No ☐
Were any protocol deviations reported at this visit? (If yes, complete a Protocol Deviation form)	Yes ☐ No ☐
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol? (Note: Pregnancy Test Results CRF required at discharge)	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit? (If yes, complete the Termination form)	Yes ☐ No ☐

Form: 180-Day Follow-up Visit Summary

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	_____

Form: Interim Visit Summary

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? (Refer to list in study manual of procedures)	Yes ☐ No ☐
Were any protocol deviations reported at this visit?	Yes ☐ No ☐
Did the participant exit/terminate the study at this visit? (If yes, complete the Termination form)	Yes ☐ No ☐
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	☐

Form: Additional Study Procedures

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	☐

Form: Missed Visit

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:	

Form: Discontinuation of Study Product

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/mm^3 ☐ Transfer to another facility ☐ Clinician withdrawal ☐ Ineligible/enrolled ☐ Other
If "Other", specify (max. 200 characters):	
If "Adverse event", select applicable adverse event.	

Form: Study Termination

Date of study exit	
Primary reason for completion/discontinuation	Scheduled exit visit/end of study ☐ Death ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up ☐ Investigator decision ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Pregnancy ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ Patient or LAR refuses further participation ☐ New scientific developments indicate that the treatment is not in the patient's best interest ☐ Ineligible/enrolled ☐ Clinician withdrawal ☐ Other ☐
If "Other", specify (max. 200 characters):	
If "Death", enter date of death	
If "Adverse event", select applicable adverse event.	

Form: ADL/IADL

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) ☐

Form: ADL/IADL

	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	

Form: ADL/IADL

	Travels independently on public transportation or drives own car (1). ☐ Arranges own travel via taxi, but does not otherwise use public transportation (1) ☐ Travels on public transportation when accompanied by another (1) ☐ Travel limited to taxi or automobile with assistance of another (0) ☐ Does not travel at all (0) ☐
7 - Responsibility for own medications	Is responsible for taking medication in correct dosages at correct time (1). ☐ Takes responsibility if medication is prepared in advance in separate dosage (0) ☐ Is not capable of dispensing own medication (0) ☐
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). ☐ Manages day-to-day purchases, but needs help with banking, major purchases, etc. (1) ☐ Incapable of handling money (0) ☐
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

Form: HADS

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 relies; 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 the 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 ☐

Form: HADS

9 - I get a sort of frightened feeling like 'butterflies' in the stomach	Not at all ☐ Occasionally ☐ Quite often ☐ Very often ☐
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)

Form: IES-R

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 ☐

Form: IES-R

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

Form: IES-R

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 ☐

Form: IES-R

	A little bit ☐
	Moderately ☐
	Quite a bit ☐
	Extremely ☐
22 - I tried not to talk about it	Not at all ☐
	A little bit ☐
	Moderately ☐
	Quite a bit ☐
	Extremely ☐
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.

Form: EQ-5D-5L

Was the EQ-5D-5L Survey done?	Yes ☐ No ☐
Date of assessment	_____
Was data for this assessment provided via a Legal Authorized Representative (LAR)?	Yes ☐ No ☐
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.	

Form: EQ-5D-5L

6 - Your health TODAY	
EQ-5D-5L TOTAL SCORE	

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

Form: APACHE III - Chronic Health

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 Select the first one in the list that applies to the participant	Cardiac (MI, cardiac arrest, arrhythmia, etc.) ☐ GI (GI bleeding, bowel obstruction, etc. – not to included 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 ☐

Form: APACHE III - Chronic Health

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 ☐

Form: APACHE III - Acute Physiology

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) ☐

Form: APACHE III - Acute Physiology

	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
If Serum Albumin not done, check this box.	☐
Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Serum Glucose: highest	Fixed Unit: mg/dL
Serum Glucose: lowest	Fixed Unit: mg/dL

Form: APACHE III - Acute Physiology

NEUROLOGICAL ABNORMALITIES: lowest	
Was the participant assessed for neurological abnormalities?	Yes ☐ No ☐
Reason not done (max. 200 characters)	
Enter reason and end form.	_____
Eye response	No eye opening ☐ Eyes open to pain ☐ Eyes open to verbal command ☐ Eyes open spontaneously ☐
Verbal response	No response ☐ Inappropriate words & Incomprehensible sounds ☐ Confused conversation ☐ Oriented, converses ☐
Motor response	Decerebrate rigidity/no response ☐ Flexion withdrawal/decorticate rigidity ☐ Localizes pain ☐ Obeys commands ☐
Neurological Abnormalities Score	_____

Form: SOFA

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)	
Enter reason and end form.	
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: 10^3/mm^3

Form: SOFA

Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL
GLASGOW COMA SCORE:	Yes ☐ No ☐
Was the participant assessed for a Glasgow Coma Score?	
Reason not done (max. 200 characters)	
Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐ To verbal stimuli, command, speech ☐ To pain only (not applied to face) ☐ No response ☐
Verbal response (lowest)	Oriented ☐ Confused conversation, but able to answer questions ☐ Inappropriate words ☐ Incomprehensible speech ☐ No response ☐
Motor response (lowest)	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)	
Enter reason and end form.	
SOFA assessment time point	Day 1 (Visit 1) ☐

Form: SOFA

	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: 10^3/mm^3
Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL

