Global WHO COVID-19 Clinical Data Platform for clinical characterization and management of hospitalized cases with COVID-19

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World Health Organization

Outline

- Overview of the COVID-19 Clinical Data Platform Initiative
- Open Clinical Platform and data curation
- Use of data and country report outline

Background

WHO's COVID-19 response focused on 3 pillars:

1. Slowing and stopping **transmission** of COVID-19
2. Minimizing the **impact** of the epidemic on **health systems**, social services and economic activity
3. Providing **optimized care** for all COVID-19 patients to reduce mortality

Goal

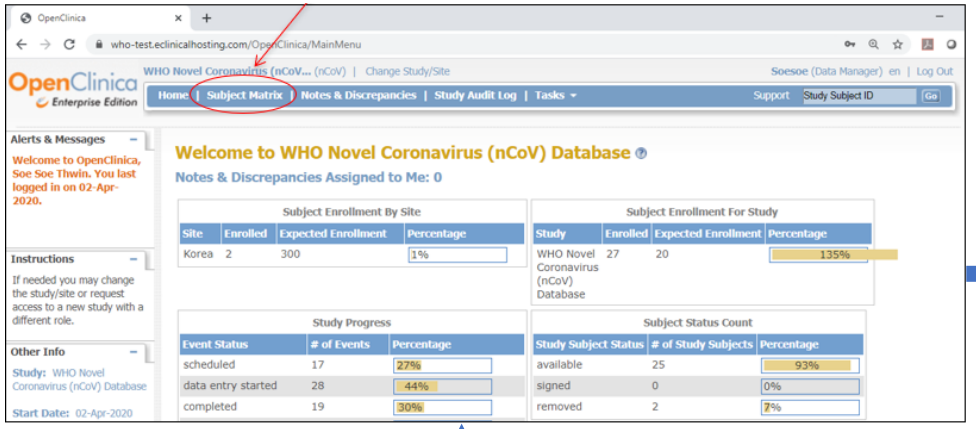
Inform appropriate clinical interventions, public health response and generation of evidence-based guidelines on clinical management of COVID-19 at country, regional and global level

Objectives

1. Characterize **regional variations** and **temporal trends** in clinical phenotypes, clinical care and interventions
2. Derive **risk factors** associated with mortality and ICU admission globally and by **region**
3. Characterize clinical phenotypes, clinical care and interventions in **subpopulations** (i.e. children, pregnant women, people living with HIV, TB, malaria)
4. Describe **mid- and long- term sequelae** of patients discharged from hospitals

Global WHO plan for clinical characterization and management of hospitalized cases

WHO COVID19 Clinical Platform



Data curation, aggregation, analysis, interpretation

2

Rapid analysis

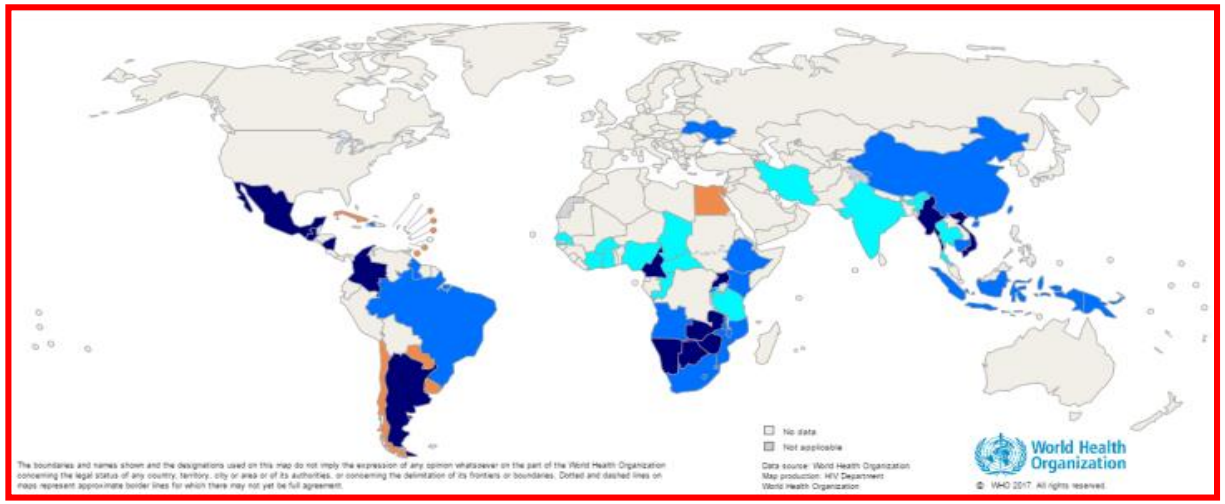
WHO GLOBAL and COUNTRY REPORT on COVID-19 clinical characterization

3

(1) Summarize demographic and clinical features and intervention globally, in regions and subgroups;
(2) Characterize the variability in the clinical features;
(3) Explore the risk factors associated with mortality and ICU admission

1

De-identified patient clinical data from different settings and subpopulations



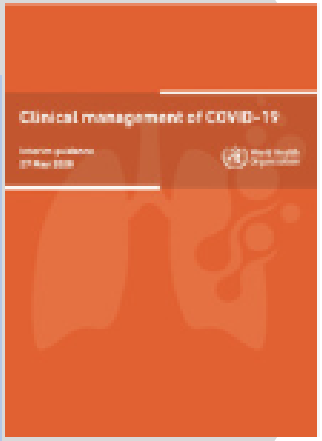
Inform national strategies to respond to COVID19

Inform modelling work

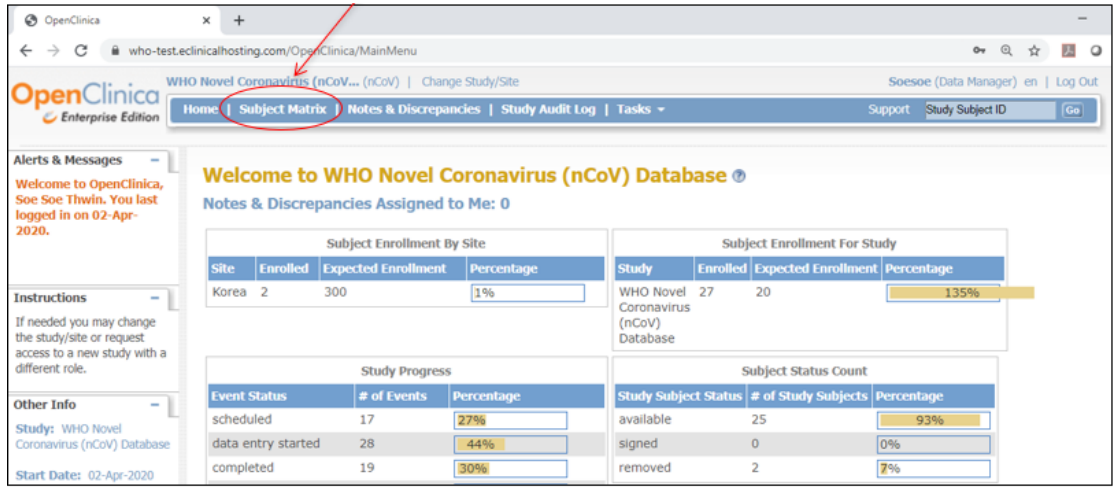
Inform vaccination strategies

Rapid Response

Inform *WHO Guidelines* on COVID-19 clinical management and public heath response



WHO Global COVID-19 Clinical Platform



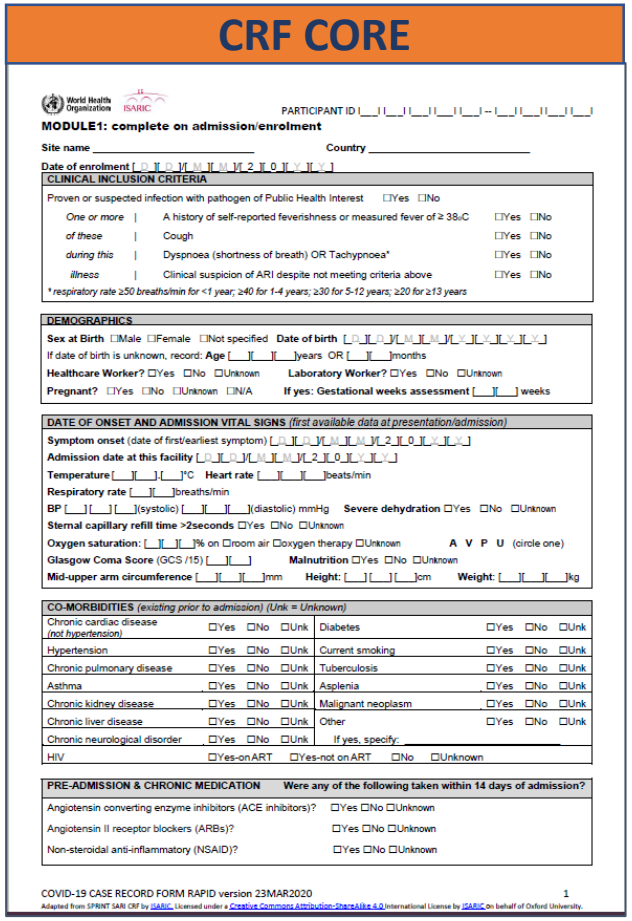
What? System that enables **rapid**, **standardized**, and **systematic** collection of anonymized **clinical data** on **hospitalized** cases with suspected or confirmed COVID19

Why? Facilitate real time aggregation, analysis, interpretation of clinical data from **different settings and sub-populations across the globe**

Where? **Secure, limited-access, password-protected** web based platform hosted on **OpenClinica**

Global WHO Clinical Data Platform for clinical characterization and management of hospitalized cases: standard clinical case report form

CRF CORE



World Health Organization ISARIC

PARTICIPANT ID

MODULE1: complete on admission/enrolment

Site name _____ Country _____

Date of enrolment [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

CLINICAL INCLUSION CRITERIA

Proven or suspected infection with pathogen of Public Health Interest ☐Yes ☐No

One or more of these during this illness	A history of self-reported feverishness or measured fever of ≥ 38ᵢC	☐Yes ☐No
	Cough	☐Yes ☐No
	Dyspnoea (shortness of breath) OR Tachypnoea*	☐Yes ☐No
	Clinical suspicion of ARI despite not meeting criteria above	☐Yes ☐No

* respiratory rate ≥50 breaths/min for <1 year; ≥40 for 1-4 years; ≥30 for 5-12 years; ≥20 for ≥13 years

DEMOGRAPHICS

Sex at Birth ☐Male ☐Female ☐Not specified **Date of birth** [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]

If date of birth is unknown, record: **Age** [___][___]___]years OR [___][___]months

Healthcare Worker? ☐Yes ☐No ☐Unknown **Laboratory Worker?** ☐Yes ☐No ☐Unknown

Pregnant? ☐Yes ☐No ☐Unknown ☐N/A **If yes: Gestational weeks assessment** [___][___] weeks

DATE OF ONSET AND ADMISSION VITAL SIGNS *(first available data at presentation/admission)*

Symptom onset (date of first/earliest symptom) [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Admission date at this facility [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Temperature [___].[___]°C **Heart rate** [___][___]beats/min

Respiratory rate [___][___]breaths/min

BP [___] [___](systolic) [___][___][___](diastolic) mmHg **Severe dehydration** ☐Yes ☐No ☐Unknown

Sternal capillary refill time >2seconds ☐Yes ☐No ☐Unknown

Oxygen saturation: [__][__][__]% on ☐room air ☐oxygen therapy ☐Unknown **A V P U** (circle one)

Glasgow Coma Score (GCS /15) [___][___] **Malnutrition** ☐Yes ☐No ☐Unknown

Mid-upper arm circumference [___][___][___]mm **Height:** [___] [___] [___]cm **Weight:** [___][___][___]kg

CO-MORBIDITIES *(existing prior to admission) (Unk = Unknown)*

Chronic cardiac disease *(not hypertension)*	☐Yes ☐No ☐Unk		Diabetes	☐Yes ☐No ☐Unk	
Hypertension	☐Yes ☐No ☐Unk		Current smoking	☐Yes ☐No ☐Unk	
Chronic pulmonary disease	☐Yes ☐No ☐Unk		Tuberculosis	☐Yes ☐No ☐Unk	
Asthma	☐Yes ☐No ☐Unk		Asplenia	☐Yes ☐No ☐Unk	
Chronic kidney disease	☐Yes ☐No ☐Unk		Malignant neoplasm	☐Yes ☐No ☐Unk	
Chronic liver disease	☐Yes ☐No ☐Unk		Other	☐Yes ☐No ☐Unk	
Chronic neurological disorder	☐Yes ☐No ☐Unk		If yes, specify:		
HIV	☐Yes-on ART ☐Yes-not on ART ☐No ☐Unknown				

PRE-ADMISSION & CHRONIC MEDICATION **Were any of the following taken within 14 days of admission?**

Angiotensin converting enzyme inhibitors (ACE inhibitors)? ☐Yes ☐No ☐Unknown

Angiotensin II receptor blockers (ARBs)? ☐Yes ☐No ☐Unknown

Non-steroidal anti-inflammatory (NSAID)? ☐Yes ☐No ☐Unknown

COVID-19 CASE RECORD FORM RAPID version 23MAR2020 1

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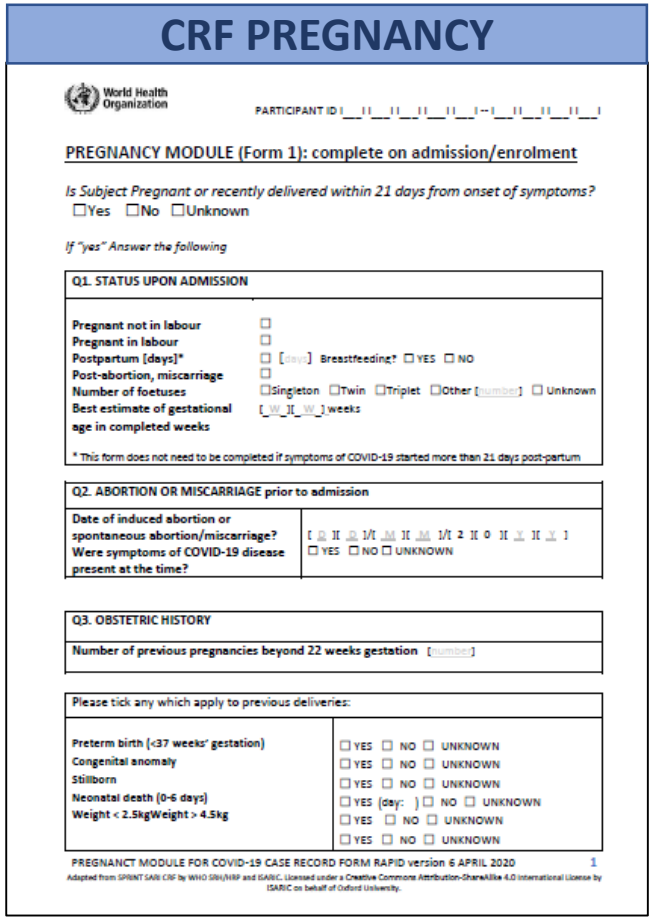
Core CRF: hospitalized children and adults with COVID19

CRF PREGNANCY



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PREGNANCY MODULE (Form 1): complete on admission/enrolment

Is Subject Pregnant or recently delivered within 21 days from onset of symptoms?

