



CASE RECORD FORM INSTRUCTIONS

SEVERE ACUTE RESPIRATORY INFECTION CLINICAL CHARACTERISATION DATA TOOLS

DESIGN OF THIS CASE RECORD FORM (CRF)

This CRF is divided into 4 main forms: a "RAPID" (page 1) form with basic admission and outcome data; a "CORE" form with more detailed presentation (pages 2-3) and outcome (pages 4-6) data; a "DAILY" form (page 7) for daily laboratory and clinical data; and a set of "SUPPLEMENTARY" (Page 8-14) forms for overflow data, study-specific inclusion criteria and other investigations. These forms should be used in one of the defined combinations below according to the site's resource availability and scientific interests.

HOW TO USE THIS CRF

Each site may choose the amount of data to collect based on available resources and the number of patients enrolled to date. Ideally, data on patients presenting early in an outbreak will be collected using the Tier 2 schedule of forms outlined below. The decision is up to the site Investigators and may be changed throughout the data collection period. All high quality data is valuable for analysis.

Tier 0 – Complete the RAPID CRF only – For low resource sites or, during an epidemic, sites that have already enrolled large numbers of patients on the Tier 1/2 schedule.

Tier 1 – Complete the CORE CRF + complete the DAILY CRF on the first day of hospital admission and the first day of ICU admission (note: this could be the same day) – For sites that do not have the resources to collect the level of daily data in Tier 2.

Tier 2 - Complete the CORE CRF + complete the DAILY CRF on the first 2 days of hospital admission and the first 2 days of all ICU admissions. For sites taking biological samples for research purposes: complete a DAILY CRF on each day that research samples are taken. – For sites with available resources.

Additional CRF modules are available (e.g. study-specific inclusion criteria, epidemiology, pharmacokinetics) to be completed in addition to any of the Tiers above according to the objectives of the site. If you would like access to additional CRFs, or to suggest a new module for inclusion in these forms please contact us at the email below.

GENERAL GUIDANCE

- The CRF is designed to collect data obtained through examination, interview and review of hospital notes. Data may be collected retrospectively if the patient is enrolled after the admission date.
- Participant Identification Numbers consist of a 3-digit network code (if you register as a network), a 3 digit site code and a 4 digit participant number. You can obtain a network code and site code by registering on the data management system at www.cliresdms.org by contacting isaric@oucru.org. Participant numbers should be assigned sequentially for each site beginning with 0001. In the case of a single site recruiting participants on different wards, or where it is otherwise difficult to assign sequential numbers, it is acceptable to assign numbers in blocks or incorporating alpha characters. E.g. Ward X will assign numbers from 0001 or A001 onwards and Ward Y will assign numbers from 5001 or B001 onwards. Enter the Participant Identification Number at the top of every page.
- Data may be entered to the central database at www.cliresdms.org or to your site/network's independent database.
- In the case of a participant transferring between study sites, it is preferred to maintain the same Participant Identification Number across the sites. When this is not possible, space for recording the new number is provided.
- Complete every line of every section, except for where the instructions say to skip a section based on certain responses.
- Selections with square boxes (□) are single selection answers (choose one answer only). Selections with circles (○) are multiple selection answers (choose as many answers as are applicable).
- Mark 'N/A' for any results of laboratory values that are not available, not applicable or unknown.
- Avoid recording data outside of the dedicated areas. Sections are available for recording additional information.
- We recommend writing clearly in ink, using BLOCK-CAPITAL LETTERS.
- Place an (X) when you choose the corresponding answer. To make corrections, strike through (-----) the data you wish to delete and write the correct data above it. Please initial and date all corrections.
- Please keep all of the sheets for a single participant together e.g. with a staple or participant-unique folder.
- Please enter data on the electronic data capture system at www.cliresdms.org. If your site would like to collect data independently, we are happy to support the establishment of locally hosted databases.
- Please contact us at data@iddo.org if we can help with databases, if you have comments and to let us know that you are using the forms.

RAPID CASE RECORD FORM - Severe Acute Respiratory Infection





PARTICIPANT IDENTIFICATION #:	[][_	_][]-[_	_][]][][_	_]
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This is the RAPID clinical data form for use in Tier 0 data collection only. Complete sections 1-3 at admission. Complete section 4 for ICU admission (if applicable). Complete sections 5&6 after discharge/death/transfer. Enter data to the database at www.cliresdms.org