Form: SOFA

GLASGOW COMA SCORE:	Yes ☐ No ☐
Was the participant assessed for a Glasgow Coma Score?	
Reason not done (max. 200 characters)	
Enter reason and end form.	_____
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐ To verbal stimuli, command, speech ☐ To pain only (not applied to face) ☐ No response ☐
Verbal response (lowest)	Oriented ☐ Confused conversation, but able to answer questions ☐ Inappropriate words ☐ Incomprehensible speech ☐ No response ☐
Motor response (lowest)	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)	
Enter reason and end form.	_____
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) ☐

Form: SOFA

	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: 10^3/mm^3
Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL
GLASGOW COMA SCORE:	Yes ☐ No ☐
Was the participant assessed for a Glasgow Coma Score?	
Reason not done (max. 200 characters)	
Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐

Form: SOFA

	To verbal stimuli, command, speech ☐
	To pain only (not applied to face) ☐
	No response ☐
Verbal response (lowest)	Oriented ☐
	Confused conversation, but able to answer questions ☐
	Inappropriate words ☐
	Incomprehensible speech ☐
	No response ☐
Motor response (lowest)	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)	
Enter reason and end form.	_____
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	_____

Form: SOFA

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: 10^3/mm^3

Total Bilirubin: highest — Fixed Unit: mg/dL

If Total Bilirubin not done, check this box. ☐

Creatinine: highest — Fixed Unit: mg/dL

Total urine output over 24 hours — Fixed Unit: mL

GLASGOW COMA SCORE: — Yes ☐ No ☐

Was the participant assessed for a Glasgow Coma Score?

Reason not done (max. 200 characters)

Enter reason and end form.

Eye response (lowest)
- ☐ Spontaneous--open with blinking at baseline
- ☐ To verbal stimuli, command, speech
- ☐ To pain only (not applied to face)
- ☐ No response

Verbal response (lowest)
- ☐ Oriented
- ☐ Confused conversation, but able to answer questions
- ☐ Inappropriate words
- ☐ Incomprehensible speech
- ☐ No response

Form: SOFA

Motor response (lowest)	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 ☐ No ☐
If "No", specify reason.	
Reason not done (max. 200 characters)	
Enter reason and end form.	_____
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: %
	_____

Form: SOFA

PaO2: lowest	Fixed Unit: mmHg
If PaO2 not done, check this box	☐
FiO2: closest to lowest SpO2	
Platelets: lowest	Fixed Unit: 10^3/mm^3
Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL
GLASGOW COMA SCORE:	Yes ☐ No ☐
Was the participant assessed for a Glasgow Coma Score?	
Reason not done (max. 200 characters)	
Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐ To verbal stimuli, command, speech ☐ To pain only (not applied to face) ☐ No response ☐
Verbal response (lowest)	Oriented ☐ Confused conversation, but able to answer questions ☐ Inappropriate words ☐ Incomprehensible speech ☐ No response ☐
Motor response (lowest)	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)	

Form: SOFA

Was SOFA assessment done?	Yes ☐
If "No", specify reason.	No ☐
Reason not done (max. 200 characters)	
Enter reason and end form.	
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: 10^3/mm^3
Total Bilirubin: highest	Fixed Unit: mg/dL

Form: SOFA

If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL
GLASGOW COMA SCORE:	Yes ☐ No ☐
Was the participant assessed for a Glasgow Coma Score?	
Reason not done (max. 200 characters)	
Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐ To verbal stimuli, command, speech ☐ To pain only (not applied to face) ☐ No response ☐
Verbal response (lowest)	Oriented ☐ Confused conversation, but able to answer questions ☐ Inappropriate words ☐ Incomprehensible speech ☐ No response ☐
Motor response (lowest)	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)	
Enter reason and end form.	
SOFA assessment time point	Day 1 (Visit 1) ☐ Day 2 (Visit 1) ☐ Day 3 (Visit 2) ☐

Form: SOFA

	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: 10^3/mm^3
Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL
GLASGOW COMA SCORE:	Yes ☐
	No ☐
Was the participant assessed for a Glasgow Coma Score?	

Form: SOFA

Reason not done (max. 200 characters)	
Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐ To verbal stimuli, command, speech ☐ To pain only (not applied to face) ☐ No response ☐
Verbal response (lowest)	Oriented ☐ Confused conversation, but able to answer questions ☐ Inappropriate words ☐ Incomprehensible speech ☐ No response ☐
Motor response (lowest)	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)	
Enter reason and end form.	
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) ☐

Form: SOFA

	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: 10^3/mm^3
Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL
GLASGOW COMA SCORE:	Yes ☐ No ☐
Was the participant assessed for a Glasgow Coma Score?	
Reason not done (max. 200 characters)	
Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐ To verbal stimuli, command, speech ☐ To pain only (not applied to face) ☐ No response ☐

Form: SOFA

Verbal response (lowest)	Oriented ☐ Confused conversation, but able to answer questions ☐ Inappropriate words ☐ Incomprehensible speech ☐ No response ☐
Motor response (lowest)	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)	
Enter reason and end form.	_____
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	_____

Form: SOFA

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: 10^3/mm^3
Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL
GLASGOW COMA SCORE: Was the participant assessed for a Glasgow Coma Score?	Yes ☐ No ☐
Reason not done (max. 200 characters) Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐ To verbal stimuli, command, speech ☐ To pain only (not applied to face) ☐ No response ☐
Verbal response (lowest)	Oriented ☐ Confused conversation, but able to answer questions ☐ Inappropriate words ☐ Incomprehensible speech ☐ No response ☐
Motor response (lowest)	Obeys commands for movement ☐ Purposeful movement to painful stimulus ☐ Withdraws in response to pain ☐ Flexion in response to pain (decorticate posturing) ☐