☐Yes ☐No ☐Unknown

If "yes" Answer the following

Q1. STATUS UPON ADMISSION

Pregnant not in labour	☐
Pregnant in labour	☐
Postpartum [days]*	☐ [days] Breastfeeding? ☐ YES ☐ NO
Post-abortion, miscarriage	☐
Number of foetuses	☐Singleton ☐Twin ☐Triplet ☐Other [number] ☐ Unknown
Best estimate of gestational age in completed weeks	[_W_][_W_] weeks

* This form does not need to be completed if symptoms of COVID-19 started more than 21 days post-partum

Q2. ABORTION OR MISCARRIAGE prior to admission

Date of induced abortion or spontaneous abortion/miscarriage? Were symptoms of COVID-19 disease present at the time?	[D][D]/[M][M]/[2][0][Y][Y] ☐ YES ☐ NO ☐ UNKNOWN

Q3. OBSTETRIC HISTORY

Number of previous pregnancies beyond 22 weeks gestation [number]

Please tick any which apply to previous deliveries:

Preterm birth (<37 weeks' gestation)	☐ YES ☐ NO ☐ UNKNOWN
Congenital anomaly	☐ YES ☐ NO ☐ UNKNOWN
Stillborn	☐ YES ☐ NO ☐ UNKNOWN
Neonatal death (0-6 days)	☐ YES (day:) ☐ NO ☐ UNKNOWN
Weight < 2.5kgWeight > 4.5kg	☐ YES ☐ NO ☐ UNKNOWN
	☐ YES ☐ NO ☐ UNKNOWN

PREGNANCT MODULE FOR COVID-19 CASE RECORD FORM RAPID version 6 APRIL 2020 1

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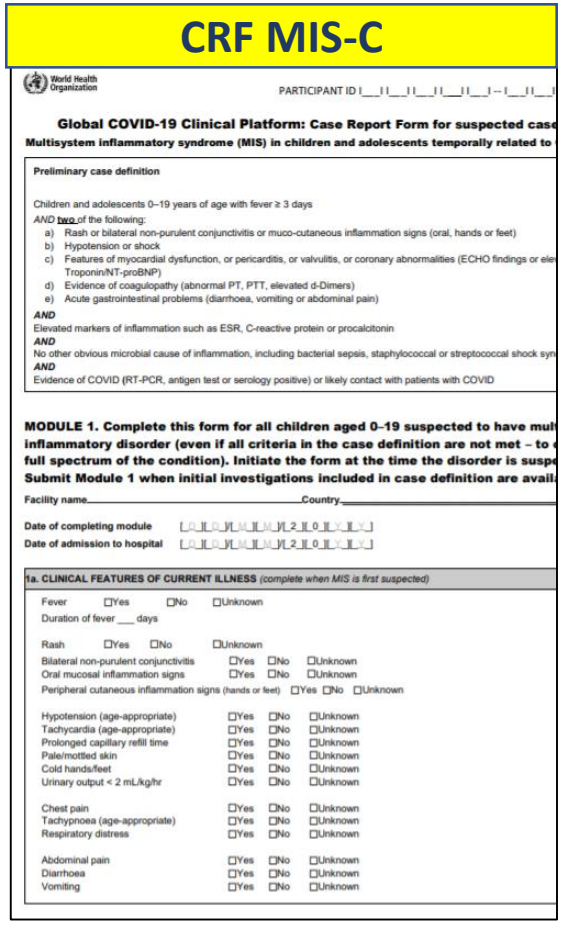
Pregnancy CRF: hospitalized pregnant women

CRF MIS-C



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Global COVID-19 Clinical Platform: Case Report Form for suspected case

Multisystem inflammatory syndrome (MIS) in children and adolescents temporally related to

Preliminary case definition

Children and adolescents 0–19 years of age with fever ≥ 3 days

AND two of the following:

a) Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs (oral, hands or feet)
b) Hypotension or shock
c) Features of myocardial dysfunction, or pericarditis, or valvulitis, or coronary abnormalities (ECHO findings or ele
Troponin/NT-proBNP)
d) Evidence of coagulopathy (abnormal PT, PTT, elevated d-Dimers)
e) Acute gastrointestinal problems (diarrhoea, vomiting or abdominal pain)

AND

Elevated markers of inflammation such as ESR, C-reactive protein or procalcitonin

AND

No other obvious microbial cause of inflammation, including bacterial sepsis, staphylococcal or streptococcal shock syn

AND

Evidence of COVID (RT-PCR, antigen test or serology positive) or likely contact with patients with COVID

MODULE 1. Complete this form for all children aged 0–19 suspected to have mul
inflammatory disorder (even if all criteria in the case definition are not met – to
full spectrum of the condition). Initiate the form at the time the disorder is susp
Submit Module 1 when initial investigations included in case definition are avail

Facility name_____Country_____

Date of completing module [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

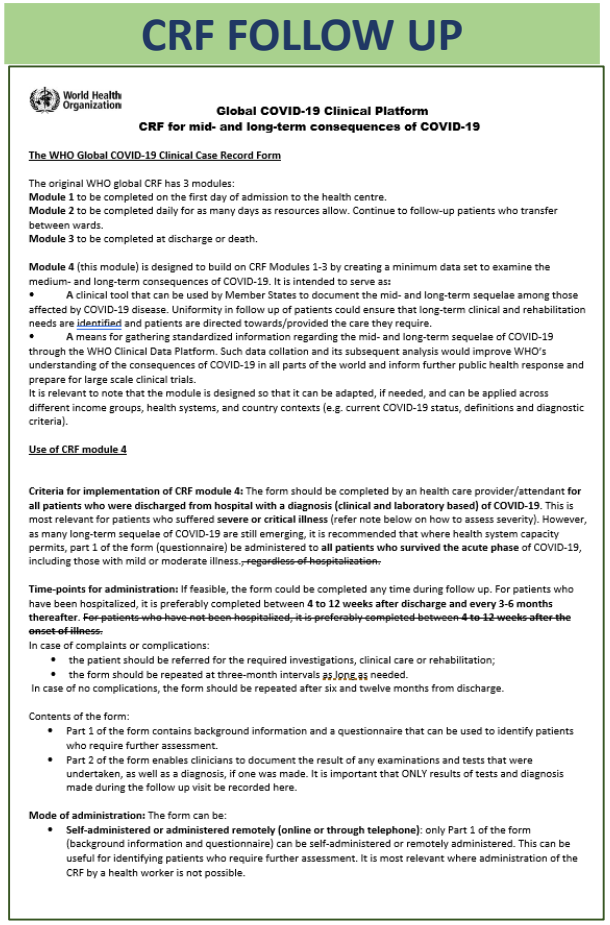
Date of admission to hospital [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

1a. CLINICAL FEATURES OF CURRENT ILLNESS *(complete when MIS is first suspected)*

Fever	☐Yes	☐No	☐Unknown
Duration of fever ___ days			
Rash	☐Yes	☐No	☐Unknown
Bilateral non-purulent conjunctivitis	☐Yes	☐No	☐Unknown
Oral mucosal inflammation signs	☐Yes	☐No	☐Unknown
Peripheral cutaneous inflammation signs (hands or feet)	☐Yes	☐No	☐Unknown
Hypotension (age-appropriate)	☐Yes	☐No	☐Unknown
Tachycardia (age-appropriate)	☐Yes	☐No	☐Unknown
Prolonged capillary refill time	☐Yes	☐No	☐Unknown
Pale/mottled skin	☐Yes	☐No	☐Unknown
Cold hands/feet	☐Yes	☐No	☐Unknown
Urinary output < 2 mL/kg/hr	☐Yes	☐No	☐Unknown
Chest pain	☐Yes	☐No	☐Unknown
Tachypnoea (age-appropriate)	☐Yes	☐No	☐Unknown
Respiratory distress	☐Yes	☐No	☐Unknown
Abdominal pain	☐Yes	☐No	☐Unknown
Diarrhoea	☐Yes	☐No	☐Unknown
Vomiting	☐Yes	☐No	☐Unknown

Multisystem inflammatory syndrome (MIS) in children and adolescents

CRF FOLLOW UP



World Health Organization

Global COVID-19 Clinical Platform
CRF for mid- and long-term consequences of COVID-19

The WHO Global COVID-19 Clinical Case Record Form

The original WHO global CRF has 3 modules:
Module 1 to be completed on the first day of admission to the health centre.
Module 2 to be completed daily for as many days as resources allow. Continue to follow-up patients who transfer between wards.
Module 3 to be completed at discharge or death.

Module 4 (this module) is designed to build on CRF Modules 1-3 by creating a minimum data set to examine the medium- and long-term consequences of COVID-19. It is intended to serve as:

- A clinical tool that can be used by Member States to document the mid- and long-term sequelae among those affected by COVID-19 disease. Uniformity in follow up of patients could ensure that long-term clinical and rehabilitation needs are identified and patients are directed towards/provided the care they require.
- A means for gathering standardized information regarding the mid- and long-term sequelae of COVID-19 through the WHO Clinical Data Platform. Such data collation and its subsequent analysis would improve WHO's understanding of the consequences of COVID-19 in all parts of the world and inform further public health response and prepare for large scale clinical trials.

It is relevant to note that the module is designed so that it can be adapted, if needed, and can be applied across different income groups, health systems, and country contexts (e.g. current COVID-19 status, definitions and diagnostic criteria).

Use of CRF module 4

Criteria for implementation of CRF module 4: The form should be completed by an health care provider/attendant **for all patients who were discharged from hospital with a diagnosis (clinical and laboratory based) of COVID-19**. This is most relevant for patients who suffered **severe or critical illness** (refer note below on how to assess severity). However, as many long-term sequelae of COVID-19 are still emerging, it is recommended that where health system capacity permits, part 1 of the form (questionnaire) be administered to **all patients who survived the acute phase** of COVID-19, including those with mild or moderate illness, ~~regardless of hospitalization.~~

Time-points for administration: If feasible, the form could be completed any time during follow up. For patients who have been hospitalized, it is preferably completed between **4 to 12 weeks after discharge and every 3-6 months thereafter**. ~~For patients who have not been hospitalized, it is preferably completed between 4 to 12 weeks after the onset of illness.~~

In case of complaints or complications:

- the patient should be referred for the required investigations, clinical care or rehabilitation;
- the form should be repeated at three-month intervals as long as needed.

In case of no complications, the form should be repeated after six and twelve months from discharge.

Contents of the form:

- Part 1 of the form contains background information and a questionnaire that can be used to identify patients who require further assessment.
- Part 2 of the form enables clinicians to document the result of any examinations and tests that were undertaken, as well as a diagnosis, if one was made. It is important that ONLY results of tests and diagnosis made during the follow up visit be recorded here.

Mode of administration: The form can be:

- **Self-administered or administered remotely (online or through telephone)**: only Part 1 of the form (background information and questionnaire) can be self-administered or remotely administered. This can be useful for identifying patients who require further assessment. It is most relevant where administration of the CRF by a health worker is not possible.

Follow up CRF: patients discharged from hospital; to assess COVID sequalae

CORE and Pregnancy CASE RECORD FORM include 3 modules

COVID-19 RESPONSE

Critical module

MODULE 1
To complete ad admission

- Demographics
- Date of onset and admission vital signs
- Co-morbidities
- Signs and symptoms
- Medication
- Supportive care received
- Lab results

MODULE 2
to complete daily during hospital stay

- Vital signs
- Daily clinical features
- Lab results
- Medication
- Supportive care received

Critical module

MODULE 3
To complete at discharge or death

- Diagnostic/pathogen testing
- Complications
- Medication
- Supportive care received
- Outcome

3e. OUTCOME

Outcome: ☐Discharged alive ☐Hospitalized ☐Transfer to other facility ☐Death ☐Palliative discharge ☐Unknown

Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Unknown

If Discharged alive: Ability to self-care at discharge versus before illness: ☐Same as before illness ☐Worse ☐Better ☐Unknown

MIS-C CASE RECORD FORM includes 2 modules

COVID-19 RESPONSE

MODULE 1
To complete ad admission

- Demographics
- Date of onset and admission vital signs
- Co-morbidities
- Signs and symptoms
- Medication
- Supportive care received
- Lab results

MODULE 3
To complete at discharge or death

- Diagnostic/pathogen testing
- Complications
- Medication
- Supportive care received
- Outcome

CORE CRF Module 1: Admission

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MODULE 1. Complete on hospital admission (within 24 hrs from hospital admission)

Facility name _____ Country _____

Date of enrolment [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

1a. CLINICAL INCLUSION CRITERIA

One or more of these during this illness	A history of self-reported feverishness or measured fever of ≥ 38°C	☐Yes	☐No
	Cough	☐Yes	☐No
	Dyspnoea (shortness of breath) OR Tachypnoea*	☐Yes	☐No
	Clinical suspicion despite not meeting criteria above	☐Yes	☐No

** Respiratory rate ≥ 50 breaths/min for < 1 year; ≥ 40 for 1–4 years; ≥ 30 for 5–12 years; ≥ 20 for ≥ 13 years*

1b. DEMOGRAPHICS

Sex at birth ☐Male ☐Female ☐Not specified **Date of birth** [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]
If date of birth is unknown, record: **Age** [___][___] **years** OR [_][_] **months** OR [_][_] **days**
Health care worker? ☐Yes ☐No ☐Unknown **Laboratory worker?** ☐Yes ☐No ☐Unknown
Pregnant?* ☐Yes ☐No ☐Unknown ☐N/A **If yes: Gestational weeks assessment** [___][_]**weeks**
If currently pregnant or recently pregnant (delivery within 21 days of symptom onset), complete Pregnancy CRF

1c. DATE OF ONSET AND ADMISSION VITAL SIGNS *(first available data at presentation/admission)*

Symptom onset (date of first/earliest symptom) [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Admission date at this facility [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Temperature [_][___].[_]°C **Heart rate** [___][___][_]beats/min
Respiratory rate [_][___]breaths/min
BP [_][_][_](systolic) [___][_](diastolic) mmHg **Severe dehydration** ☐Yes ☐No ☐Unknown
Sternal capillary refill time > 2 seconds ☐Yes ☐No ☐Unknown
Oxygen saturation: [__][__]% on ☐Room air ☐Oxygen therapy ☐Unknown **A V P U** (circle one)
Glasgow Coma Score (GCS/15) [_][_] **Malnutrition** ☐Yes ☐No ☐Unknown
Mid-upper arm circumference [_][_][___]mm **Height** [___][___][___]cm **Weight** [_][_][___]kg