1. SITE
Clinical centre name: Country:
Enrolment date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
2. DEMOGRAPHICS
Sex at Birth: □ Male □ Female Birth date: □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □
If birth date unknown: Estimated age [][]years OR [][]months
Pregnant? □YES □NO □Unknown □N/A If YES: Gestational weeks assessment: [][] weeks
3. ONSET & ADMISSION
Symptom onset date of first/earliest symptom: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Admission date at this facility: [_D_](_M_](_M_]/[_2_](_0_](_Y_](_Y_]
4. INTENSIVE CARE OR HIGH DEPENDENCY CARE UNIT ADMISSION
ICU admission (or high dependency unit)? \Box YES (complete the rest of this section) \Box NO (skip this section)
First ICU admission date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Record the worst value in first 24 hours of first ICU admission:
Mechanical ventilation \square YES \square NO \square N/A FiO ₂ (0.21-1.0) [].[] or []L/min
SaO_2 at time of $FiO_2[_][_][]$ PaO ₂ at time of $FiO_2[_][_][]$ kPa or \square mmHg
Platelet Count [][]x10 9/L
Glasgow Coma Score (GCS / 15): [][] Urine flow rate [][][]mL/24 hours - □Check if estimated
Record the highest value in first 24 hours of first ICU admission:
Total Bilirubin [][]μmol/L Creatinine [][][] □μmol/L or □mg/dL
Vasopressor/inotropic support on 1 st day of ICU admission? □YES □NO (if NO, answer the next 3 questions NO) □N/A
Dopamine <5µg/kg/min OR Dobutamine OR Milrinone OR Levosimendan: □YES □NO
Dopamine 5-15μg/kg/min OR Epinephrine/Norepinephrine ≤0.1μg/kg/min OR vasopressin OR phenylephrine: □YES □NO
Dopamine >15 μ g/kg/min OR Epinephrine/Norepinephrine > 0.1 μ g/kg/min:
Most recent ICU discharge date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Total ICU duration: [_][_][_] days
5. INFECTIOUS RESPIRATORY DIAGNOSIS
Influenza: □YES- Confirmed □YES- Probable □NO If YES: □A/H3N2 □A/H1N1pdm09 □A/H7N9 □A/H5N1 □B □Other:
Coronavirus: YES- Confirmed YES- Probable NO If YES: MERS-CoV Other:
Other: YES- Confirmed YES- Probable NO If YES: Other:
Clinical pneumonia: □YES □NO If NONE OF THE ABOVE: Unknown/Non-infective: □YES
6. OUTCOME
During hospital admission did the patient at any time receive:
Oxygen therapy: □YES □NO □N/A Invasive ventilation □YES □NO □N/A Non-invasive ventilation: □YES □NO □N/A ECMO/ECLS: □YES □NO □N/A Dialysis: □YES □NO □N/A Multiple ICU admissions: □YES □NO □N/A
Outcome: □Alive at discharge □Hospitalization □Transfer to other facility □Death □Palliative discharge □N/A
Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

CORE CASE RECORD FORM - Severe Acute Respiratory Infection



1. DEMOGRAPHICS



This is the CORE Data Form for use in Tier 1 and Tier 2 data collection. Complete CORE PRESENTATION sections 1-3 at admission. Enter data at www.cliresdms.org

Clinical centre name:			Country:		
Enrolment date: [_D_][_D_]/[_M_][_I	M_]/[_2_][_0_][_	Y_][_Y_]			
Sex at Birth: ☐Male ☐Female B	irth date: [_D_][_	D_]/[_M_]	[_M_]/[_Y_][_Y_][_Y_]		
1	f birth date unkn	own: Estim	nated age [][]years OR [_][]months	
Pregnant? □YES □NO □Unknown	□N/A	If YES: Ge	stational weeks assessment: [][] weeks □N/A	
Admission weight (whole number) [][][]□kg <i>or</i> [□lbs □N/	A Height : $[_][_][_]$ cm or \Box inch	es □N/A	
If age <5 years: Mid-upper-arm circun	nference [][]	[]mm]n/A		
Ethnic group (check all that apply): O	Arab O Black	O East Asi	ian OSouth Asian OWest Asian	OLatin American	
0)	White O Aborigi	nal/First Na	ations OOther:	□N/A	
Admission date at this facility: [_D_][D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]		
Transfer from other facility? □YES-fac	cility is a study site	e □YES-fa	cility is not a study site NO N/A		
If YES: Name of transfer facility:_			□n/A		
If YES: Admission date at transfer facility (DD/MM/YYYY): [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]					
If YES-Study Site: Participant # at t	ransfer facility: [□Same as a	bove Different: [][][]–[_][][] □N/A	
Travel in the 14 days prior to first sym	ptom onset?	□YES □NO	D □N/A		
If YES, state location(s) & date(s):	Country:		City/Geographic area:		
Return Date: [_D_][_D_]/[_M_][_	M_]/[_2_][_0_][_	Y_][_Y_]	\square N/A (more space on SUPPLEMENTARY DATA	FORM)	
Contact with animals, raw meat or insect bites in the 14 days prior to symptom onset? □YES □NO □ N/A If YES, complete the ANIMAL EXPOSURE section (see SUPPLEMENTARY DATA FORM).					
2. CO-MORBIDITIES & RISK FAC	CTORS (existing PR	RIOR TO ADMIS	SSION & that are active problems)		
Chronic cardiac disease (not hypertension)	□YES □NO [□N/A	Metastatic solid tumour	□YES □NO □N/A	
Chronic pulmonary disease (not asthma)	□YES □NO [□N/A	Malignant neoplasm (including leukaemia & lymphoma)	□YES □NO □N/A	
Asthma (physician diagnosed)	□YES □NO [□N/A	AIDS / HIV	□YES □NO □N/A	
Chronic kidney disease	□YES □NO [□N/A	Obesity (as defined by clinical staff)	□YES □NO □N/A	
Moderate or severe liver disease	□YES □NO [□N/A	Diabetes with complications	□YES □NO □N/A	
Mild liver disease	□YES □NO [□N/A	Rheumatologic disorder	□YES □NO □N/A	
Chronic neurological disorder	□YES □NO [□N/A	Dementia	□YES □NO □N/A	
Hemiplegia / Paraplegia	□YES □NO [□N/A			