Form: SOFA

	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)	
Enter reason and end form.	
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: 10^3/mm^3
GRAIL3_Version_11.0_PROD_KS_19	

Form: SOFA

Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL
GLASGOW COMA SCORE:	Yes ☐ No ☐
Was the participant assessed for a Glasgow Coma Score?	
Reason not done (max. 200 characters)	
Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐ To verbal stimuli, command, speech ☐ To pain only (not applied to face) ☐ No response ☐
Verbal response (lowest)	Oriented ☐ Confused conversation, but able to answer questions ☐ Inappropriate words ☐ Incomprehensible speech ☐ No response ☐
Motor response (lowest)	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)	
Enter reason and end form.	
SOFA assessment time point	Day 1 (Visit 1) ☐

Form: SOFA

	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: 10^3/mm^3
Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL

Form: SOFA

GLASGOW COMA SCORE:	Yes ☐ No ☐
Was the participant assessed for a Glasgow Coma Score?	
Reason not done (max. 200 characters)	
Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐ To verbal stimuli, command, speech ☐ To pain only (not applied to face) ☐ No response ☐
Verbal response (lowest)	Oriented ☐ Confused conversation, but able to answer questions ☐ Inappropriate words ☐ Incomprehensible speech ☐ No response ☐
Motor response (lowest)	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)	
Enter reason and end form.	
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) ☐

Form: SOFA

	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: 10^3/mm^3
Total Bilirubin: highest	Fixed Unit: mg/dL
If Total Bilirubin not done, check this box.	☐
Creatinine: highest	Fixed Unit: mg/dL
Total urine output over 24 hours	Fixed Unit: mL
GLASGOW COMA SCORE:	Yes ☐ No ☐
Was the participant assessed for a Glasgow Coma Score?	
Reason not done (max. 200 characters)	
Enter reason and end form.	
Eye response (lowest)	Spontaneous--open with blinking at baseline ☐

Form: SOFA

	To verbal stimuli, command, speech ☐
	To pain only (not applied to face) ☐
	No response ☐
Verbal response (lowest)	Oriented ☐
	Confused conversation, but able to answer questions ☐
	Inappropriate words ☐
	Incomprehensible speech ☐
	No response ☐
Motor response (lowest)	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)	
Enter reason and end form.	_____
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	_____

Form: SOFA

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: 10^3/mm^3

Total Bilirubin: highest — Fixed Unit: mg/dL

If Total Bilirubin not done, check this box. ☐

Creatinine: highest — Fixed Unit: mg/dL

Total urine output over 24 hours — Fixed Unit: mL

GLASGOW COMA SCORE: — Yes ☐ No ☐

Was the participant assessed for a Glasgow Coma Score?

Reason not done (max. 200 characters)

Enter reason and end form.

Eye response (lowest)
- ☐ Spontaneous--open with blinking at baseline
- ☐ To verbal stimuli, command, speech
- ☐ To pain only (not applied to face)
- ☐ No response

Verbal response (lowest)
- ☐ Oriented
- ☐ Confused conversation, but able to answer questions
- ☐ Inappropriate words
- ☐ Incomprehensible speech
- ☐ No response

Form: SOFA

Motor response (lowest)	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)	_____

Form: Study Product Administration (Daily)

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	_____

Form: Study Product Administration (Daily)

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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

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 ☐

Form: Study Product Administration (Daily)

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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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
	_____

Form: Study Product Administration (Daily)

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	_____

Form: Study Product Administration (Daily)

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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ■

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

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 ☐

Form: Study Product Administration (Daily)

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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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 ☐

Form: Study Product Administration (Daily)

	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
	_____

Form: Participant Status (Daily)

Collect point-in-time 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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____

Form: Participant Status (Daily)

2 - Is the participant in the ICU? (assess by calendar day) Yes ☐ No ☐

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

ICU admission time

or ICU continued from previous calendar day? ☐

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next calendar day? ☐

Cumulative fluid balance Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day) Yes ☐ No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank

or Ventilator continued from previous calendar day? ☐

Ventilator stop time

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) Fixed Unit: mL

Plateau pressure (Pplat) Fixed Unit: cmH2O

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH20

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

If Static Compliance (Cstat) not done, check this box ☐

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

Form: Participant Status (Daily)

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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min

Form: Participant Status (Daily)

7 - Is the participant undergoing ECMO?	Yes ☐
If "No", skip to "ECMO stop time"	No ☐
ECMO start time	_____
or ECMO continued from previous calendar day?	☐
ECMO stop time	_____
or ECMO continued to next calendar 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	_____

Form: Participant Status (Daily)

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

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

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? (assess by calendar day) Yes ☐ No ☐

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

ICU admission time _____

or ICU continued from previous calendar day? ☐

ICU discharge time

If discharged on previous date, leave empty _____

or ICU Continued to next calendar day? ☐

Cumulative fluid balance Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

_____

3 - Is the participant on ventilator? (assess by calendar day) Yes ☐ No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time _____