1d. CO-MORBIDITIES *(existing at admission) (Unk = Unknown)*

Chronic cardiac disease *(not hypertension)*	☐Yes	☐No	☐Unk	Diabetes	☐Yes	☐No	☐Unk
Hypertension	☐Yes	☐No	☐Unk	Current smoking	☐Yes	☐No	☐Unk
Chronic pulmonary disease	☐Yes	☐No	☐Unk	Tuberculosis (*active*)	☐Yes	☐No	☐Unk
Asthma	☐Yes	☐No	☐Unk	Tuberculosis (*previous*)	☐Yes	☐No	☐Unk
Chronic kidney disease	☐Yes	☐No	☐Unk	Asplenia	☐Yes	☐No	☐Unk
Chronic liver disease	☐Yes	☐No	☐Unk	Malignant neoplasm	☐Yes	☐No	☐Unk
Chronic neurological disorder	☐Yes	☐No	☐Unk	Other	☐Yes	☐No	☐Unk
				If yes, specify: _____			
HIV	☐Yes (on ART)			☐Yes (not on ART) ☐No ☐Unknown		ART regimen_____	

1e. PRE-ADMISSION AND CHRONIC MEDICATION Were any of the following taken within 14 days of admission

Angiotensin converting enzyme inhibitors (ACE inhibitors)? ☐Yes ☐No ☐Unknown
Angiotensin II receptor blockers (ARBs)? ☐Yes ☐No ☐Unknown
Non-steroidal anti-inflammatory (NSAID)? ☐Yes ☐No ☐Unknown
Antiviral? ☐Chloroquine/hydroxychloroquine ☐Azithromycin ☐Lopinavir/Ritonavir ☐Other: _____

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1f. SIGNS AND SYMPTOMS ON ADMISSION *(Unk = Unknown)*

History of fever	☐Yes	☐No	☐Unk	Lower chest indrawing	☐Yes	☐No	☐Unk
Cough	☐Yes	☐No	☐Unk	Headache	☐Yes	☐No	☐Unk
with sputum production	☐Yes	☐No	☐Unk	Altered consciousness/confusion	☐Yes	☐No	☐Unk
with haemoptysis	☐Yes	☐No	☐Unk	Seizures	☐Yes	☐No	☐Unk
Sore throat	☐Yes	☐No	☐Unk	Abdominal pain	☐Yes	☐No	☐Unk
Runny nose	☐Yes	☐No	☐Unk	Vomiting/nausea	☐Yes	☐No	☐Unk
Wheezing	☐Yes	☐No	☐Unk	Diarrhoea	☐Yes	☐No	☐Unk
Chest pain	☐Yes	☐No	☐Unk	Conjunctivitis	☐Yes	☐No	☐Unk
Muscle aches	☐Yes	☐No	☐Unk	Skin rash	☐Yes	☐No	☐Unk
Joint pain (arthralgia)	☐Yes	☐No	☐Unk	Skin ulcers	☐Yes	☐No	☐Unk
Fatigue/malaise	☐Yes	☐No	☐Unk	Lymphadenopathy	☐Yes	☐No	☐Unk
Loss of taste	☐Yes	☐No	☐Unk	Inability to walk	☐Yes	☐No	☐Unk
Loss of smell	☐Yes	☐No	☐Unk	Bleeding	☐Yes	☐No	☐Unk
Shortness of breath	☐Yes	☐No	☐Unk	If bleeding, specify site(s):			
Stroke: ischaemic stroke	☐Yes	☐No	☐Unk				
Stroke: intracerebral haemorrhage	☐Yes	☐No	☐Unk				
Other:	☐Yes	☐No	☐Unk				
If yes, specify: _____							

1g. MEDICATION On the day of admission, did the patient receive any of the following:

Oral/orogastric fluids? ☐Yes ☐No ☐Unknown **Intravenous fluids?** ☐Yes ☐No ☐Unknown
Antiviral? ☐Yes ☐No ☐Unknown **If yes:** ☐Ribavirin ☐Lopinavir/Ritonavir ☐Neuraminidase inhibitor ☐Interferon alpha ☐Interferon beta ☐Other, specify: _____
Corticosteroid? ☐Yes ☐No ☐Unknown **If yes,** route: ☐Oral ☐Intravenous ☐Inhaled
If yes, please provide agent and maximum daily dose: _____
Antibiotic? ☐Yes ☐No ☐Unknown **If yes,** specify:_____
Antifungal agent? ☐Yes ☐No ☐Unknown
Antimalarial agent? ☐Yes ☐No ☐Unknown **If yes,** specify:_____
Experimental agent? ☐Yes ☐No ☐Unknown **If yes,** specify:_____
Non-steroidal anti-inflammatory (NSAID) ☐Yes ☐No ☐Unknown
Angiotensin converting enzyme inhibitors (ACE inhibitors) ☐Yes ☐No ☐Unknown
Angiotensin II receptor blockers (ARBs) ☐Yes ☐No ☐ Unknown
Systemic anticoagulation ☐Yes ☐No ☐Unknown

1h. SUPPORTIVE CARE On the day of admission, did the patient receive any of the following:

ICU or high dependency unit admission? ☐Yes ☐No ☐Unknown
Oxygen therapy? ☐Yes ☐No ☐Unknown **If yes,** complete all below
O_2 flow: ☐1–5 L/min ☐6–10 L/min ☐11–15 L/min ☐> 15 L/min ☐Unknown
Source of oxygen: ☐Piped ☐Cylinder ☐Concentrator ☐Unknown
Interface: ☐Nasal prongs ☐HF nasal cannula ☐Mask ☐Mask with reservoir ☐CPAP/NIV mask ☐Unknown
Non-invasive ventilation? (e.g. BIPAP/CPAP) ☐Yes ☐No ☐Unknown
Invasive ventilation (any)? ☐Yes ☐No ☐Unknown
If yes, what were the following values closest to 08:00:
PEEP (cm H_2O) ____; FiO_2 (%) _____; Plateau pressure (cm H_2O) ____; $PaCO_2$ ____; PaO_2_____
Extracorporeal (ECMO) support? ☐Yes ☐No ☐Unknown
Prone position? ☐Yes ☐No ☐Unknown
Inotropes/vasopressors? ☐Yes ☐No ☐Unknown

World Health Organization PARTICIPANT ID |__|__|__|__|__|__|__|__|__|__|__|__|__|__| Module 1 – page 3

1i. LABORATORY RESULTS ON ADMISSION *(*record units if different from those listed)*

Parameter	Value*	Units			Parameter	Value*	Units	
Haemoglobin		☐ g/L	☐ g/dL		Creatinine		☐ mg/L	☐ µmol/L
WBC count		☐ /mm³	☐ G/L (= x10⁹/L)		Sodium		☐ mEq/L = mmol/L	
Haematocrit		☐ %			Potassium		☐ mEq/L = mmol/L	
Platelets		☐ /mm³	☐ G/L (= x10⁹/L)		Procalcitonin		☐ ng/mL	☐ µg/L
APTT/APTR		☐ seconds			CRP		☐ mg/L	
PT (seconds)		☐ seconds			LDH		☐ IU/L	
INR					Creatine kinase		☐ IU/L	☐ UKAT/L
ALT/SGPT		☐ IU/L			Troponin		☐ ng/mL	☐ µg/L
AST/SGOT		☐ IU/L			ESR		☐mm/hour	
Total bilirubin		☐ mg/L	☐ µmol/L		D-dimer		☐ ng/mL	☐ µg/L
Urea (BUN)		☐ g/L	☐ mg/dL	☐ mmol/L	Ferritin		☐ ng/mL	☐ µg/L
Lactate		☐ mg/dL	☐ mmol/L		IL-6		☐ pg/mL	

CORE CRF Module 1 includes information on co-morbidities, co-infections

1d. CO-MORBIDITIES *(existing at admission) (Unk = Unknown)*							
Chronic cardiac disease *(not hypertension)*	☐Yes	☐No	☐Unk	Diabetes	☐Yes	☐No	☐Unk
Hypertension	☐Yes	☐No	☐Unk	Current smoking	☐Yes	☐No	☐Unk
Chronic pulmonary disease	☐Yes	☐No	☐Unk	Tuberculosis	☐Yes	☐No	☐Unk
Asthma	☐Yes	☐No	☐Unk	Asplenia	☐Yes	☐No	☐Unk
Chronic kidney disease	☐Yes	☐No	☐Unk	Malignant neoplasm	☐Yes	☐No	☐Unk
Chronic liver disease	☐Yes	☐No	☐Unk	Other	☐Yes	☐No	☐Unk
Chronic neurological disorder	☐Yes	☐No	☐Unk	If yes, specify: _____			
HIV	☐Yes (on ART)	☐Yes (not on ART)	☐No ☐Unknown	ART regimen_____			

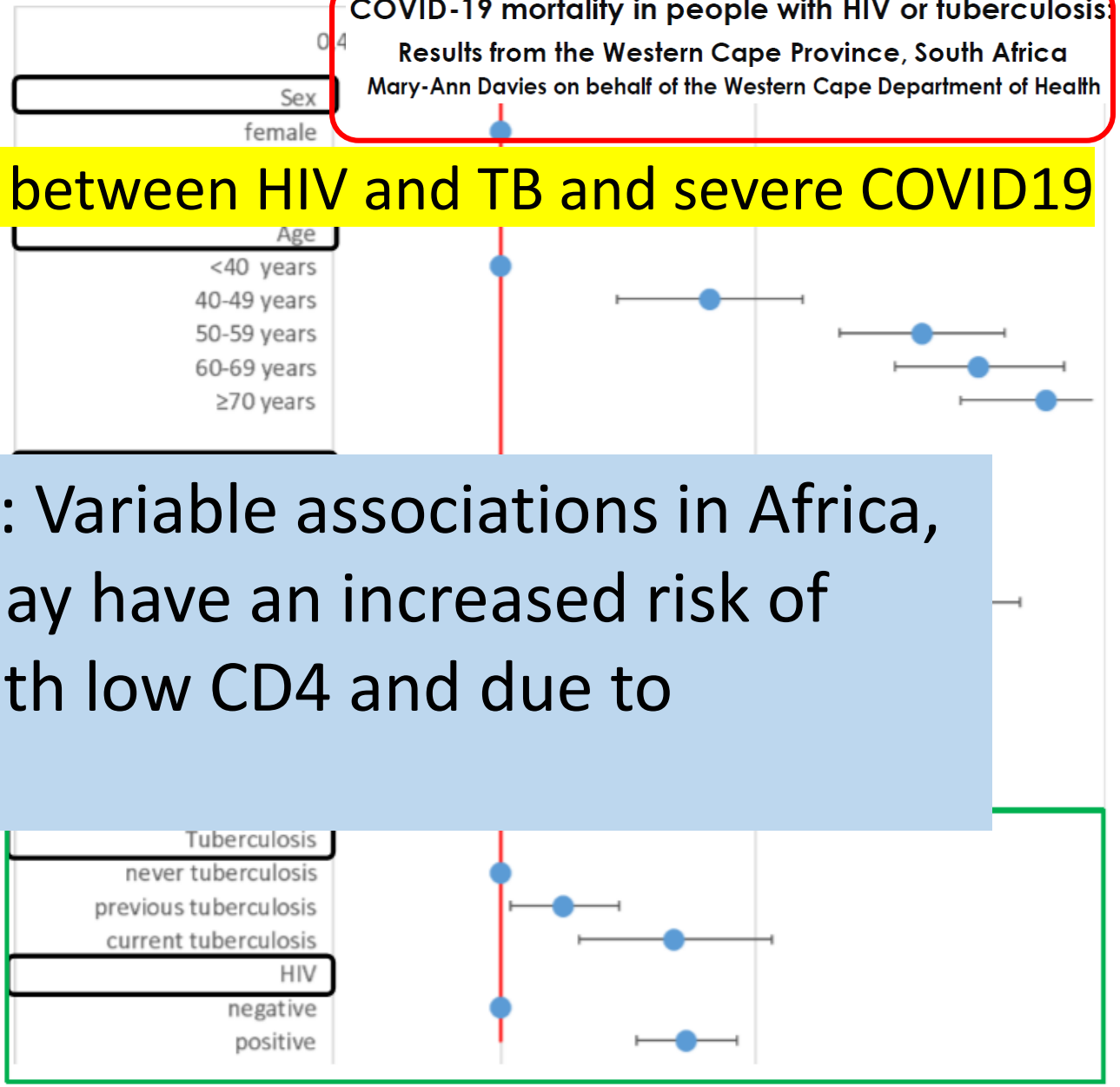
What are the chances of dying from COVID-19 for different risk factors?