CORE CASE RECORD FORM - Severe Acute Respiratory Infection





2. CO-MORBIDITIES & RISK F	ACTOR	S cor	ntinued					
Recurrent fever prior to admission	ı ? □Yes	□No □	∃N/A					
Malaria diagnosis after symptom onset? □YES □NO □N/A								
		_	-	corticosteroids prior to admission ection of the SUPPLEMENTARY DATA				
Treatment with anti-infectives for If YES, complete the ADMISSION		-	-	admission? □YES □NO □N/A f the SUPPLEMENTARY DATA FORM.				
POST PARTUM? □YES □NO or N,	/A (skip t	his sect	ion - go to IN	IFANT)				
Pregnancy Outcome: ☐Live birth ☐Still birth ☐Still birth ☐Delivery date: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐								
Baby tested for Mom's infection	n? □YES	S □NO	□N/A If Y	ES : □Positive □Negative Method :	□PCR □Other:			
INFANT – Less than 1 year old?	′ES □N	IO (skip	this section)	Birth weight: [][].[]	kg or □lbs □N/A			
Gestational outcome: ☐ Term b	irth (≥37	7wk GA)	□Pretern	n birth (<37wk GA) □N/A				
Breastfed? □YES □NO □N/	A If Y	res: □	Currently bro	eastfed Breastfeeding discontinue	ed at [][]weeks □N/A			
Appropriate development for age? □YES □NO □N/A Vaccinations appropriate for age/country? □YES □NO □N/A								
Other relevant risk factor(s):								
3. SIGNS AND SYMPTOMS A	r HOSP	ITAL A	DMISSION	(first available data at presentation	/admission – within 24 hours)			
Symptom onset date (first/earliest symptom): [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]								
Temperature: [][].[_]□°C <i>or</i>	· □°F	HR: [][][]beats per minute RR:	[][]breaths per minute			
Systolic BP: [][]mmHg			Diastolic E	BP: [][]mmHg				
Severe dehydration? □YES □NO	□N/A		Sternal ca	pillary refill time >2 seconds? □YES	□NO □N/A			
Oxygen saturation: [][][]% O n	:□Roo	m air □Oxy	gen therapy □N/A				
Admission signs and symptoms	s (observ	ed/repo	orted at adm	ission and associated with this episoc	de of acute illness)			
History of fever	□YES	□NO	□N/A	Lower chest wall indrawing	□YES □NO □N/A			
Cough	□YES	□NO	□N/A	Headache	□YES □NO □N/A			
with sputum production	□YES	□NO	□N/A	Altered consciousness/confusion	□YES □NO □N/A			
bloody sputum/haemoptysis	□YES	□NO	□N/A	Seizures	□YES □NO □N/A			
Sore throat	□YES	□NO	□N/A	Abdominal pain	□YES □NO □N/A			
Runny nose (Rhinorrhoea)	□YES	□NO	□N/A	Vomiting / Nausea	□YES □NO □N/A			
Ear pain	□YES	□NO	□N/A	Diarrhoea	□YES □NO □N/A			
Wheezing	□YES	□NO	□N/A	Conjunctivitis	□YES □NO □N/A			
Chest pain	□YES	□NO	□N/A	Skin rash	□YES □NO □N/A			
Muscle aches (Myalgia)	□YES	□NO	□N/A	Skin ulcers	□YES □NO □N/A			
Joint pain (Arthralgia)	□YES	□NO	□N/A	Lymphadenopathy	□YES □NO □N/A			
Fatigue / Malaise	□YES	□NO	□N/A	Bleeding (Haemorrhage)	□YES □NO □N/A			
Shortness of breath (Dyspnea)	□YES	□ио	□N/A	If Bleeding: specify site(s):				

CORE CASE RECORD FORM - Severe Acute Respiratory Infection





PARTICIPANT IDENTIFICATION #:	[_][_][_]-	[_][_	_][_	_][_	_]
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This is the CORE Data Form for use in Tier 1 and Tier 2 data collection. Complete CORE OUTCOME sections 4-8 after discharge/death/transfer.