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank _____

or Ventilator continued from previous calendar day? ☐

Ventilator stop time _____

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) Fixed Unit: mL

_____

Plateau pressure (Pplat) Fixed Unit: cmH2O

_____

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH20

_____

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

_____

If Static Compliance (Cstat) not done, check this box ☐

Form: Participant Status (Daily)

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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ○ No ○
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ○ No ○
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ○ BiPAP ○
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ○ No ○
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	

Form: Participant Status (Daily)

If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)_____

If yes, what is the flow rate? (closest to 8am or last setting prior to 8am) 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 calendar day? ☐

ECMO stop time _____

or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	Day 26 ☐ Day 27 ☐ Day 28 ☐
Date of assessment	_____
1 - Is the participant in hospital or discharged?	In Hospital ☐
If "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐ No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance If the participant is not in the ICU, this field may be left blank.	Fixed Unit: mL _____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐ No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	_____
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL _____
Plateau pressure (Pplat)	Fixed Unit: cmH2O _____
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20 _____

Form: Participant Status (Daily)

Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O

Form: Participant Status (Daily)

6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? Yes ☐ No ☐

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

Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour) _____

If yes, what is the FiO2? (closest to 8am or last setting prior to 8am) _____

If yes, what is the flow rate? (closest to 8am or last setting prior to 8am) 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 calendar day? ☐

ECMO stop time _____

or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance	Fixed Unit: mL
If the participant is not in the ICU, this field may be left blank.	_____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐
	No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	_____
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
	_____

Form: Participant Status (Daily)

Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ○ No ○
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ○ No ○
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ○ BiPAP ○
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O

Form: Participant Status (Daily)

If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day?	Yes ☐ No ☐
If "No", skip to item 7 "Is participant undergoing ECMO?"	
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	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 calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time	
If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance	Fixed Unit: mL
If the participant is not in the ICU, this field may be left blank.	_____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐
	No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	_____

Form: Participant Status (Daily)

or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O

Form: Participant Status (Daily)

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? Yes / No

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

Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)

If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)

If yes, what is the flow rate? (closest to 8am or last setting prior to 8am) 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 calendar day? ☐

ECMO stop time

or ECMO continued to next calendar 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

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance If the participant is not in the ICU, this field may be left blank.	Fixed Unit: mL _____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐
	No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____

Form: Participant Status (Daily)

or Ventilator continued from previous calendar day?	☐
Ventilator stop time	
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐

Form: Participant Status (Daily)

	BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day?	Yes ☐ No ☐
If "No", skip to item 7 "Is participant undergoing ECMO?"	
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	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 calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance	Fixed Unit: mL
If the participant is not in the ICU, this field may be left blank.	_____

Form: Participant Status (Daily)

3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐ No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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

Form: Participant Status (Daily)

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	_____
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O _____
If BiPAP, what is iPAP?	Fixed Unit: cmH2O _____
If BiPAP, what is ePAP?	Fixed Unit: cmH2O _____
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	_____
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	_____
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min _____
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	_____
or ECMO continued from previous calendar day?	☐
ECMO stop time	_____
or ECMO continued to next calendar day?	☐
Was assessment done? If "No", specify reason.	Yes ☐ No ☐
If "No", reason not done (max. 200 characters)	_____
Participant status assessment time point	Day 1 ☐ Day 2 ☐ Day 3 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time	
If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐

Form: Participant Status (Daily)

Cumulative fluid balance	Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐ No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time	
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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	

Form: Participant Status (Daily)

If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	
or ECMO continued from previous calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar day?	☐
Was assessment done? If "No", specify reason.	Yes ☐ No ☐
If "No", reason not done (max. 200 characters)	

Form: Participant Status (Daily)

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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐

Form: Participant Status (Daily)

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next calendar day? ☐

Cumulative fluid balance — Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day) — Yes ◯ No ◯

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank

or Ventilator continued from previous calendar day? ☐

Ventilator stop time

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) — Fixed Unit: mL

Plateau pressure (Pplat) — Fixed Unit: cmH2O

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) — Fixed Unit: cmH20

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

If Static Compliance (Cstat) not done, check this box ☐

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 ◯

Form: Participant Status (Daily)

	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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	
or ECMO continued from previous calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar day?	☐

Form: Participant Status (Daily)

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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	

Form: Participant Status (Daily)

ICU admission time

or ICU continued from previous calendar day? ☐

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next calendar day? ☐

Cumulative fluid balance Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day) Yes ◯ No ◯

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank

or Ventilator continued from previous calendar day? ☐

Ventilator stop time

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) Fixed Unit: mL

Plateau pressure (Pplat) Fixed Unit: cmH2O

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH20

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

If Static Compliance (Cstat) not done, check this box ☐

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

If PaO2 not done, check this box ☐

FiO2

Mode of mechanical ventilation AC ◯

Form: Participant Status (Daily)

	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 _____
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	_____
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O _____
If BiPAP, what is iPAP?	Fixed Unit: cmH2O _____
If BiPAP, what is ePAP?	Fixed Unit: cmH2O _____
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	_____
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	_____
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min _____
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	_____

Form: Participant Status (Daily)

or ECMO continued from previous calendar day?	☐
ECMO stop time	_____
or ECMO continued to next calendar 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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____

Form: Participant Status (Daily)