Patient characteristics	Adjusted Hazard ratio	95% Confidence Interval
Sex		
female	1	
Age		
<40 years	1	
40-49 years	3,12	1,88; 5,17
50-59 years	9,92	6,34; 15,54
60-69 years	13,55	8,55; 21,48
≥70 years	19,53	12,20; 31,26
Non-communicable diseases		
none		
diabetes well controlled (HbA1c <7%)		
diabetes poorly controlled (HbA1c 7 - 9%)		
diabetes uncontrolled (HbA1c ≥9%)		
diabetes – no measure of control		
hypertension		
chronic kidney disease		
chronic pulmonary disease		
Tuberculosis		
never tuberculosis	1	
previous tuberculosis	1,41	1,05; 1,90
current tuberculosis	2,58	1,53; 4,37
HIV		
negative	1	
positive	2,75	2,09; 3,61

COVID-19 mortality in people with HIV or tuberculosis:
Results from the Western Cape Province, South Africa
Mary-Ann Davies on behalf of the Western Cape Department of Health

Critical to better understand relationship between HIV and TB and severe COVID19

COVID19 and HIV: Variable associations in Africa, the US and UK; may have an increased risk of hospitalization with low CD4 and due to comorbidities



CORE CRF Module 2: daily follow up

World Health Organization PARTICIPANT ID |___|___|___|___|___|___|___|___|___|___|___|___|___|___| Module 2 – page 4

MODULE 2. Daily follow up during hospital stay (daily or as frequent as possible based on feasibility)

Date of follow up [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

2a. VITAL SIGNS *(record most abnormal value between 00:00 to 24:00)*

Temperature [_][___].[_]°C **Heart rate** [___][___][_]beats per min **Respiratory rate** [_][___]breaths/min

BP [_] [_] [_](systolic) [___][_][_](diastolic) mmHg **Severe dehydration** ☐Yes ☐No ☐Unknown

Sternal capillary refill time > 2 seconds ☐Yes ☐No ☐Unknown **A V P U** (circle one)

Oxygen saturation on ☐Room air ☐Oxygen therapy ☐Unknown **GCS/15** [_][___]

2b. DAILY CLINICAL FEATURES *(Unk = Unknown)*

Cough	☐Yes ☐No ☐Unk		Confusion	☐Yes ☐No ☐Unk	
and sputum production	☐Yes ☐No ☐Unk		Seizures	☐Yes ☐No ☐Unk	
Sore throat	☐Yes ☐No ☐Unk		Vomiting/nausea	☐Yes ☐No ☐Unk	
Chest pain	☐Yes ☐No ☐Unk		Diarrhoea	☐Yes ☐No ☐Unk	
Shortness of breath	☐Yes ☐No ☐Unk		Conjunctivitis	☐Yes ☐No ☐Unk	
Loss of smell	☐Yes ☐No ☐Unk		Myalgia	☐Yes ☐No ☐Unk	
Loss of taste	☐Yes ☐No ☐Unk		Other, specify: _____	☐Yes ☐No ☐Unk	

2c. LABORATORY RESULTS *(*record units if different from those listed)*

Parameter	Value*	Units			Parameter	Value*	Units		
Haemoglobin		__ g/L	__ g/dL		Creatinine		__ mg/L	__ µmol/L	
WBC count		___ /mm³	___ G/L (= x10⁹/L)		Sodium		___ mEq/L = mmol/L		
Haematocrit		___ %			Potassium		___ mEq/L = mmol/L		
Platelets		___ /mm³	___ G/L (= x10⁹/L)		Procalcitonin		___ ng/mL	__ µg/L	
APTT/APTR		___ seconds			CRP		___ mg/L		
PT (seconds)		___ seconds			LDH		___ IU/L		
INR					Creatine kinase		___ IU/L	__ UKAT/L	
ALT/SGPT		___ IU/L			Troponin		___ ng/mL	__ µg/L	
AST/SGOT		___ IU/L			ESR		__ mm/hour		
Total bilirubin		___ mg/L	__ µmol/L		D-dimer		___ ng/mL	___ µg/L	
Urea (BUN)		___ g/L	___ mg/dL	___ mmol/L	Ferritin		___ ng/mL	___ µg/L	
Lactate		___ mg/dL	___ mmol/L		IL-6		___ pg/mL		

World Health Organization PARTICIPANT ID |___|___|___|___|___|___|___|___|___|___|___|___|___|___| Module 2 – page 5

2d. MEDICATION At any time during this 24-hour hospital day, did the patient receive:

Oral/orogastric fluids? ☐Yes ☐No ☐Unknown **Intravenous fluids?** ☐Yes ☐No ☐Unknown

Antiviral? ☐Yes ☐No ☐Unknown **If yes:** ☐Ribavirin ☐Lopinavir/Ritonavir ☐Neuraminidase inhibitor ☐Interferon alpha ☐Interferon beta ☐Other, specify: _____

Corticosteroid? ☐Yes ☐No ☐Unknown **If yes,** route: ☐Oral ☐Intravenous ☐Inhaled **If yes,** please provide agent and maximum daily dose: _____

Antibiotic? ☐Yes ☐No ☐Unknown **If yes,** specify: _____

Antifungal agent? ☐Yes ☐No ☐Unknown

Antimalarial agent? ☐Yes ☐No ☐Unknown **If yes,** specify: _____

Experimental agent? ☐Yes ☐No ☐Unknown **If yes,** specify: _____

Non-steroidal anti-inflammatory (NSAID) ☐Yes ☐No ☐Unknown

Angiotensin converting enzyme inhibitors (ACE inhibitors) ☐Yes ☐No ☐Unknown

Angiotensin II receptor blockers (ARBs) ☐Yes ☐No ☐Unknown

Systemic anticoagulation ☐Yes ☐No ☐ Unknown

2e. SUPPORTIVE CARE At any time during this 24-hour hospital day, did the patient receive:

ICU or high dependency unit admission? ☐Yes ☐No ☐Unknown

Date of ICU/HDU admission [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Unknown

ICU/HDU discharge date [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Not discharged yet ☐Unknown

Oxygen therapy? ☐Yes ☐No ☐Unknown **If yes,** complete all below:

O_2 flow: ☐1–5 L/min ☐6–10 L/min ☐11–15 L/min ☐ > 15 L/min ☐Unknown

Source of oxygen: ☐Piped ☐Cylinder ☐Concentrator ☐Unknown

Interface: ☐Nasal prongs ☐HF nasal cannula ☐Mask ☐Mask with reservoir ☐CPAP/NIV mask ☐Unknown

Non-invasive ventilation? (e.g. BIPAP, CPAP) ☐Yes ☐No ☐Unknown

Invasive ventilation (any)? ☐Yes ☐No ☐Unknown

If yes, what were the following values closest to 08:00:

PEEP (cm H_2O) _____; FiO_2 (%) _____; Plateau pressure (cm H_2O) _____; $PaCO_2$ _____; PaO_2_____

Extracorporeal (ECMO) support? ☐Yes ☐No ☐Unknown

Prone position? ☐Yes ☐No ☐Unknown

Inotropes/vasopressors? ☐Yes ☐No ☐Unknown

Renal replacement therapy (RRT) or dialysis? ☐Yes ☐No ☐Unknown

CORE CRF Module 3: discharge/death

World Health Organization PARTICIPANT ID I__I I__I I__I I__I I__I -- I__I I__I I__I I__I Module 3 – page 6

MODULE 3. Complete at discharge/death

3a. DIAGNOSTIC/PATHOGEN TESTING

Chest X-ray/CT performed? ☐Yes ☐No ☐Unknown **If yes, infiltrates present?** ☐Yes ☐No ☐Unknown
Was pathogen testing done during this illness episode? ☐Yes ☐No ☐Unknown **If yes**, complete all below:
Influenza virus: ☐Positive ☐Negative ☐Not done **If positive,** type _____
Coronavirus: ☐Positive ☐Negative ☐Not done **If positive:** ☐MERS-CoV ☐**SARS-CoV-2** ☐Other _____
Other respiratory pathogen: ☐Positive ☐Negative ☐Not done **If positive,** specify _____
Viral haemorrhagic fever: ☐Positive ☐Negative ☐Not done **If positive,** specify virus _____
Other pathogen of public health interest detected: **If yes, specify:** _____
Falciparum malaria: ☐Positive ☐Negative ☐Not done
Non-falciparum malaria: ☐Positive ☐Negative ☐Not done
HIV: ☐Positive ☐Negative ☐Not done

3b. COMPLICATIONS At any time during hospitalization, did the patient experience:

Shock	☐Yes ☐No ☐Unknown	Bacteraemia	☐Yes ☐No ☐Unknown
Seizure	☐Yes ☐No ☐Unknown	Bleeding	☐Yes ☐No ☐Unknown
Meningitis/encephalitis	☐Yes ☐No ☐Unknown	Endocarditis	☐Yes ☐No ☐Unknown
Anaemia	☐Yes ☐No ☐Unknown	Myocarditis/pericarditis	☐Yes ☐No ☐Unknown
Cardiac arrhythmia	☐Yes ☐No ☐Unknown	Acute renal injury	☐Yes ☐No ☐Unknown
Cardiac arrest	☐Yes ☐No ☐Unknown	Pancreatitis	☐Yes ☐No ☐Unknown
Pneumonia	☐Yes ☐No ☐Unknown	Liver dysfunction	☐Yes ☐No ☐Unknown
Bronchiolitis	☐Yes ☐No ☐Unknown	Cardiomyopathy	☐Yes ☐No ☐Unknown
Acute respiratory distress syndrome (ARDS)	☐Yes ☐No ☐Unknown	Other If yes, specify	☐Yes ☐No ☐Unknown
Stroke: ischaemic stroke	☐Yes ☐No ☐Unknown		
Stroke: intracerebral haemorrhage	☐Yes ☐No ☐Unknown		

3c. MEDICATION While hospitalized or at discharge, were any of the following administered:

Oral/orogastric fluids? ☐Yes ☐No ☐Unknown **Intravenous fluids?** ☐Yes ☐No ☐Unknown
Antiviral? ☐Yes ☐No ☐Unknown **If yes:** ☐Ribavirin ☐Lopinavir/Ritonavir ☐Neuraminidase inhibitor ☐Interferon alpha ☐Interferon beta ☐Other, specify: _____
Corticosteroid? ☐Yes ☐No ☐Unknown **If yes,** route: ☐Oral ☐Intravenous ☐Inhaled
If yes, specify agent and maximum daily dose: ____
Antibiotic? ☐Yes ☐No ☐Unknown **If yes,** specify: _____
Antifungal agent? ☐Yes ☐No ☐Unknown **If yes,** specify: _____
Antimalarial agent? ☐Yes ☐No ☐Unknown **If yes,** specify: _____
Experimental agent? ☐Yes ☐No ☐Unknown **If yes,** specify: _____
Non-steroidal anti-inflammatory (NSAID) ☐Yes ☐No ☐Unknown **If yes,** specify: _____
Systemic anticoagulation ☐Yes ☐No ☐Unknown

World Health Organization PARTICIPANT ID I__I I__I I__I I__I I__I -- I__I I__I I__I I__I Module 3 – page 7

3d. SUPPORTIVE CARE At any time during hospitalization, did the patient receive/undergo:

ICU or high dependency unit admission? ☐Yes ☐No ☐Unknown **If yes,** total duration: _____ days
Date of ICU admission [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/A
Date of ICU discharge [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐In ICU at outcome ☐N/A
Oxygen therapy? ☐Yes ☐No ☐Unknown **If yes,** complete all: Total duration: _____ days
O_2 flow: ☐1–5 L/min ☐6–10 L/min ☐11–15 L/min ☐ > 15 L/min
Source of oxygen: ☐Piped ☐Cylinder ☐Concentrator
Interface: ☐Nasal prongs ☐HF nasal cannula ☐Mask ☐Mask with reservoir ☐CPAP/NIV mask
Non-invasive ventilation? (e.g. BIPAP, CPAP) ☐Yes ☐No ☐Unknown **If yes,** total duration: _____ days
Invasive ventilation (any)? ☐Yes ☐No ☐Unknown **If yes,** total duration: _____ days
Extracorporeal (ECMO) support? ☐Yes ☐No ☐Unknown **If yes,** total duration: _____ days
Prone position? ☐Yes ☐No ☐Unknown **If yes,** total duration: _____ days
Inotropes/vasopressors? ☐Yes ☐No ☐Unknown **If yes,** total duration: _____ days
Renal replacement therapy (RRT) or dialysis? ☐Yes ☐No ☐Unknown

3e. OUTCOME

Outcome: ☐Discharged alive ☐Hospitalized ☐Transfer to other facility ☐Death ☐Palliative discharge ☐Unknown
Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Unknown
If discharged alive, ability to self-care at discharge versus before illness: ☐Same as before illness ☐Worse ☐Better ☐Unknown

World Health Organization

Global COVID-19 Clinical Platform — NOVEL CORONAVIRUS (COVID-19) – RAPID CORE CRF

RAPID CORE CRF Completion Guidance

DESIGN OF THIS CASE REPORT FORM (CRF)

This CRF has 3 modules:

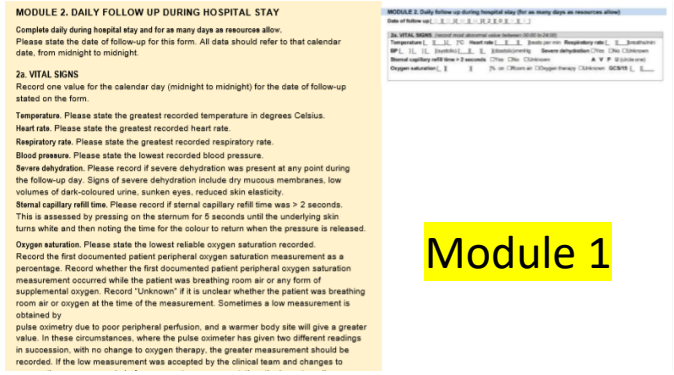
Module 1 to be completed on the first day of admission to the health centre.

Module 2 to be completed daily during hospital stay for as many days as resources allow. Continue to follow-up patients who transfer between wards.

Module 3 to be completed at discharge or death.

GENERAL GUIDANCE (ADAPTED FROM ISARIC GUIDANCE)

- The Rapid Core 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 site code and a participant number.
  You can obtain a site code and register on the data management system by contacting COVID ClinPlatform@who.int
  Participant numbers should be assigned sequentially for each site beginning with 00001. 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. For example, Ward X will assign numbers from 00001 or A0001 onwards and Ward Y will assign numbers from 50001 or B0001 onwards. Enter the participant identification number at the top of every page.
- Data are entered on the central electronic WHO OpenClinica database at https://who.eclinicalhosting.com/OpenClinica/ Printed paper CRFs may be used for later transfer of the data onto the electronic database.
- In the case of a participant transferring between 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 section. Questions marked "If yes, ..." should be left blank when they do not apply (i.e. when the answer is not yes).
- As necessary, where there are multiple selection answers, choose as many as are applicable.
- Mark "Unknown" for any data that are not available, not applicable or unknown.
- Avoid recording data outside of the dedicated areas. Sections are available for recording additional information.
- If using paper CRFs, 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 the sheets for a single participant together, e.g. with a staple or participant-unique folder.
- All paper CRFs can be stored by the institution responsible for them.
- Please enter data on the electronic data capture system at https://who.eclinicalhosting.com/OpenClinica/
- Please contact us at COVID ClinPlatform@who.int to contribute data to the WHO Clinical Data Platform.



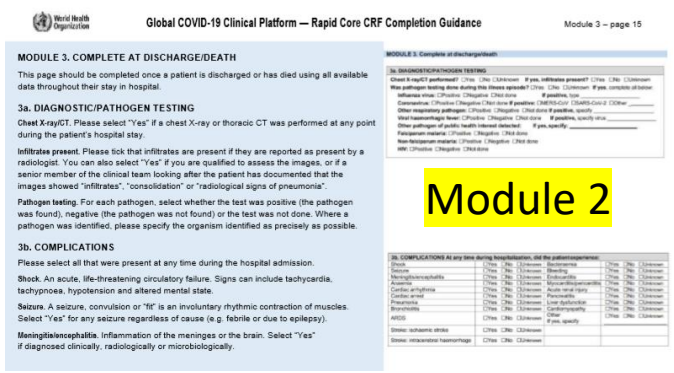
MODULE 2. DAILY FOLLOW UP DURING HOSPITAL STAY

Complete daily during hospital stay and for as many days as resources allow.
Please state the date of follow-up for this form. All data should refer to that calendar date, from midnight to midnight.

2a. VITAL SIGNS
Record one value for the calendar day (midnight to midnight) for the date of follow-up stated on the form.