<u> </u>				implete cone our cone sections 4 o after als	3-,-	, , , ,	-,-
4. COMPLICATIONS: At any time du	ring hosp	oitalisat	ion did t	ne patient experience:			
Viral pneumonitis	□YES	□NO	□N/A	Cardiac arrest	□YES	□NO	□N/A
Bacterial pneumonia	□YES	□NO	□N/A	Bacteraemia	□YES	□NO	□N/A
Acute lung injury / Acute Respiratory Distress Syndrome	□YES	□NO	□N/A	Coagulation disorder / Disseminated Intravascular Coagluation	□YES	□NO	□N/A
Pneumothorax	□YES	□NO	□N/A	Anaemia	□YES	□NO	□N/A
Pleural effusion	□YES	□NO	□N/A	Rhabdomyolysis / Myositis	□YES	□NO	□N/A
Bronchiolitis	□YES	□NO	□N/A	Acute renal injury/ Acute renal failure	□YES	□NO	□N/A
Meningitis / Encephalitis	□YES	□NO	□N/A	Gastrointestinal haemorrhage	□YES	□NO	□N/A
Seizure	□YES	□NO	□N/A	Pancreatitis	□YES	□NO	□N/A
Stroke / Cerebrovascular accident	□YES	□NO	□N/A	Liver dysfunction	□YES	□NO	□N/A
Congestive heart failure	□YES	□NO	□N/A	Hyperglycemia	□YES	□NO	□N/A
Endocarditis / Myocarditis / Pericarditis	□YES	□NO	□N/A	Hypoglycemia	□YES	□NO	□N/A
Cardiac arrhythmia	□YES	□NO	□N/A	Other	□YES	□NO	□N/A
Cardiac ischaemia	□YES	□NO	□N/A	Specify:			

5. PATHOGEN TES	TING: Was pathogen testing done during this	s illness episode? □Y	'ES (complete se	ction) □NO □N/A
Collection Date (DD/MM/YYYY)	Biospecimen Type	Laboratory Test Method	Result	Pathogen Tested/Detected
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify: □	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A	
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify: □	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A	
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify:	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A	
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify:	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A	
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify: □	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A	

CORE CASE RECORD FORM - Severe Acute Respiratory Infection





PARTICIPANT IDENTIFICATION #: [][]- [_111111_	III
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6. TREATMENT: At ANY time during hospitalisation, did the patient receive/un	dergo:
ICU or High Dependency Unit admission? □YES □NO □N/A If YES, total num	ber of ICU/HDU admissions:
If YES: First admission date: $[D][D]/[M][M]/[2][0][Y][Y]$	If YES, total duration:days
Most recent discharge date: $[D][D]/[M][M]/[2][0][Y][Y$	/A
Oxygen therapy? □YES □NO □N/A	. If YES, total duration:days
If YES: First/Start date: $[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]$ \square N/A	
Last/End date: $[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]$ \square N/A	
Non-invasive ventilation? (e.g. BIPAP, CPAP) □YES □NO □N/A	
Invasive ventilation (Any)? □YES □NO □N/A	. If YES, total duration:days
If YES: First/Start date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	
Last/End date: $[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]$ \square N/A	
Oscillatory Ventilation?	If YES, total duration:days
Prone Ventilation? □YES □NO □N/A	. If YES, total duration:days
Inhaled Nitric Oxide? YES NO N/A	. If YES, total duration:days
Extracorporeal membrane oxygenation (ECMO) or interventional lung-assist therapy (iL	A)?
□ECMO □iLA □None □Not available at site □N/A	If YES, total duration: days
If YES: First/Start date: $[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]$ \square N/A	
Last/End date: $[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]$ \square N/A	
Renal replacement therapy (RRT) or dialysis? □YES □NO □N/A	If YES, total duration: days
If YES: First/Start date: $[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]$ \square N/A	
Last/End date: $[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]$ \square N/A	
Inotropes/vasopressors?	If YES, total duration:days
If YES: First/Start date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	
Last/End date: $[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]$ \square N/A	
Plasmapheresis/exchange? □YES □NO □N/A Oral rehydration therapy	only? □YES □NO □ N/A
Intravenous Immunoglobulin? □YES □NO □ N/A Blood transfusion or pro	ducts? □YES □NO □ N/A
OTHER intervention or procedure (please specify):	
7. MEDICATION: While hospitalised or at discharge, were any of the following a	administered?
Antiviral agent? ☐YES ☐NO ☐N/A If YES: ONeuraminidase Inhibitors OOther	Antibiotic? □YES □NO □N/A
Corticosteroid? □YES □NO □N/A If YES, Route: OOral OIntravenous OInhaled	Antifungal agent? □YES □NO □N/A
If any of the anti-infectives or corticosteroids listed above were administered, please complete CORTICOSTEROIDS section of the SUPPLEMENTAL DATA FORM.	lete the MEDICATION: ANTI-INFECTIVES &
Angiotensin converting enzyme inhibitors (ACE-Is) or angiotensin receptor blockers (ARB	s)? □YES □NO □N/A
Statins (HMG-CoA Reductase Inhibitor)? □YES □NO □N/A If YES: Taking statins prior	to admission? □YES □NO □N/A