2 - Is the participant in the ICU? (assess by calendar day) Yes ☐ No ☐

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

ICU admission time

or ICU continued from previous calendar day? ☐

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next calendar day? ☐

Cumulative fluid balance Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day) Yes ☐ No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank

or Ventilator continued from previous calendar day? ☐

Ventilator stop time

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) Fixed Unit: mL

Plateau pressure (Pplat) Fixed Unit: cmH2O

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH20

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

If Static Compliance (Cstat) not done, check this box ☐

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

Form: Participant Status (Daily)

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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min

Form: Participant Status (Daily)

7 - Is the participant undergoing ECMO?	Yes ☐
If "No", skip to "ECMO stop time"	No ☐
ECMO start time	_____
or ECMO continued from previous calendar day?	☐
ECMO stop time	_____
or ECMO continued to next calendar 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	_____

Form: Participant Status (Daily)

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

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

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? (assess by calendar day) Yes ☐ No ☐

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

ICU admission time _____

or ICU continued from previous calendar day? ☐

ICU discharge time

If discharged on previous date, leave empty _____

or ICU Continued to next calendar day? ☐

Cumulative fluid balance Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

_____

3 - Is the participant on ventilator? (assess by calendar day) Yes ☐ No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time _____

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank _____

or Ventilator continued from previous calendar day? ☐

Ventilator stop time _____

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) Fixed Unit: mL

_____

Plateau pressure (Pplat) Fixed Unit: cmH2O

_____

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH20

_____

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

_____

If Static Compliance (Cstat) not done, check this box ☐

Form: Participant Status (Daily)

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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ○ No ○
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ○ No ○
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ○ BiPAP ○
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ○ No ○
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	

Form: Participant Status (Daily)

If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)_____

If yes, what is the flow rate? (closest to 8am or last setting prior to 8am) 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 calendar day? ☐

ECMO stop time _____

or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	Day 26 ☐ Day 27 ☐ Day 28 ☐
Date of assessment	_____
1 - Is the participant in hospital or discharged?	In Hospital ☐
If "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐ No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance If the participant is not in the ICU, this field may be left blank.	Fixed Unit: mL _____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐ No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	_____
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL _____
Plateau pressure (Pplat)	Fixed Unit: cmH2O _____
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20 _____

Form: Participant Status (Daily)

Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O

Form: Participant Status (Daily)

6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? Yes ☐ No ☐

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

Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour) _____

If yes, what is the FiO2? (closest to 8am or last setting prior to 8am) _____

If yes, what is the flow rate? (closest to 8am or last setting prior to 8am) 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 calendar day? ☐

ECMO stop time _____

or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance	Fixed Unit: mL
If the participant is not in the ICU, this field may be left blank.	_____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐
	No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	_____
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
	_____

Form: Participant Status (Daily)

Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ○ No ○
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ○ No ○
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ○ BiPAP ○
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O

Form: Participant Status (Daily)

If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day?	Yes ☐ No ☐
If "No", skip to item 7 "Is participant undergoing ECMO?"	
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	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 calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time	
If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance	Fixed Unit: mL
If the participant is not in the ICU, this field may be left blank.	_____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐
	No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	_____

Form: Participant Status (Daily)

or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O

Form: Participant Status (Daily)

If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day?	Yes ☐ No ☐
If "No", skip to item 7 "Is participant undergoing ECMO?"	
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	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 calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar 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 ■

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance If the participant is not in the ICU, this field may be left blank.	Fixed Unit: mL _____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐
	No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____

Form: Participant Status (Daily)

or Ventilator continued from previous calendar day?	☐
Ventilator stop time	
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐

Form: Participant Status (Daily)

	BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day?	Yes ☐ No ☐
If "No", skip to item 7 "Is participant undergoing ECMO?"	
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	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 calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance	Fixed Unit: mL
If the participant is not in the ICU, this field may be left blank.	_____

Form: Participant Status (Daily)

3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐ No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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

Form: Participant Status (Daily)

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	_____
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O _____
If BiPAP, what is iPAP?	Fixed Unit: cmH2O _____
If BiPAP, what is ePAP?	Fixed Unit: cmH2O _____
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	_____
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	_____
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min _____
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	_____
or ECMO continued from previous calendar day?	☐
ECMO stop time	_____
or ECMO continued to next calendar day?	☐
Was assessment done? If "No", specify reason.	Yes ☐ No ☐
If "No", reason not done (max. 200 characters)	_____
Participant status assessment time point	Day 1 ☐ Day 2 ☐ Day 3 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time	
If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐

Form: Participant Status (Daily)

Cumulative fluid balance	Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐ No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time	
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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	

Form: Participant Status (Daily)

If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	
or ECMO continued from previous calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar day?	☐
Was assessment done? If "No", specify reason.	Yes ☐ No ☐
If "No", reason not done (max. 200 characters)	

Form: Participant Status (Daily)

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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐

Form: Participant Status (Daily)

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next calendar day? ☐

Cumulative fluid balance — Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day) — Yes ◯ No ◯

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank

or Ventilator continued from previous calendar day? ☐

Ventilator stop time

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) — Fixed Unit: mL

Plateau pressure (Pplat) — Fixed Unit: cmH2O

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) — Fixed Unit: cmH20

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

If Static Compliance (Cstat) not done, check this box ☐

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 ◯

Form: Participant Status (Daily)

	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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	
or ECMO continued from previous calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar day?	☐

Form: Participant Status (Daily)

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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	

Form: Participant Status (Daily)