Temperature. Please state the greatest recorded temperature in degrees Celsius.
Heart rate. Please state the greatest recorded heart rate.
Respiratory rate. Please state the greatest recorded respiratory rate.
Blood pressure. Please state the lowest recorded blood pressure.
Severe dehydration. Please record if severe dehydration was present at any point during the follow-up day. Signs of severe dehydration include dry mucous membranes, low volumes of dark-coloured urine, sunken eyes, reduced skin elasticity.
Sternal capillary refill time. Please record if sternal capillary refill time was > 2 seconds. This is assessed by pressing on the sternum for 5 seconds until the underlying skin turns white and then noting the time for the colour to return when the pressure is released.
Oxygen saturation. Please state the lowest reliable oxygen saturation recorded. Record the first documented patient peripheral oxygen saturation measurement as a percentage. Record whether the first documented patient peripheral oxygen saturation measurement occurred while the patient was breathing room air or any form of supplemental oxygen. Record "Unknown" if it is unclear whether the patient was breathing room air or oxygen at the time of the measurement. Sometimes a low measurement is obtained by
pulse oximetry due to poor peripheral perfusion, and a warmer body site will give a greater value. In these circumstances, where the pulse oximeter has given two different readings in succession, with no change to oxygen therapy, the greater measurement should be recorded. If the low measurement was accepted by the clinical team and changes to

Module 1



World Health Organization — Global COVID-19 Clinical Platform — Rapid Core CRF Completion Guidance — Module 3 – page 15

MODULE 3. COMPLETE AT DISCHARGE/DEATH

This page should be completed once a patient is discharged or has died using all available data throughout their stay in hospital.

3a. DIAGNOSTIC/PATHOGEN TESTING

Chest X-ray/CT. Please select "Yes" if a chest X-ray or thoracic CT was performed at any point during the patient's hospital stay.

Infiltrates present. Please tick that infiltrates are present if they are reported as present by a radiologist. You can also select "Yes" if you are qualified to assess the images, or if a senior member of the clinical team looking after the patient has documented that the images showed "infiltrates", "consolidation" or "radiological signs of pneumonia".

Pathogen testing. For each pathogen, select whether the test was positive (the pathogen was found), negative (the pathogen was not found) or the test was not done. Where a pathogen was identified, please specify the organism identified as precisely as possible.

3b. COMPLICATIONS

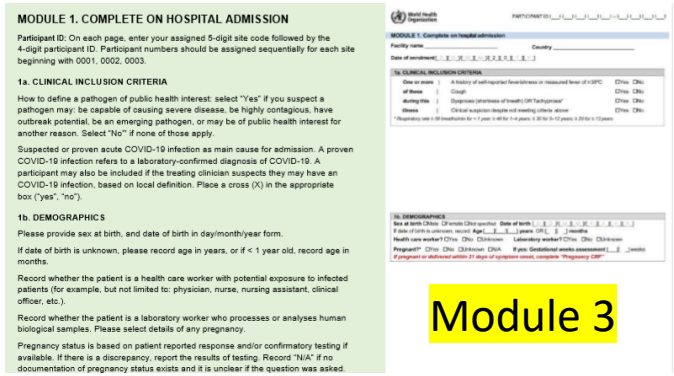
Please select all that were present at any time during the hospital admission.

Shock. An acute, life-threatening circulatory failure. Signs can include tachycardia, tachypnoea, hypotension and altered mental state.

Seizure. A seizure, convulsion or "fit" is an involuntary rhythmic contraction of muscles. Select "Yes" for any seizure regardless of cause (e.g. febrile or due to epilepsy).

Meningitis/encephalitis. Inflammation of the meninges or the brain. Select "Yes" if diagnosed clinically, radiologically or microbiologically.

Module 2



MODULE 1. COMPLETE ON HOSPITAL ADMISSION

Participant ID: On each page, enter your assigned 5-digit site code followed by the 4-digit participant ID. Participant numbers should be assigned sequentially for each site beginning with 0001, 0002, 0003.

1a. CLINICAL INCLUSION CRITERIA

How to define a pathogen of public health interest: select "Yes" if you suspect a pathogen may: be capable of causing severe disease, be highly contagious, have outbreak potential, be an emerging pathogen, or may be of public health interest for another reason. Select "No" if none of those apply.

Suspected or proven acute COVID-19 infection as main cause for admission. A proven COVID-19 infection refers to a laboratory-confirmed diagnosis of COVID-19. A participant may also be included if the treating clinician suspects they may have an COVID-19 infection, based on local definition. Place a cross (X) in the appropriate box ("yes", "no").

1b. DEMOGRAPHICS

Please provide sex at birth, and date of birth in day/month/year form.

If date of birth is unknown, please record age in years, or if < 1 year old, record age in months.

Record whether the patient is a health care worker with potential exposure to infected patients (for example, but not limited to: physician, nurse, nursing assistant, clinical officer, etc.).

Record whether the patient is a laboratory worker who processes or analyses human biological samples. Please select details of any pregnancy.

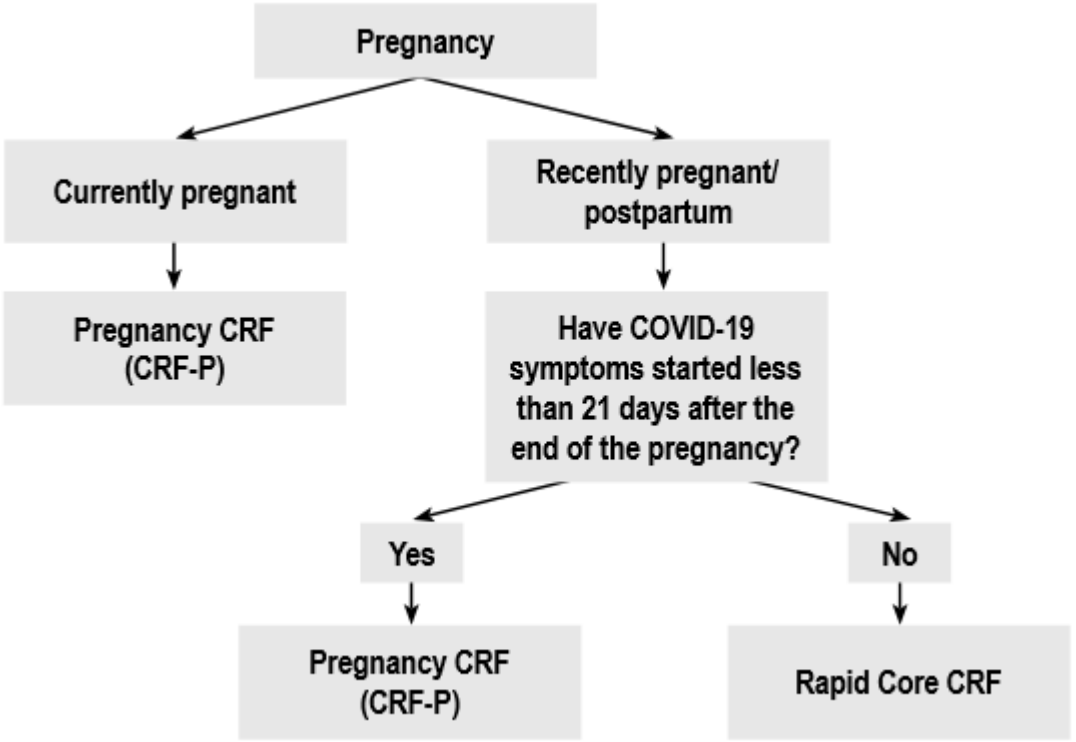
Pregnancy status is based on patient reported response and/or confirmatory testing if available. If there is a discrepancy, report the results of testing. Record "N/A" if no documentation of pregnancy status exists and it is unclear if the question was asked.

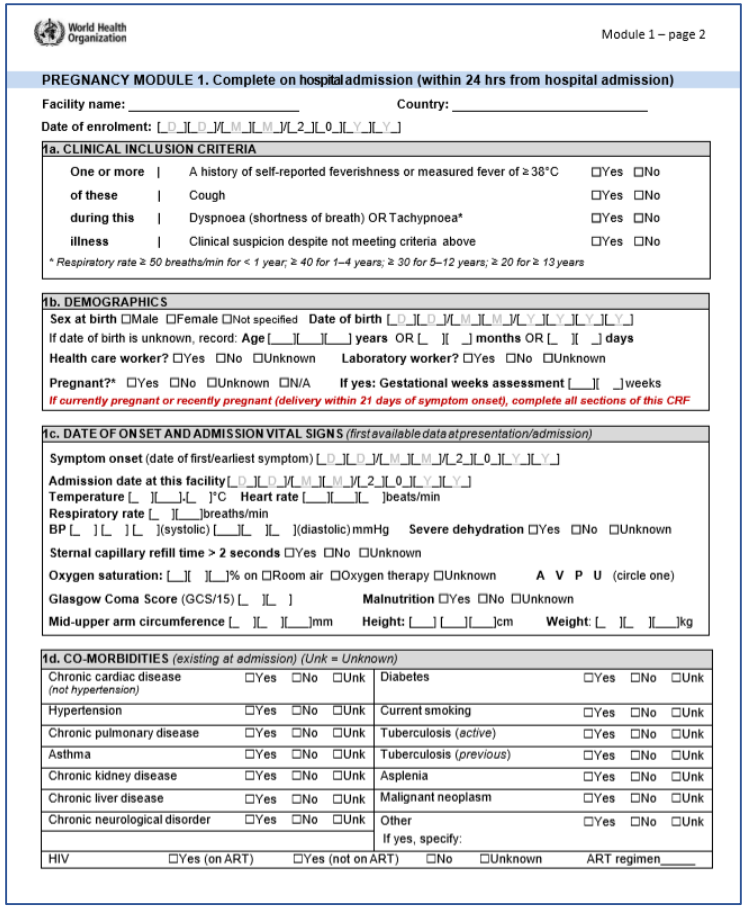
Module 3

Core CRF Completion Guidance

Pregnancy CRF

This CRF-P should be completed for pregnant women or recently pregnant women who delivered **within 21 days from onset of symptoms.** If COVID symptoms started more than 21 days after the end of the pregnancy, please complete the Rapid Core CRF only.





World Health Organization — Module 1 – page 2

PREGNANCY MODULE 1. Complete on hospital admission (within 24 hrs from hospital admission)

Facility name: _____ Country: _____

Date of enrolment: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

1a. CLINICAL INCLUSION CRITERIA

One or more of these during this illness	A history of self-reported feverishness or measured fever of ≥ 38°C	☐Yes	☐No
	Cough	☐Yes	☐No
	Dyspnoea (shortness of breath) OR Tachypnoea*	☐Yes	☐No
	Clinical suspicion despite not meeting criteria above	☐Yes	☐No

* *Respiratory rate ≥ 50 breaths/min for < 1 year; ≥ 40 for 1–4 years; ≥ 30 for 5–12 years; ≥ 20 for ≥ 13 years*

1b. DEMOGRAPHICS

Sex at birth ☐Male ☐Female ☐Not specified Date of birth [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]

If date of birth is unknown, record: Age [___][___][___] years OR [_][_] months OR [_][_] days

Health care worker? ☐Yes ☐No ☐Unknown Laboratory worker? ☐Yes ☐No ☐Unknown

Pregnant?* ☐Yes ☐No ☐Unknown ☐N/A If yes: Gestational weeks assessment [___][_]weeks

If currently pregnant or recently pregnant (delivery within 21 days of symptom onset), complete all sections of this CRF

1c. DATE OF ONSET AND ADMISSION VITAL SIGNS *(first available data at presentation/admission)*

Symptom onset (date of first/earliest symptom) [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Admission date at this facility [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Temperature [_][___].[_]°C Heart rate [___][___][_]beats/min

Respiratory rate [_][___]breaths/min

BP [_] [_] [_](systolic) [___][_][_](diastolic) mmHg Severe dehydration ☐Yes ☐No ☐Unknown

Sternal capillary refill time > 2 seconds ☐Yes ☐No ☐Unknown

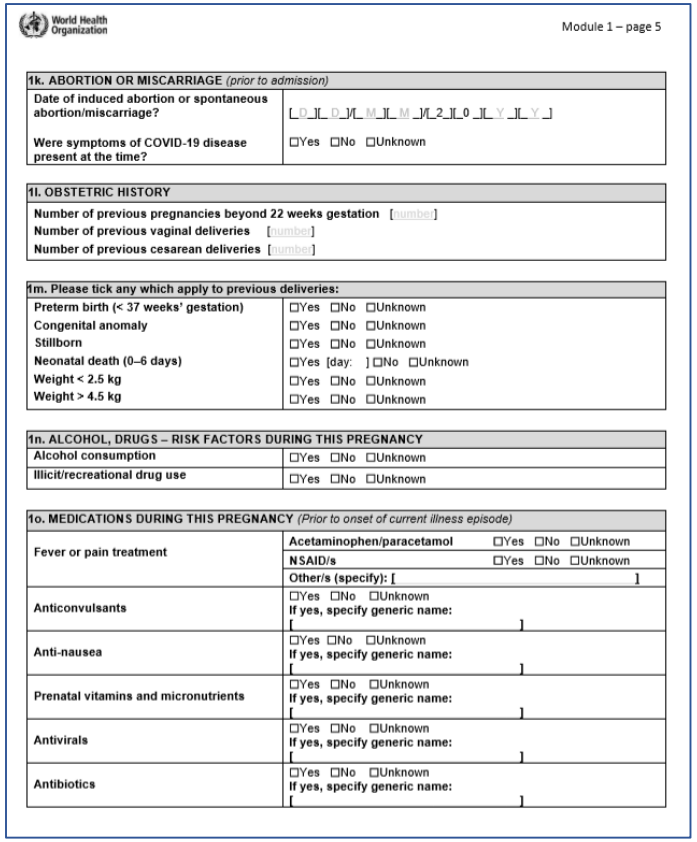
Oxygen saturation: [__][ ][__]% on ☐Room air ☐Oxygen therapy ☐Unknown A V P U (circle one)

Glasgow Coma Score (GCS/15) [_][_] Malnutrition ☐Yes ☐No ☐Unknown

Mid-upper arm circumference [_][_][___]mm Height: [___] [___][___]cm Weight: [_][_][___]kg

1d. CO-MORBIDITIES *(existing at admission) (Unk = Unknown)*

Chronic cardiac disease *(not hypertension)*	☐Yes	☐No	☐Unk	Diabetes	☐Yes	☐No	☐Unk
Hypertension	☐Yes	☐No	☐Unk	Current smoking	☐Yes	☐No	☐Unk
Chronic pulmonary disease	☐Yes	☐No	☐Unk	Tuberculosis (*active*)	☐Yes	☐No	☐Unk
Asthma	☐Yes	☐No	☐Unk	Tuberculosis (*previous*)	☐Yes	☐No	☐Unk
Chronic kidney disease	☐Yes	☐No	☐Unk	Asplenia	☐Yes	☐No	☐Unk
Chronic liver disease	☐Yes	☐No	☐Unk	Malignant neoplasm	☐Yes	☐No	☐Unk
Chronic neurological disorder	☐Yes	☐No	☐Unk	Other If yes, specify:	☐Yes	☐No	☐Unk
HIV ☐Yes (on ART) ☐Yes (not on ART) ☐No ☐Unknown ART regimen_____							