CORE CASE RECORD FORM - Severe Acute Respiratory Infection





PARTICIPANT IDENTIFICATION #: [_	11	11	1- f	11	11	П.	1
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8. OUTCOME							
Outcome: □Alive at discharge □Hosp	talization □Transfer to ot	her facility □Death □Palliative disc	harge □N/A				
Outcome date: [_D_][_D_]/[_M_](_M_]/[_2_][_0_][_Y_][_Y_]							
If Discharged alive: Ability to self-care at discharge versus before illness: Same as before illness Worse Better N/A							
	_	Tore liness: Lisame as before limess	□worse □Better □N/A				
If Discharged alive: Post-discharge Oxygen therap	treatment:	Dialysis/renal treatment	:? □YES □NO □N/A				
Other interven	ion or procedure? □YES [□NO □N/A					
If YES: Specif	y (multiple permitted):						
If Transferred: Facility name:			□N/A				
If Transferred: Is the transfer facilit	y a study site? □YES □N	O □N/A					
If a Study Site: Participant # at	new facility: □Same as ab	ove □Different: [][] – [_][][] □N/A				
If Died: Primary cause of death (on	e only):						
☐Multi-organ dysfunction syndrome	☐Acute lung injury	□Pneumonia	☐Myocardial infarction				
☐Congestive heart failure	□Dysrhythmia	☐Chronic obstructive lung disease	□Pulmonary emboli				
□Cerebrovascular disease	☐Renal failure	□Liver failure	☐Malignant neoplasm				
□Other, specify:			□N/A				
If Died: Secondary cause(s) of deat	h (check all that apply):	□N/A					
OMulti-organ dysfunction syndrome	OAcute lung injury	O Pneumonia	OMyocardial infarction				
OCongestive heart failure	O Dysrhythmia	OChronic obstructive lung disease	OPulmonary emboli				
• Cerebrovascular disease	ORenal failure	O Liver failure	O Malignancy				
OOther, specify:		Other, specify:					
Diagnosis (check/complete all that apply	<i>י</i>):						
Influenza: □YES- Confirmed □YES-	Probable □NO If YES	:: □A/H3N2 □A/H1N1pdm09 □A/F	I7N9 □A/H5N1 □B				
		Other:					
Coronavirus: □YES- Confirmed □YES-	Probable □NO If YES	: MERS-CoV Other:					
Clinical pneumonia: □YES	\square NO						
Other (1):	Probable □NO If YES	5: □Other:					
Other (2): YES- Confirmed YES-	Probable □NO If YES	S: □Other:					
Other (3):							
If none of the above: Unknown/Non-in	factive: DVFS						

DAILY CASE RECORD FORM - Severe Acute Respiratory Infection





PARTICIPANT IDENTIFICATION #: [_][][_	_]- [_][][_	_][]
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Tier 1 - complete DAILY form on first day of hospital admission + first day of ICU/HDU admission. Tier 2 – Complete DAILY form on 1^{st} & 2^{nd} days of hospital admission; 1^{st} & 2^{nd} day of all ICU admissions; and any day that research samples are taken.

1. DATE OF ASSESSMENT (DD/MM/YYYY): [][]/[]/[2_][0_][] (may not be the date of completion)						
2. DAILY TREATMENT (complete every line):						
Current admission to ICU/ITU/IMC/HDU? □YES □NO □N/A						
Record the worst value in the previous 24 hours (if Not Available write 'N/A'):						
FiO ₂ (0.21-1.0) [].[] or [][]L/min SaO ₂ [][][]%						
PaO₂ at time of FiO₂ above [][]						
From same blood gas record as PaO ₂ PCO ₂						
HCO ₃ mEq/L Base excess mmol/L						
Glasgow Coma Score (GCS / 15) [][] Mean Arterial Blood Pressure [][]mmHg						
Urine flow rate [][][]mL/24 hours □ Check if estimated						
Is the patient currently receiving, or has received in the past 24 hours (apply to all questions in this section):						
Non-invasive ventilation (eg. BIPAP, CPAP)? □YES □NO □N/A Invasive ventilation? □YES □NO □N/A						
Oscillatory Ventilation? YES NO N/A Extracorporeal membrane oxygenation (ECMO/ECLS)? YES NO N/A						
Interventional lung-assist therapy (iLA)? □YES □NO □N/A Dialysis/Hemofiltration? □YES □NO □N/A						
Any vasopressor/inotropic support? \Box YES \Box NO (if NO, answer the next 3 questions NO) \Box N/A						
Dopamine <5µg/kg/min OR Dobutamine OR milrinone OR levosimendan: □YES □NO						
Dopamine 5-15 μ g/kg/min OR Epinephrine/Norepinephrine < 0.1 μ g/kg/min OR vasopressin OR phenylephrine: \Box YES \Box NO						
Dopamine >15 μ g/k/min OR Epinephrine/Norepinephrine > 0.1 μ g/kg/min:						
Oral rehydration only? □YES □NO □N/A Intravenous Immunoglobulin? □YES □NO □N/A						
Blood transfusion or products? □YES □NO □N/A Plasmapheresis/Exchange? □YES □NO □N/A						
Other intervention or procedure: NO N/A If YES, Specify:						
3. DAILY LABORATORY RESULTS						
Results available for samples taken on the date in section 1 above? YES (complete below) NO (skip section)						
Haemoglobin \square g/L or \square g/dL Haematocrit % WBC count \square x10 9 /L or \square x10 3 /μL						
Platelets □x10 ⁹ /L or □x10 ³ /μL APTT/APTR PT seconds or INR						
ALT/SGPT U/L Total Bilirubin □μmol/L or □mg/dL C-reactive protein □mg/L or						
□nmol/L						
AST/SGOT U/L Glucose mmol/L or mg/dL Erythrocyte Sed Rate mm/h						
Blood Urea Nitrogen (urea) □mmol/L or □mg/d Lactate □mmol/L or □mg/dL						
LDHU/L Creatine kinase CPKU/L Creatinine□μmol/L or □mg/dL						
4. CHEST X-RAY Are results available for a chest x-ray performed on the date in section 1 above?						
Are infiltrates present? YES NO N/A If YES:						
Check all quadrants where infiltrates are present: ○Right upper ○Right lower ○Left upper ○Left lower □N/A						