ICU admission time

or ICU continued from previous calendar day? ☐

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next calendar day? ☐

Cumulative fluid balance Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day) Yes ◯ No ◯

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank

or Ventilator continued from previous calendar day? ☐

Ventilator stop time

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) Fixed Unit: mL

Plateau pressure (Pplat) Fixed Unit: cmH2O

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH20

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

If Static Compliance (Cstat) not done, check this box ☐

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

If PaO2 not done, check this box ☐

FiO2

Mode of mechanical ventilation AC ◯

Form: Participant Status (Daily)

	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 _____
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	_____
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O _____
If BiPAP, what is iPAP?	Fixed Unit: cmH2O _____
If BiPAP, what is ePAP?	Fixed Unit: cmH2O _____
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	_____
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	_____
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min _____
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	_____

Form: Participant Status (Daily)

or ECMO continued from previous calendar day?	☐
ECMO stop time	_____
or ECMO continued to next calendar 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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____

Form: Participant Status (Daily)

2 - Is the participant in the ICU? (assess by calendar day) Yes ☐ No ☐

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

ICU admission time

or ICU continued from previous calendar day? ☐

ICU discharge time

If discharged on previous date, leave empty

or ICU Continued to next calendar day? ☐

Cumulative fluid balance Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day) Yes ☐ No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank

or Ventilator continued from previous calendar day? ☐

Ventilator stop time

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) Fixed Unit: mL

Plateau pressure (Pplat) Fixed Unit: cmH2O

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH20

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

If Static Compliance (Cstat) not done, check this box ☐

SpO2 Fixed Unit: %

PaO2 Fixed Unit: mmHG

Form: Participant Status (Daily)

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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min

Form: Participant Status (Daily)

7 - Is the participant undergoing ECMO?	Yes ☐
If "No", skip to "ECMO stop time"	No ☐
ECMO start time	_____
or ECMO continued from previous calendar day?	☐
ECMO stop time	_____
or ECMO continued to next calendar 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	_____

Form: Participant Status (Daily)

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

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

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? (assess by calendar day) Yes ☐ No ☐

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

ICU admission time _____

or ICU continued from previous calendar day? ☐

ICU discharge time

If discharged on previous date, leave empty _____

or ICU Continued to next calendar day? ☐

Cumulative fluid balance Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

_____

3 - Is the participant on ventilator? (assess by calendar day) Yes ☐ No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time _____

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank _____

or Ventilator continued from previous calendar day? ☐

Ventilator stop time _____

or Ventilator continued to next calendar day? ☐

Tidal volume (Vt) Fixed Unit: mL

_____

Plateau pressure (Pplat) Fixed Unit: cmH2O

_____

If Plateau pressure (Pplat) not done, check this box ☐

Positive End-expiratory Pressure (PEEP) Fixed Unit: cmH20

_____

Static Compliance (Cstat) Fixed Unit: mL/cmH2O

_____

If Static Compliance (Cstat) not done, check this box ☐

Form: Participant Status (Daily)

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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ○ No ○
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ○ No ○
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ○ BiPAP ○
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ○ No ○
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	

Form: Participant Status (Daily)

If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)_____

If yes, what is the flow rate? (closest to 8am or last setting prior to 8am) 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 calendar day? ☐

ECMO stop time _____

or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	Day 26 ☐ Day 27 ☐ Day 28 ☐
Date of assessment	_____
1 - Is the participant in hospital or discharged?	In Hospital ☐
If "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐ No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance If the participant is not in the ICU, this field may be left blank.	Fixed Unit: mL _____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐ No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	_____
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL _____
Plateau pressure (Pplat)	Fixed Unit: cmH2O _____
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20 _____

Form: Participant Status (Daily)

Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O

Form: Participant Status (Daily)

6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? Yes ☐ No ☐

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

Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour) _____

If yes, what is the FiO2? (closest to 8am or last setting prior to 8am) _____

If yes, what is the flow rate? (closest to 8am or last setting prior to 8am) 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 calendar day? ☐

ECMO stop time _____

or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance	Fixed Unit: mL
If the participant is not in the ICU, this field may be left blank.	_____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐
	No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	_____
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
	_____

Form: Participant Status (Daily)

Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ○ No ○
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ○ No ○
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ○ BiPAP ○
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O

Form: Participant Status (Daily)

If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day?	Yes ☐ No ☐
If "No", skip to item 7 "Is participant undergoing ECMO?"	
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	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 calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time	
If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance	Fixed Unit: mL
If the participant is not in the ICU, this field may be left blank.	_____
3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐
	No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	_____
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	_____
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	_____

Form: Participant Status (Daily)

or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O

Form: Participant Status (Daily)

If BiPAP, what is iPAP? Fixed Unit: cmH2O

If BiPAP, what is ePAP? Fixed Unit: cmH2O

6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? Yes ☐ No ☐

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

Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)

If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)

If yes, what is the flow rate? (closest to 8am or last setting prior to 8am) 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 calendar day? ☐

ECMO stop time

or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

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 "In Hospital", skip to item 2 "Is the participant in the ICU?"