World Health Organization — Module 1 – page 5

1k. ABORTION OR MISCARRIAGE *(prior to admission)*

Date of induced abortion or spontaneous abortion/miscarriage?	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Were symptoms of COVID-19 disease present at the time?	☐Yes ☐No ☐Unknown

1l. OBSTETRIC HISTORY

Number of previous pregnancies beyond 22 weeks gestation [number]

Number of previous vaginal deliveries [number]

Number of previous cesarean deliveries [number]

1m. Please tick any which apply to previous deliveries:

Preterm birth (< 37 weeks' gestation)	☐Yes ☐No ☐Unknown
Congenital anomaly	☐Yes ☐No ☐Unknown
Stillborn	☐Yes ☐No ☐Unknown
Neonatal death (0–6 days)	☐Yes [day:] ☐No ☐Unknown
Weight < 2.5 kg	☐Yes ☐No ☐Unknown
Weight > 4.5 kg	☐Yes ☐No ☐Unknown

1n. ALCOHOL, DRUGS – RISK FACTORS DURING THIS PREGNANCY

Alcohol consumption	☐Yes ☐No ☐Unknown
Illicit/recreational drug use	☐Yes ☐No ☐Unknown

1o. MEDICATIONS DURING THIS PREGNANCY *(Prior to onset of current illness episode)*

Fever or pain treatment	Acetaminophen/paracetamol	☐Yes ☐No ☐Unknown
	NSAID/s	☐Yes ☐No ☐Unknown
	Other/s (specify): [ ]	
Anticonvulsants	☐Yes ☐No ☐Unknown If yes, specify generic name: [ ]	
Anti-nausea	☐Yes ☐No ☐Unknown If yes, specify generic name: [ ]	
Prenatal vitamins and micronutrients	☐Yes ☐No ☐Unknown If yes, specify generic name: [ ]	
Antivirals	☐Yes ☐No ☐Unknown If yes, specify generic name: [ ]	
Antibiotics	☐Yes ☐No ☐Unknown If yes, specify generic name: [ ]	

Pregnancy CRF = Core CRF + pregnancy module

Pregnancy CRF Completion Guidelines

World Health Organization

ISARIC

Global COVID-19 Clinical Platform — NOVEL CORONAVIRUS (COVID-19)

RAPID CORE CASE REPORT FORM WITH PREGNANCY
MODULE CRF-P Completion Guidance

DESIGN OF THIS CASE REPORT FORM FOR PREGNANCY (CRF-P)

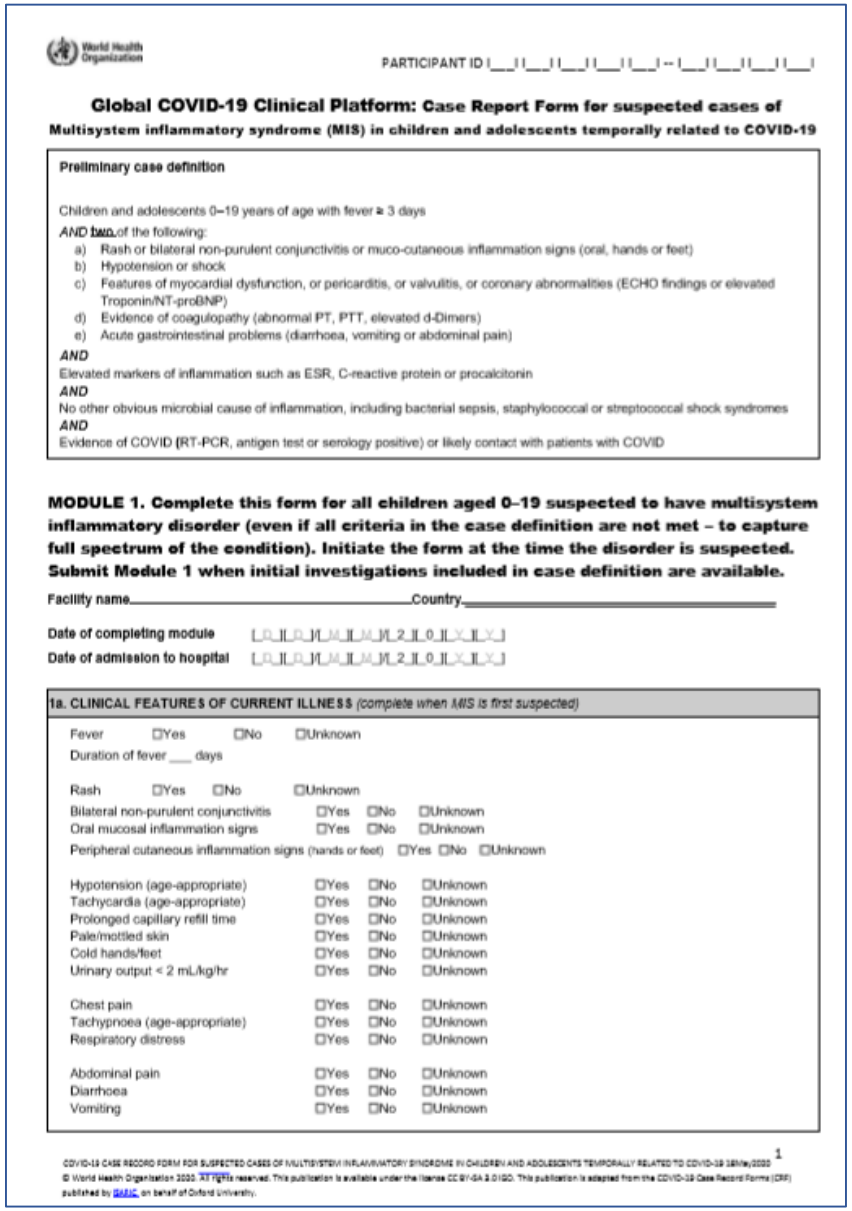
This CRF-P has 3 modules:

Module 1 to be completed on the first day of admission to the health centre.

Module 2 to be completed daily during hospital stay for as many days as resources allow. Continue to follow-up women who transfer between wards.

Module 3 to be completed at discharge or death.

MIS-C CRF



World Health Organization

PARTICIPANT ID [__][__][__][__][__]-[__][__][__][__][__]

Global COVID-19 Clinical Platform: Case Report Form for suspected cases of Multisystem inflammatory syndrome (MIS) in children and adolescents temporally related to COVID-19

Preliminary case definition

Children and adolescents 0–19 years of age with fever ≥ 3 days
AND two of the following:
a) Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs (oral, hands or feet)
b) Hypotension or shock
c) Features of myocardial dysfunction, or pericarditis, or valvulitis, or coronary abnormalities (ECHO findings or elevated Troponin/NT-proBNP)
d) Evidence of coagulopathy (abnormal PT, PTT, elevated d-Dimers)
e) Acute gastrointestinal problems (diarrhoea, vomiting or abdominal pain)
AND
Elevated markers of inflammation such as ESR, C-reactive protein or procalcitonin
AND
No other obvious microbial cause of inflammation, including bacterial sepsis, staphylococcal or streptococcal shock syndromes
AND
Evidence of COVID (RT-PCR, antigen test or serology positive) or likely contact with patients with COVID

MODULE 1. Complete this form for all children aged 0–19 suspected to have multisystem inflammatory disorder (even if all criteria in the case definition are not met – to capture full spectrum of the condition). Initiate the form at the time the disorder is suspected. Submit Module 1 when initial investigations included in case definition are available.

Facility name_____Country_____

Date of completing module [D][D]/[M][M]/[2][0][Y][Y]
Date of admission to hospital [D][D]/[M][M]/[2][0][Y][Y]

1a. CLINICAL FEATURES OF CURRENT ILLNESS *(complete when MIS is first suspected)*

Fever ☐Yes ☐No ☐Unknown
Duration of fever ___ days

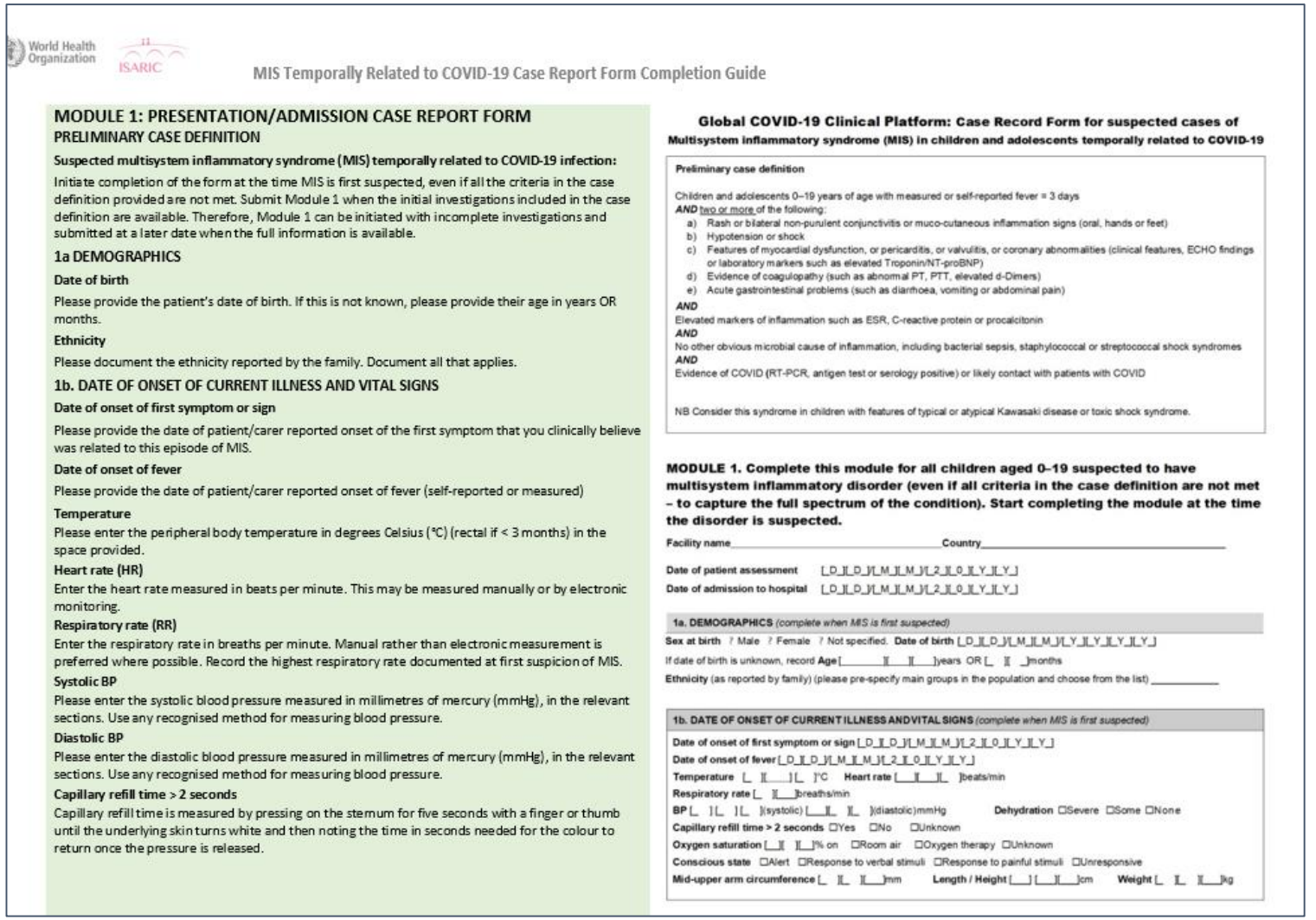
Rash ☐Yes ☐No ☐Unknown
Bilateral non-purulent conjunctivitis ☐Yes ☐No ☐Unknown
Oral mucosal inflammation signs ☐Yes ☐No ☐Unknown
Peripheral cutaneous inflammation signs (hands or feet) ☐Yes ☐No ☐Unknown

Hypotension (age-appropriate) ☐Yes ☐No ☐Unknown
Tachycardia (age-appropriate) ☐Yes ☐No ☐Unknown
Prolonged capillary refill time ☐Yes ☐No ☐Unknown
Pale/mottled skin ☐Yes ☐No ☐Unknown
Cold hands/feet ☐Yes ☐No ☐Unknown
Urinary output < 2 mL/kg/hr ☐Yes ☐No ☐Unknown

Chest pain ☐Yes ☐No ☐Unknown
Tachypnoea (age-appropriate) ☐Yes ☐No ☐Unknown
Respiratory distress ☐Yes ☐No ☐Unknown

Abdominal pain ☐Yes ☐No ☐Unknown
Diarrhoea ☐Yes ☐No ☐Unknown
Vomiting ☐Yes ☐No ☐Unknown

MIS-C CRF Completion Guidelines



World Health Organization ISARIC

MIS Temporally Related to COVID-19 Case Report Form Completion Guide

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

PRELIMINARY CASE DEFINITION

Suspected multisystem inflammatory syndrome (MIS) temporally related to COVID-19 infection:

Initiate completion of the form at the time MIS is first suspected, even if all the criteria in the case definition provided are not met. Submit Module 1 when the initial investigations included in the case definition are available. Therefore, Module 1 can be initiated with incomplete investigations and submitted at a later date when the full information is available.

1a DEMOGRAPHICS

Date of birth

Please provide the patient's date of birth. If this is not known, please provide their age in years OR months.

Ethnicity

Please document the ethnicity reported by the family. Document all that applies.

1b. DATE OF ONSET OF CURRENT ILLNESS AND VITAL SIGNS

Date of onset of first symptom or sign

Please provide the date of patient/carer reported onset of the first symptom that you clinically believe was related to this episode of MIS.

Date of onset of fever

Please provide the date of patient/carer reported onset of fever (self-reported or measured)

Temperature

Please enter the peripheral body temperature in degrees Celsius (°C) (rectal if < 3 months) in the space provided.

Heart rate (HR)

Enter the heart rate measured in beats per minute. This may be measured manually or by electronic monitoring.

Respiratory rate (RR)

Enter the respiratory rate in breaths per minute. Manual rather than electronic measurement is preferred where possible. Record the highest respiratory rate documented at first suspicion of MIS.

Systolic BP

Please enter the systolic blood pressure measured in millimetres of mercury (mmHg), in the relevant sections. Use any recognised method for measuring blood pressure.