EXTRA SPACE FOR INFORMATION ON THE CORE DATA FORM

Use this form to record information that does not fit the space provided in the CASE REPORT FORM or where detailed. All information from the CASE REPORT FORM and this SUPPLEMENTARY DATA FORM should be entered into the appropriate sections of the electronic CASE REPORT FORM at https://www.cliresdms.org

CORE - SECTION 1 - TRAVEL: Did the patient travel in the 14 days prior to first symptom onset? If > 1 location & date list:

•	· ·	· ·
Country: City/Geogra	phic area:	Return Date (DD/MM/20YY):/20
Country: City/Geogra	phic area:	Return Date (DD/MM/20YY)://20
Country: City/Geogra	phic area:	Return Date (DD/MM/20YY)://20
14 days prior to first symptom onset? Con	mplete each line below. ify the animal/insect, type of contac	live/dead animals, raw meat or insect bites in the et and date of exposure (DD/MM/YYYY) here:
Bird/Aves (e.g. chickens, turkeys, ducks)	□YES □NO □N/A	
Bat	□YES □NO □N/A	
	·	
Hare/ Rabbit		
Pigs	□YES □NO □N/A	
Non-human primates	□YES □NO □N/A	
Rodent (e.g. rats, mice, squirrels)	□YES □NO □N/A	
Insect bite (e.g. tick, flea, mosquito)	□YES □NO □N/A	
Reptile / Amphibian	□YES □NO □N/A	
Domestic animals living in his/her home (e.g. cats, dogs, other)	□YES □NO □N/A	
Animal feces or nests	□YES □NO □N/A	
Sick animal or dead animal	□YES □NO □N/A	
Raw animal meat / animal blood	□YES □NO □N/A	
Skinned, dressed or eaten wild game	□YES □NO □N/A	
Visit to live animal market, farm or zoo	□YES □NO □N/A	
Participated in animal surgery or necropsy	□YES □NO □N/A	
Other animal contacts:	□YES □NO □N/A	
Livestock (e.g. goats, cattle, camels) Horse Hare/ Rabbit Pigs Non-human primates Rodent (e.g. rats, mice, squirrels) Insect bite (e.g. tick, flea, mosquito) Reptile / Amphibian Domestic animals living in his/her home (e.g. cats, dogs, other) Animal feces or nests Sick animal or dead animal Raw animal meat / animal blood Skinned, dressed or eaten wild game Visit to live animal market, farm or zoo Participated in animal surgery or necropsy	□YES □NO □N/A □YES □NO □N/A	





PARTICIPANT IDENTIFICATION #:	: [_][_][_]· [_][_][_]]
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EXTRA SPACE FOR INFORMATION ON THE CORE DATA FORM - CONTINUED