If "Discharged", hospital discharge time _____

2 - Is the participant in the ICU? (assess by calendar day)
Yes ☐
No ☐

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

ICU admission time _____

or ICU continued from previous calendar day? ☐

ICU discharge time

If discharged on previous date, leave empty _____

or ICU Continued to next calendar day? ☐

Cumulative fluid balance Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

_____

3 - Is the participant on ventilator? (assess by calendar day)
Yes ☐
No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time _____

If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank _____

Form: Participant Status (Daily)

or Ventilator continued from previous calendar day?	☐
Ventilator stop time	
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐

Form: Participant Status (Daily)

	BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day?	Yes ☐ No ☐
If "No", skip to item 7 "Is participant undergoing ECMO?"	
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	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 calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar 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 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐
Cumulative fluid balance	Fixed Unit: mL
If the participant is not in the ICU, this field may be left blank.	_____

Form: Participant Status (Daily)

3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐ No ☐
If participant was extubated during the calendar day, complete "Ventilator stop time"	
If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"	
Ventilator start time	
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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

Form: Participant Status (Daily)

4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	_____
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O _____
If BiPAP, what is iPAP?	Fixed Unit: cmH2O _____
If BiPAP, what is ePAP?	Fixed Unit: cmH2O _____
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	_____
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	_____
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min _____
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	_____
or ECMO continued from previous calendar day?	☐
ECMO stop time	_____
or ECMO continued to next calendar day?	☐
Was assessment done? If "No", specify reason.	Yes ☐ No ☐
If "No", reason not done (max. 200 characters)	_____
Participant status assessment time point	Day 1 ☐ Day 2 ☐ Day 3 ☐

Form: Participant Status (Daily)

	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 "In Hospital", skip to item 2 "Is the participant in the ICU?"	Discharged ☐
If "Discharged", hospital discharge time	_____
2 - Is the participant in the ICU? (assess by calendar day)	Yes ☐
	No ☐
If "No", skip to "ICU discharge time"	
ICU admission time	_____
or ICU continued from previous calendar day?	☐
ICU discharge time	
If discharged on previous date, leave empty	_____
or ICU Continued to next calendar day?	☐

Form: Participant Status (Daily)

Cumulative fluid balance	Fixed Unit: mL

If the participant is not in the ICU, this field may be left blank.

3 - Is the participant on ventilator? (assess by calendar day)	Yes ☐ No ☐

If participant was extubated during the calendar day, complete "Ventilator stop time"

If participant was intubated or re-intubated during the calendar day, complete "Ventilator start time"

Ventilator start time	
If the participant was extubated and re-intubated during the day, enter a second Ventilator start time, otherwise leave blank	
or Ventilator continued from previous calendar day?	☐
Ventilator stop time	
or Ventilator continued to next calendar day?	☐
Tidal volume (Vt)	Fixed Unit: mL
Plateau pressure (Pplat)	Fixed Unit: cmH2O
If Plateau pressure (Pplat) not done, check this box	☐
Positive End-expiratory Pressure (PEEP)	Fixed Unit: cmH20
Static Compliance (Cstat)	Fixed Unit: mL/cmH2O
If Static Compliance (Cstat) not done, check this box	☐
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	

Form: Participant Status (Daily)

If "PS", specify iPAP	Fixed Unit: cmH2O
If "PS", specify ePAP	Fixed Unit: cmH2O
4 - Has the participant been in the prone position over the past 24 hours as a therapy for ARDS? If "No", skip to item 5 "Is the participant on non-invasive ventilation?"	Yes ☐ No ☐
5 - Was the participant on non-invasive ventilation at any point during the calendar day? If "No", skip to item 6 "Is the participant on high flow nasal cannula oxygen?"	Yes ☐ No ☐
Number of hours on non-invasive ventilation for the calendar day. (closest whole hour)	
If yes, CPAP or BiPAP?	CPAP ☐ BiPAP ☐
If CPAP, what is the pressure level? (closest to 8am or last setting prior to 8am)	Fixed Unit: cmH2O
If BiPAP, what is iPAP?	Fixed Unit: cmH2O
If BiPAP, what is ePAP?	Fixed Unit: cmH2O
6 - Was the participant on high flow nasal cannula oxygen at any point during the calendar day? If "No", skip to item 7 "Is participant undergoing ECMO?"	Yes ☐ No ☐
Number of hours on high flow nasal cannula oxygen for the calendar day. (closest whole hour)	
If yes, what is the FiO2? (closest to 8am or last setting prior to 8am)	
If yes, what is the flow rate? (closest to 8am or last setting prior to 8am)	Fixed Unit: L/min
7 - Is the participant undergoing ECMO? If "No", skip to "ECMO stop time"	Yes ☐ No ☐
ECMO start time	
or ECMO continued from previous calendar day?	☐
ECMO stop time	
or ECMO continued to next calendar day?	☐

Form: Post Day-28 Status

Was the participant still in the ICU, hospitalized, on any type of respiratory support (MV, NIV, HFNC), or on ECMO after study day 28.	Yes ☐ No ☐
If "No", then end form.	
If "Yes", please complete all questions below, as applicable.	
Enter the date of hospital discharge. If still hospitalized at Visit 10 (Day 180), then enter the Visit 10 date.	_____
Enter the date of ICU discharge. If still in the ICU at Visit 10 (Day 180), then enter the Visit 10 date.	_____
Enter the date of cessation of mechanical ventilation. If still on mechanical ventilation at Visit 10 (Day 180), then enter the Visit 10 date.	_____
Enter the date of cessation of non-invasive ventilation. If still on non-invasive ventilation at Visit 10 (Day 180), then enter the Visit 10 date.	_____
Enter the date of cessation of high nasal-flow cannula. If still on high nasal-flow cannula at Visit 10 (Day 180), then enter the Visit 10 date.	_____
Enter the date of cessation of ECMO. If still on ECMO at Visit 10 (Day 180), then enter the Visit 10 date.	_____