Diastolic BP

Please enter the diastolic blood pressure measured in millimetres of mercury (mmHg), in the relevant sections. Use any recognised method for measuring blood pressure.

Capillary refill time > 2 seconds

Capillary refill time is measured by pressing on the sternum for five seconds with a finger or thumb until the underlying skin turns white and then noting the time in seconds needed for the colour to return once the pressure is released.

Global COVID-19 Clinical Platform: Case Record Form for suspected cases of Multisystem inflammatory syndrome (MIS) in children and adolescents temporally related to COVID-19

Preliminary case definition

Children and adolescents 0–19 years of age with measured or self-reported fever ≥ 3 days
AND two or more of the following:
a) Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs (oral, hands or feet)
b) Hypotension or shock
c) Features of myocardial dysfunction, or pericarditis, or valvulitis, or coronary abnormalities (clinical features, ECHO findings or laboratory markers such as elevated Troponin/NT-proBNP)
d) Evidence of coagulopathy (such as abnormal PT, PTT, elevated d-Dimers)
e) Acute gastrointestinal problems (such as diarrhoea, vomiting or abdominal pain)
AND
Elevated markers of inflammation such as ESR, C-reactive protein or procalcitonin
AND
No other obvious microbial cause of inflammation, including bacterial sepsis, staphylococcal or streptococcal shock syndromes
AND
Evidence of COVID (RT-PCR, antigen test or serology positive) or likely contact with patients with COVID

NB Consider this syndrome in children with features of typical or atypical Kawasaki disease or toxic shock syndrome.

MODULE 1. Complete this module for all children aged 0–19 suspected to have multisystem inflammatory disorder (even if all criteria in the case definition are not met – to capture the full spectrum of the condition). Start completing the module at the time the disorder is suspected.

Facility name_____Country_____

Date of patient assessment [D][D]/[M][M]/[2][0][Y][Y]
Date of admission to hospital [D][D]/[M][M]/[2][0][Y][Y]

1a. DEMOGRAPHICS *(complete when MIS is first suspected)*

Sex at birth ? Male ? Female ? Not specified. Date of birth [D][D]/[M][M]/[Y][Y][Y][Y]
If date of birth is unknown, record Age [___] years OR [__] months
Ethnicity (as reported by family) (please pre-specify main groups in the population and choose from the list) _____

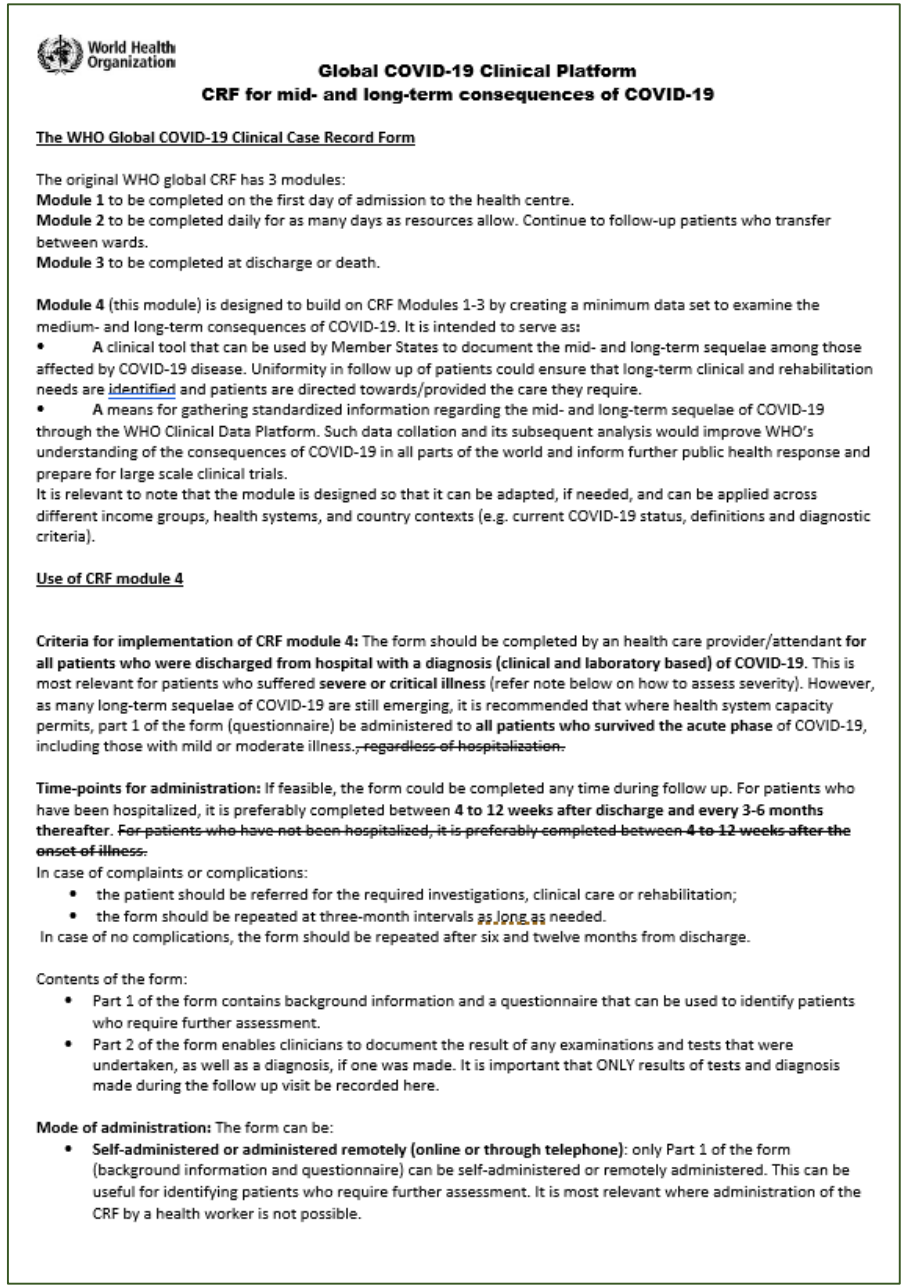
1b. DATE OF ONSET OF CURRENT ILLNESS AND VITAL SIGNS *(complete when MIS is first suspected)*

Date of onset of first symptom or sign [D][D]/[M][M]/[2][0][Y][Y]
Date of onset of fever [D][D]/[M][M]/[2][0][Y][Y]
Temperature [__.__]°C Heart rate [___]beats/min
Respiratory rate [___]breaths/min
BP [___]/[___](systolic) [___]/[___](diastolic) mmHg Dehydration ☐Severe ☐Some ☐None
Capillary refill time > 2 seconds ☐Yes ☐No ☐Unknown
Oxygen saturation [___]% on ☐Room air ☐Oxygen therapy ☐Unknown
Conscious state ☐Alert ☐Response to verbal stimuli ☐Response to painful stimuli ☐Unresponsive
Mid-upper arm circumference [__.__]mm Length / Height [___.___]cm Weight [__.__]kg

Follow up CRF

For patients discharged from the hospitals who completed the CORE CRF and are assessed in FU visits

CRF will be finalized soon



World Health Organization

Global COVID-19 Clinical Platform
CRF for mid- and long-term consequences of COVID-19

The WHO Global COVID-19 Clinical Case Record Form

The original WHO global CRF has 3 modules:
Module 1 to be completed on the first day of admission to the health centre.
Module 2 to be completed daily for as many days as resources allow. Continue to follow-up patients who transfer between wards.
Module 3 to be completed at discharge or death.

Module 4 (this module) is designed to build on CRF Modules 1-3 by creating a minimum data set to examine the medium- and long-term consequences of COVID-19. It is intended to serve as:

- A clinical tool that can be used by Member States to document the mid- and long-term sequelae among those affected by COVID-19 disease. Uniformity in follow up of patients could ensure that long-term clinical and rehabilitation needs are identified and patients are directed towards/provided the care they require.
- A means for gathering standardized information regarding the mid- and long-term sequelae of COVID-19 through the WHO Clinical Data Platform. Such data collation and its subsequent analysis would improve WHO's understanding of the consequences of COVID-19 in all parts of the world and inform further public health response and prepare for large scale clinical trials.

It is relevant to note that the module is designed so that it can be adapted, if needed, and can be applied across different income groups, health systems, and country contexts (e.g. current COVID-19 status, definitions and diagnostic criteria).

Use of CRF module 4

Criteria for implementation of CRF module 4: The form should be completed by an health care provider/attendant **for all patients who were discharged from hospital with a diagnosis (clinical and laboratory based) of COVID-19**. This is most relevant for patients who suffered **severe or critical illness** (refer note below on how to assess severity). However, as many long-term sequelae of COVID-19 are still emerging, it is recommended that where health system capacity permits, part 1 of the form (questionnaire) be administered to **all patients who survived the acute phase** of COVID-19, including those with mild or moderate illness.~~, regardless of hospitalization.~~

Time-points for administration: If feasible, the form could be completed any time during follow up. For patients who have been hospitalized, it is preferably completed between **4 to 12 weeks after discharge and every 3-6 months thereafter**. ~~For patients who have not been hospitalized, it is preferably completed between 4 to 12 weeks after the onset of illness.~~
In case of complaints or complications:

- the patient should be referred for the required investigations, clinical care or rehabilitation;
- the form should be repeated at three-month intervals as long as needed.

In case of no complications, the form should be repeated after six and twelve months from discharge.

Contents of the form:

- Part 1 of the form contains background information and a questionnaire that can be used to identify patients who require further assessment.
- Part 2 of the form enables clinicians to document the result of any examinations and tests that were undertaken, as well as a diagnosis, if one was made. It is important that ONLY results of tests and diagnosis made during the follow up visit be recorded here.

Mode of administration: The form can be:

- **Self-administered or administered remotely (online or through telephone)**: only Part 1 of the form (background information and questionnaire) can be self-administered or remotely administered. This can be useful for identifying patients who require further assessment. It is most relevant where administration of the CRF by a health worker is not possible.

CRF available in different languages

Core CRF

Arabic | Chinese | English | French | Russian | Spanish Portoguese

Pregnancy CRF

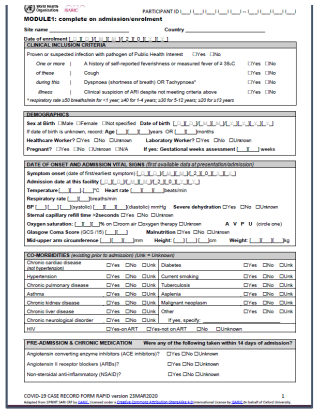
Arabic |Chinese | English | French | Russian | Spanish Portoguese

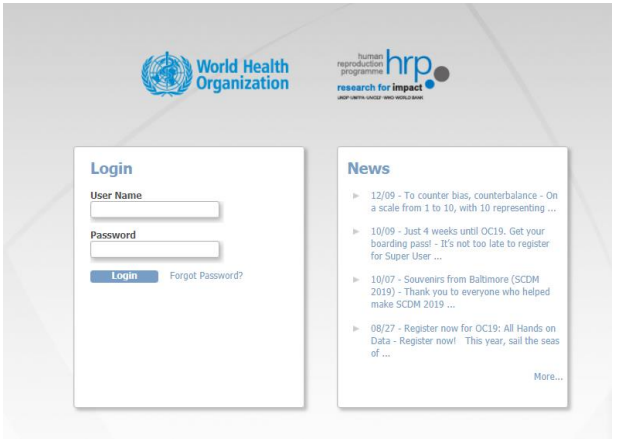
Multisystem inflammatory syndrome CRF

Arabic | Chinese | English | French | Russian | Spanish Portoguese

2 options for contributing data to WHO Platform

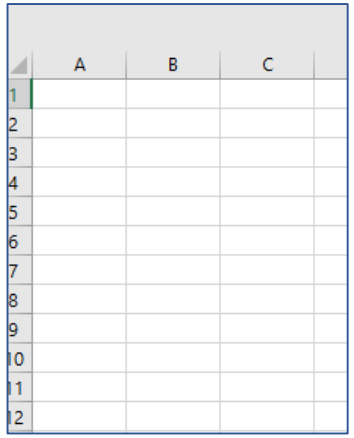
1) WHO CRF used to collect data (paper based or electronic)





Web-based System (Open Clinica)

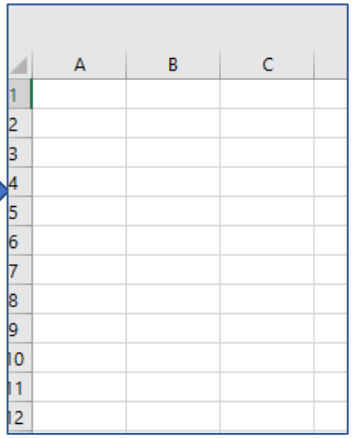
2) Data entered in local system

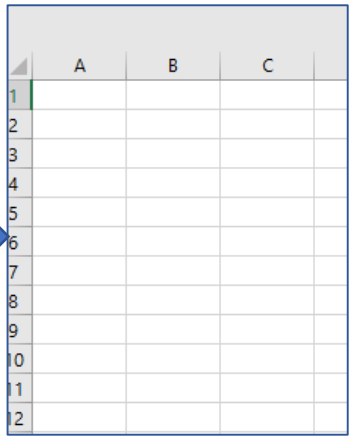


Variables aligned and transferred to WHO

WHO work with data contributors to transfer relevant variables from local databases to the WHO COVID-19 Clinical Data Platform

Pool Data





Data collection and data entry

Collection:

- **Paper-based** CRF or **web-based** CRF (Open Clinica); or
- through transfer from **local databases**

Data entry:

prospectively and

retrospectively through examination and review of medical records

World Health Organization

https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19/

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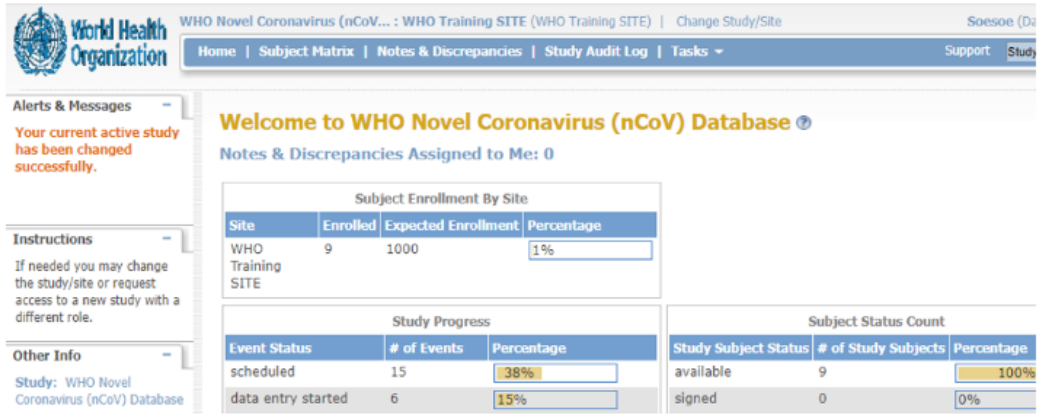
Global COVID-19 Clinical Data Platform for clinical characterization and management of hospitalized patients with suspected or confirmed COVID-19

COVID-19 Clinical Data Platform

The platform is a secure, limited-access, password-protected platform hosted on OpenClinica. WHO will use the anonymized COVID-19 data solely for the permitted purpose(s) for which it is provided to WHO, and will protect the confidentiality and security of the Anonymized Data, in each case, in accordance with the Terms of Use (LINK) applicable to the Global COVID-19 Clinical Data Platform.