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Name of immunosuppressa	nt Dose and frequency	uency	Route of a	administratio	on	Duration	
				ral 🗆 Inhale	d	□day	s 🗆 week
	[⊐unknown	□Other □N				□N/.
	_			ral □Inhale	d	□day	s □week
		□unknown	□Other □N				
	, , , , , , , , , , , , , , , , , , ,	⊐unknown		ral □Inhale	d	∐day	s □weel □N/
		uiikiiowii	□Other □N	<u>/A</u> ral □Inhale	4	□day	s □weel
		⊐unknown	□Other □N		u	шаау	
				ral □Inhale	h	□dav	s □weel
	[⊐unknown	□Other □N			,	□N/
episode prior to admission						·	
episode prior to admission	? Enter details below.					·	
		Sta	rt date ///////////////////////////////////	End	date M/20YY)	virals) for this i Rout adminis	e of
episode prior to admission Name of medication	? Enter details below.	Sta	rt date	End	I date M/20YY) □On-going	Rout adminis	e of tration
episode prior to admission Name of medication	? Enter details below. Dose and frequency	Sta	rt date	End	date M/20YY) On-going /20	Route adminis	e of tration Inha N/A
episode prior to admission Name of medication	? Enter details below. Dose and frequency	Sta	rt date ////////////////////////////////////	End	date M/20YY) On-going /20 On-going	Route adminis □IV □Oral □Other □IV □Oral	e of tration Inha N/A
episode prior to admission Name of medication	Penter details below. Dose and frequency N/A N/A	Sta	rt date MM/20YY)	End	date M/20YY) On-going /20 On-going /20	Rout adminis Other Other Other	e of tration Inha N/A Inha
episode prior to admission Name of medication	? Enter details below. Dose and frequency	Sta	rt date ////////////////////////////////////	End	date M/20YY) On-going /20 On-going /20 On-going	Route adminis IV Oral Other IV Oral Other IV Oral	e of tration Inha N/A Inha N/A
episode prior to admission Name of medication	Penter details below. Dose and frequency N/A N/A	Sta	rt date ////////////////////////////////////	End	date M/20YY) On-going /20 On-going /20 On-going /20	Route adminis IV	e of tration Inha N/A Inha N/A Inha
episode prior to admission Name of medication	Penter details below. Dose and frequency N/A N/A	Sta	rt date ////////////////////////////////////	End	date M/20YY) On-going /20 On-going /20 On-going	Route adminis IV Oral Other IV Oral Other IV Oral	e of tration Inha N/A Inha N/A Inha N/A
episode prior to admission Name of medication	Penter details below. Dose and frequency N/A N/A	Sta	rt date ////////////////////////////////////	End	date M/20YY) On-going /20 On-going /20 On-going /20 On-going /20 On-going	Route adminis IV	e of tration Inha N/A Inha N/A Inha N/A Inha N/A

CORE – ADDITIONAL INFORMATION: Detail any additional information not captured in the CASE REPORT FORM.





EXTRA SPACE FOR INFORMATION ON THE CORE DATA FORM - CONTINUED

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CORE - SECTION 5 -PATHOGEN TESTING: Results of pathogen testing done during this illness episode.							
Sample Collection Date (DD/MM/YYYY)	Biospecimen Type	Laboratory Test Method	Result	Pathogen			
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify: □	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A				
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify:	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A				
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify:	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A				
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify:	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A				
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify:	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A				
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify:	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A				
//20	□Nasal/NP swab □Throat swab □Combined nasal/NP+throat swab □Sputum □BAL □ETA □Urine □Feces/rectal swab □Blood □Other, Specify:	□PCR □Culture □Other, Specify:	□Positive □Negative □N/A				





PARTICIPANT IDENTIFICATION #:	[][.][]-	[][.][_][]
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EXTRA SPACE FOR INFORMATION ON THE CORE DATA FORM - CONTINUED

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CORE - SECTION 7 - MEDICA	ATION: ANTI-INFECTIVES &	CORTICOSTEROIDS – List	t all anti-infectives and cor	ticosteroids administered
during hospitalisation and a		ages as required.		
Name of medication (generic name preferred)	Dose and frequency (specify or unknown)	Start date (DD/MM/20YY)	End date (DD/MM/20YY)	Route of administration
	□n/a	/ /20	□On-going /_0/20	□IV □Oral □Inhaled □Other □N/A
	□n/a	/ /20	□On-going //20	□IV □Oral □Inhaled □Other □N/A
	□n/a	/ /20	□On-going //20	□IV □Oral □Inhaled □Other □N/A
		/ /20	□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	□IV □Oral □Inhaled □Other □N/A
	□n/a		//20 //20	□IV □Oral □Inhaled
		//20	□On-going	□Other □N/A □IV □Oral □Inhaled
	□N/A	//20	//20	□Other □N/A □IV □Oral □Inhaled
	· ·	//20	//20	□Other □N/A □IV □Oral □Inhaled
	□N/A	//20	//20 □On-going	□Other □N/A □IV □Oral □Inhaled
	□N/A	//20	//20 □On-going	□Other □N/A □IV □Oral □Inhaled
	□N/A	//20	//20 □On-going	□Other □N/A □IV □Oral □Inhaled
	□n/a	//20	//20	□Other □N/A □IV □Oral □Inhaled
	□n/a	//20	//20 □On-going	□Other □N/A □IV □Oral □Inhaled
	□n/a	//20	//20	□Other □N/A □IV □Oral □Inhaled
	□n/A	//20	//20	□Other □N/A □IV □Oral □Inhaled
	□n/a	//20	//20	□Other □N/A □IV □Oral □Inhaled
	□n/a	//20	//20	□Other □N/A
	□n/a	//20	On-going/	□IV □Oral □Inhaled □Other □N/A
	□N/A	//20	On-going//20	□IV □Oral □Inhaled □Other □N/A
	□n/a	//20	□On-going //20	□IV □Oral □Inhaled □Other □N/A
	□n/a	//20	□On-going //20	□IV □Oral □Inhaled □Other □N/A
	□n/a	//20	□On-going //20	□IV □Oral □Inhaled □Other □N/A