Form: Safety Labs

Lab Name:

CBC	
Was CBC with differential collected?	Yes ☐ No ☐
CBC with differential collection date	
Hemoglobin	
Hemoglobin severity grade Update Adverse Event log as applicable.	Not gradable ☐ 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 Update Adverse Event log as applicable.	Not gradable ☐ 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 Update Adverse Event log as applicable.	Not gradable ☐ 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 Update Adverse Event log as applicable.	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐

Form: Safety Labs

Lab Name:

Neutrophils adverse event, if applicable	
Neutrophils not reportable as an adverse event	☐
Lymphocytes	
Lymphocytes severity grade Update Adverse Event log as applicable.	Not gradable ☐ 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 ☐
Chemistry collection date	
Creatinine	
Creatinine severity grade Update Adverse Event log as applicable.	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Creatinine adverse event, if applicable	
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, if applicable	
Creatinine Clearance not reportable as an adverse event	☐
Comments (max. 200 characters):	

Form: Specimen Collection and Storage

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).	_____

Form: Specimen Collection and Storage

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).	

Form: Specimen Collection and Storage

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).	_____

Form: Adverse Event Y/N

Has the participant experienced an adverse event during the study?	Yes ☐ No ☐

If "Yes", update the Adverse Event log.

Form: Adverse Event

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 Record pertinent details for relationship assessment in "Comments".	Definitely related ☐ Probably related ☐ Possibly related ☐ Not related ☐
Action taken with study product	Dose not changed ☐ Dose reduced ☐ Drug withdrawn ☐ Drug interrupted ☐ Not applicable ☐

Form: Adverse Event

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 If "Severity/Frequency increased" is selected, report as a new adverse event.	Recovered/Resolved ☐ Recovering/Resolving ☐ 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? If "No", go to "Has or will this AE be reported as an SAE?".	Yes ☐ 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):	_____

Form: Medical History Y/N

Does the participant have any medical history to report?	Yes ☐ No ☐

If "Yes", update the Medical History log.

Form: Medical History

Refer to the Manual of Procedures for a list of conditions that 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	_____
Or	☐

Check this box if the start date is completely unknown and leave the start date blank.

Is the condition ongoing?	Yes ☐ No ☐

If "Yes", skip to "Comments" or End form.

Date medical history/condition ended/resolved	_____
Or	☐

Check this box if the end date is completely unknown and leave the end date blank.

Comments (max. 200 characters):	_____

Form: Concomitant Medications Y/N

Were there any concomitant medications?	Yes ☐
	No ☐

If "Yes", update the Concomitant Medications Log

Form: Concomitant Medications

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 _____

If the medication entered was used to treat VAP, check this box and indicate VAP below. ☐

Indication _____

Was this medication ongoing before enrollment? ☐

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: _____

Form: Concomitant Medications

Route	Oral ☐ Intramuscular ☐ Intravenous ☐ Subcutaneous ☐ Other ☐
If "Other", specify:	_____
Taken for a reported AE?	Yes ☐ No ☐
If "Yes", select adverse event.	_____

Form: Product Hold Y/N

Does the participant have any clinical product holds to be applied?	Yes ☐ No ☐

If Yes, complete the Product Hold Log.

Form: Product Hold

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/mm^3 ☐ Other ☐
If "Other", specify:	_____
Adverse Event:	_____
Will the study product resume? If 'no - permanently discontinued', 'no - early termination' or 'no - hold continuing at scheduled product use end visit', complete the Product Discontinuation form.	Yes ☐ No - hold continuing for another reason ☐ No - early termination ☐ No - hold continuing at scheduled product use end visit ☐ No - permanently discontinued ☐
Date study product resumed	_____
Date study product hold continuing for another reason	_____

Form: Protocol Deviations Y/N

Have any protocol deviations been reported?	Yes ☐ No ☐

If "Yes", update the Protocol Deviations log.

Form: Protocol Deviations

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	_____

Form: Pregnancy Outcome

Is the outcome of this pregnancy obtainable? If "No", end of form.	Yes ☐ 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 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?".	Full term live birth (greater than or equal to 37 weeks) ☐ 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? If "No", go to "Were any fetal/infant congenital anomalies identified?".	Yes ☐ No ☐
Delivery-related complications. Mark "None" or all that apply.	☐
None	
Intrapartum hemorrhage	☐
Postpartum hemorrhage	☐
Non-reassuring fetal status	☐
Chorioamnionitis	☐
Other	☐

Form: Pregnancy Outcome

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. If "No" or "Unknown", go to "Complete the infant items below for live births only."	Yes ☐ No ☐ 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	

Form: Pregnancy Outcome

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): _____

Form: Pregnancy Report

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:	_____

Form: Pregnancy Test Results

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 ☐

Form: Microbiology Y/N

Did any microbiological specimens result in a positive finding?	Yes ☐ No ☐

If "Yes", update the Microbiology log.

Form: Microbiology

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 ☐
(NOTE: question does not need to be answered for non-Sputum/BAL cultures)	
Select adverse event, if applicable	