PARTICIPANT IDENTIFICATION #:	[][_	_][_	.]-[_	_][.][][]]
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ADDITIONAL EPIDEMIOLOGICAL INVESTIGATIONS (Tier 3)

Investigations additional to those on the CASE REPORT FORMs may be of interest to some sites. Some examples of relevant data are below and can be completed at the discretion of the site. All information should be entered into the appropriate sections of the electronic database at https://www.cliresdms.org

EXPOSURES IN THE PREVIOUS 14 DAYS:						
Confirmed case contact? \Box YES \Box NO \Box N/A	Probable case contact? □YES □NO □N/A					
Travel? □YES □NO □N/A Animal? □YES □NO	□N/A Occupational? □YES □NO □N/A					
LIVING ARRANGEMENT: What was the primary living situation	on of the patient in the 14 days before presentation to hospital?					
☐Home. # of people in home (including patient):	☐Military base ☐Correctional institution ☐Shelter					
☐Boarding school/dormitory	□Nursing home/long-term healthcare facility					
□Other:	□N/A					
OCCUPATION: What is the patient's occupation?						
VACCINATION HISTORY:						
Influenza immunization this season? □YES this season □YES-this year, but no clear season □NO □N/A If YES: □ ≥14 days prior to illness □ <14 days prior to illness If YES: Immunization type received this season: □TIV (injected) □QIV (injected) □LAIV (inhaled) If YES, <9 years old and first flu vaccination: How many vaccinations were received this season? □1 dose □2 doses Pneumococcal vaccination ever? □Yes □No □N/A						
If Yes: Age at receipt of pneumococcal vaccine:	years old □N/A					
Haemophilus influenzae type b vaccination □Yes □No □N/A If Yes, age at receipt of haemophilus vaccine: years old □N/A						
RSV immunization Palivizumab (if applicable) □Yes □	No □N/A					
Are other vaccines relevant to the infection being studied If YES: Name of Disease If YES: Has the patient ever been vaccinated against the						
If YES: Age at first receipt of vaccine: years						
If YES: Time since last dose: □≥14 days prior to illness □<14 days prior to illness □N/A						
Any other relevant details:						





PHARMACOKINETIC INVESTIGATIONS (Tier 3)

Pharmacokinetic data can be collected on this form. All information should be entered into the appropriate sections of the electronic database at https://www.cliresdms.org

PHARMACOKINETICS (PK	()					
Drug under study:						
Start date of drug prescripti	on:	Date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]				
Date of PK sampling listed be (one page per day):	elow	Date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]				
Prescribed times of administration:		Specify All:				
Precise time of 1 st PK samp	oling:	Time (24 hour clock H H : M M) ::				
Precise time of 2 nd PK samp	oling:					
Precise time of 3 rd PK samp	oling:					
Precise time of 4 th PK samp	oling:	Time (24 hour clock H H : M M) : :				
Record all doses of the drug	g unde	r study give	n on the PK sar	mpling day and in the 24hrs prec	ceding the first PK sampling:	
Dose:	Ro	Route of administration		*Precise* Time Drug Given (if infusion: Start Time) (24 hour clock HH:MM)	*Precise* End Time (infusion only) (24 hour clock HH:MM)	
Amount:	□ıv	□Oral her:	□Inhaled	: : □Same day as PK sample(s) □Day before PK sample(s)	: : □Same day as PK sample(s) □Day before PK sample(s)	
Amount:	□IV	□Oral her:	□Inhaled	:: □Same day as PK sample(s) □Day before PK sample(s)	:: □Same day as PK sample(s) □Day before PK sample(s)	
Amount:	□ıv	□Oral her:	□Inhaled 	:: □Same day as PK sample(s) □Day before PK sample(s)	: : □Same day as PK sample(s) □Day before PK sample(s)	
Amount:	□IV	□Oral her:	□Inhaled	:: □Same day as PK sample(s) □Day before PK sample(s)	:: □Same day as PK sample(s) □Day before PK sample(s)	
Amount:	□IV	□Oral her:	□Inhaled	:: □Same day as PK sample(s) □Day before PK sample(s)	:: □Same day as PK sample(s) □Day before PK sample(s)	
Amount:	□ıv	□Oral her:	□Inhaled	:: □Same day as PK sample(s) □Day before PK sample(s)	:: □Same day as PK sample(s) □Day before PK sample(s)	





SPRINT SARI INCLUSION CRITERIA						
Suspected or proven acute respiratory infection	□YES	□NO				
New admission with symptom onset within the previous 14 days:	□YES	□NO	(required for inclusion)			
Experience of the following symptoms during this illness episode:			(one or more required for inclusion)			
 A history of feverishness or measured fever of ≥ 38°C: 	□YES	\square NO				
· Cough:	\square YES	\square NO				
· Dyspnoea (shortness of breath) OR Tachypnoea*:	\square YES	\square NO				
* respiratory rate ≥50 breaths/min for <1 year; ≥40 breaths/min for 1-4 years; ≥30 breaths/min for 5-12 years; ≥20 breaths/min for ≥13 years						