Screenshot of the data portal

Clinical characterization case report form (CRF)

To harmonize data collection across diverse global settings, WHO has developed a standard CRF. This contains a minimum set of key variables and forms the basis of three types of CRFs:

1. **Core CRF:** to record data relating to hospitalized adults and children with suspected or confirmed infection with COVID-19.
2. **Pregnancy CRF:** to record additional key information relating to the subgroup of hospitalized pregnant women with suspected or confirmed infection with COVID-19.
3. **Multisystem inflammatory syndrome (MIS) in children and adolescents temporally related to COVID-19 CRF:** to record data relating to suspected cases with this syndrome.

Information Package

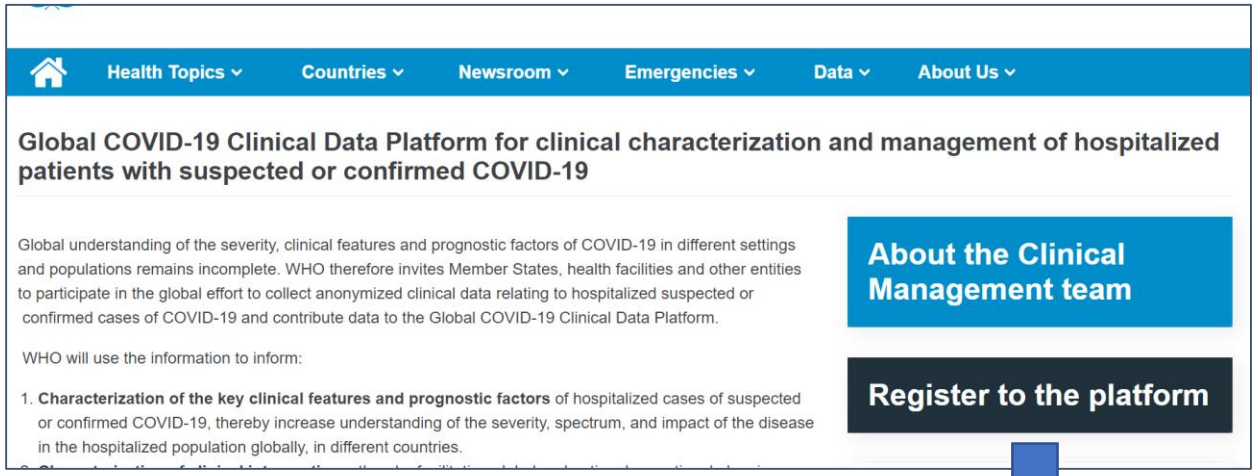
- Information sheet
- Updated CRFs: (i) rapid core CRF; (ii) pregnancy CRF (iii) MIS CRF
- Term of Use
- Instructions to complete CRF
- Instructions to upload clinical data to the Global Clinical Platform

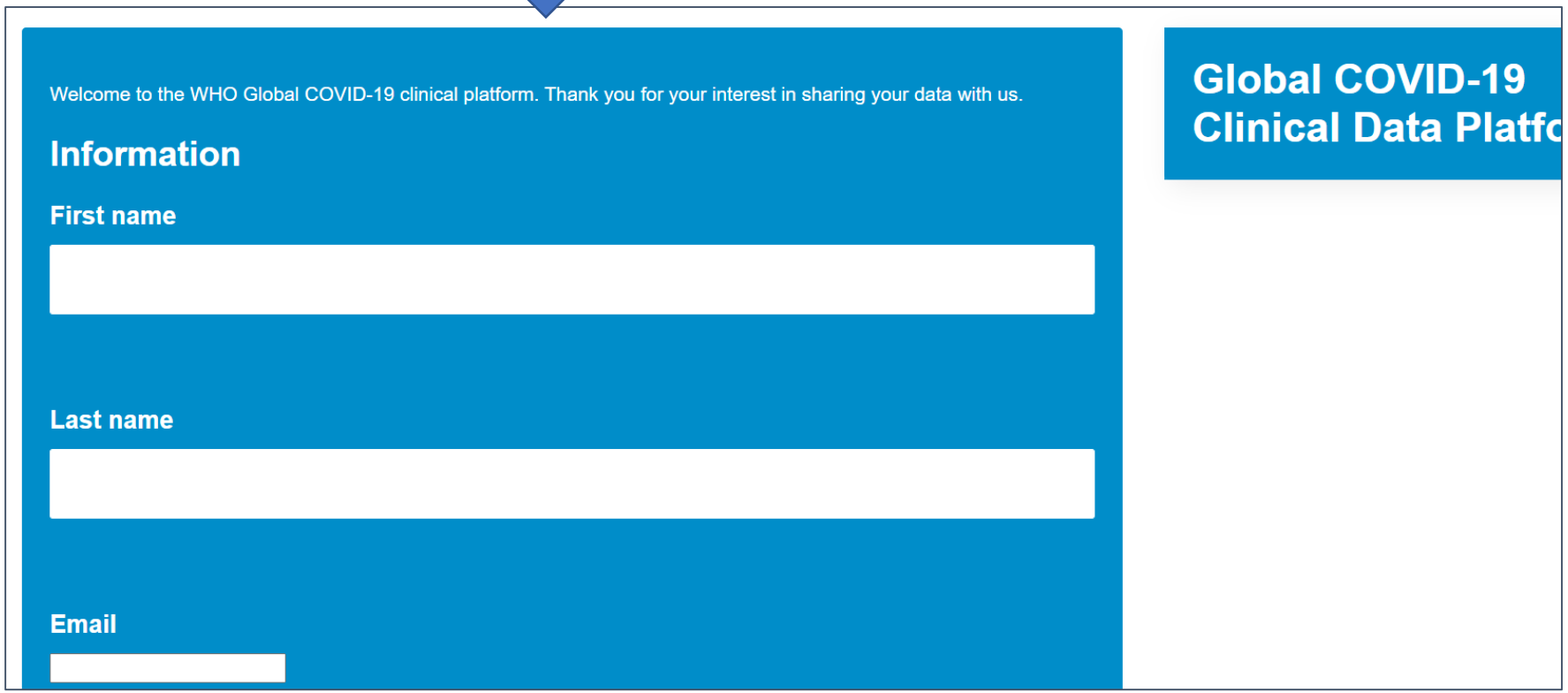
3 simple steps to contribute to the platform

1. Create your profile
2. Review Terms of Use
3. After 1-2 day, you'll receive an email with the log in credential to access the Global COVID-19 Clinical Data Platform or, in case you have an established database, other instructions to share data.

If you have any questions, please contact COVID_ClinPlatform@who.int.

Step 1. Create you profile Registration to the Platform





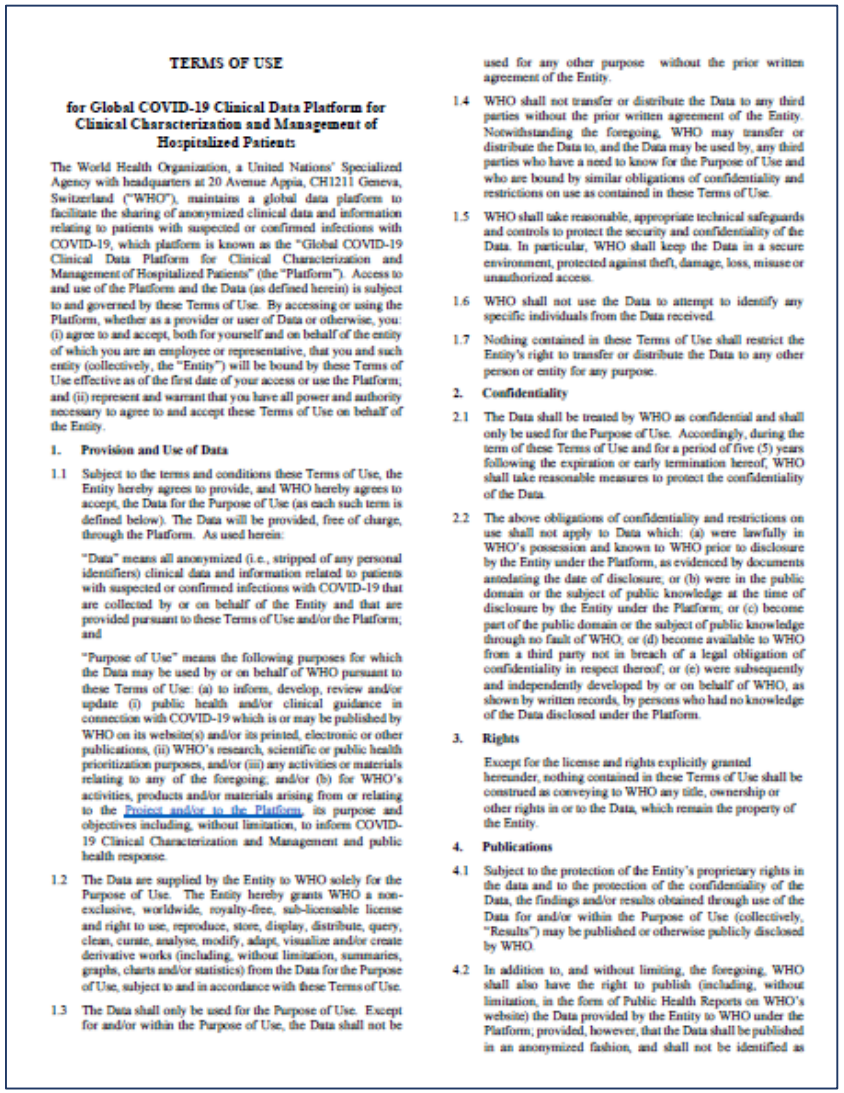
Step 2
Agree to the Terms of Use

Agree to the **Terms of Use (WHO standard DSA available upon request)**

Step 3

Receive **log-in credentials to access the Platform and start entering data**

Terms of Use



TERMS OF USE

for Global COVID-19 Clinical Data Platform for Clinical Characterization and Management of Hospitalized Patients

The World Health Organization, a United Nations' Specialized Agency with headquarters at 20 Avenue Appia, CH1211 Geneva, Switzerland ("WHO"), maintains a global data platform to facilitate the sharing of anonymized clinical data and information relating to patients with suspected or confirmed infections with COVID-19, which platform is known as the "Global COVID-19 Clinical Data Platform for Clinical Characterization and Management of Hospitalized Patients" (the "Platform"). Access to and use of the Platform and the Data (as defined herein) is subject to and governed by these Terms of Use. By accessing or using the Platform, whether as a provider or user of Data or otherwise, you: (i) agree to and accept, both for yourself and on behalf of the entity of which you are an employee or representative, that you and such entity (collectively, the "Entity") will be bound by these Terms of Use effective as of the first date of your access or use the Platform; and (ii) represent and warrant that you have all power and authority necessary to agree to and accept these Terms of Use on behalf of the Entity.

1. Provision and Use of Data

1.1 Subject to the terms and conditions these Terms of Use, the Entity hereby agrees to provide, and WHO hereby agrees to accept, the Data for the Purpose of Use (as each such term is defined below). The Data will be provided, free of charge, through the Platform. As used herein:

"Data" means all anonymized (i.e., stripped of any personal identifiers) clinical data and information related to patients with suspected or confirmed infections with COVID-19 that are collected by or on behalf of the Entity and that are provided pursuant to these Terms of Use and/or the Platform; and

"Purpose of Use" means the following purposes for which the Data may be used by or on behalf of WHO pursuant to these Terms of Use: (a) to inform, develop, review and/or update (i) public health and/or clinical guidance in connection with COVID-19 which is or may be published by WHO on its website(s) and/or its printed, electronic or other publications, (ii) WHO's research, scientific or public health prioritization purposes, and/or (iii) any activities or materials relating to any of the foregoing; and/or (b) for WHO's activities, products and/or materials arising from or relating to the Project and/or to the Platform, its purpose and objectives including, without limitation, to inform COVID-19 Clinical Characterization and Management and public health response.

1.2 The Data are supplied by the Entity to WHO solely for the Purpose of Use. The Entity hereby grants WHO a non-exclusive, worldwide, royalty-free, sub-licensable license and right to use, reproduce, store, display, distribute, query, clean, curate, analyse, modify, adapt, visualize and/or create derivative works (including, without limitation, summaries, graphs, charts and/or statistics) from the Data for the Purpose of Use, subject to and in accordance with these Terms of Use.

1.3 The Data shall only be used for the Purpose of Use. Except for and/or within the Purpose of Use, the Data shall not be used for any other purpose without the prior written agreement of the Entity.

1.4 WHO shall not transfer or distribute the Data to any third parties without the prior written agreement of the Entity. Notwithstanding the foregoing, WHO may transfer or distribute the Data to, and the Data may be used by, any third parties who have a need to know for the Purpose of Use and who are bound by similar obligations of confidentiality and restrictions on use as contained in these Terms of Use.

1.5 WHO shall take reasonable, appropriate technical safeguards and controls to protect the security and confidentiality of the Data. In particular, WHO shall keep the Data in a secure environment, protected against theft, damage, loss, misuse or unauthorized access.

1.6 WHO shall not use the Data to attempt to identify any specific individuals from the Data received.

1.7 Nothing contained in these Terms of Use shall restrict the Entity's right to transfer or distribute the Data to any other person or entity for any purpose.

2. Confidentiality

2.1 The Data shall be treated by WHO as confidential and shall only be used for the Purpose of Use. Accordingly, during the term of these Terms of Use and for a period of five (5) years following the expiration or early termination hereof, WHO shall take reasonable measures to protect the confidentiality of the Data.

2.2 The above obligations of confidentiality and restrictions on use shall not apply to Data which: (a) were lawfully in WHO's possession and known to WHO prior to disclosure by the Entity under the Platform, as evidenced by documents antedating the date of disclosure; or (b) were in the public domain or the subject of public knowledge at the time of disclosure by the Entity under the Platform; or (c) become part of the public domain or the subject of public knowledge through no fault of WHO; or (d) become available to WHO from a third party not in breach of a legal obligation of confidentiality in respect thereof; or (e) were subsequently and independently developed by or on behalf of WHO, as shown by written records, by persons who had no knowledge of the Data disclosed under the Platform.

3. Rights

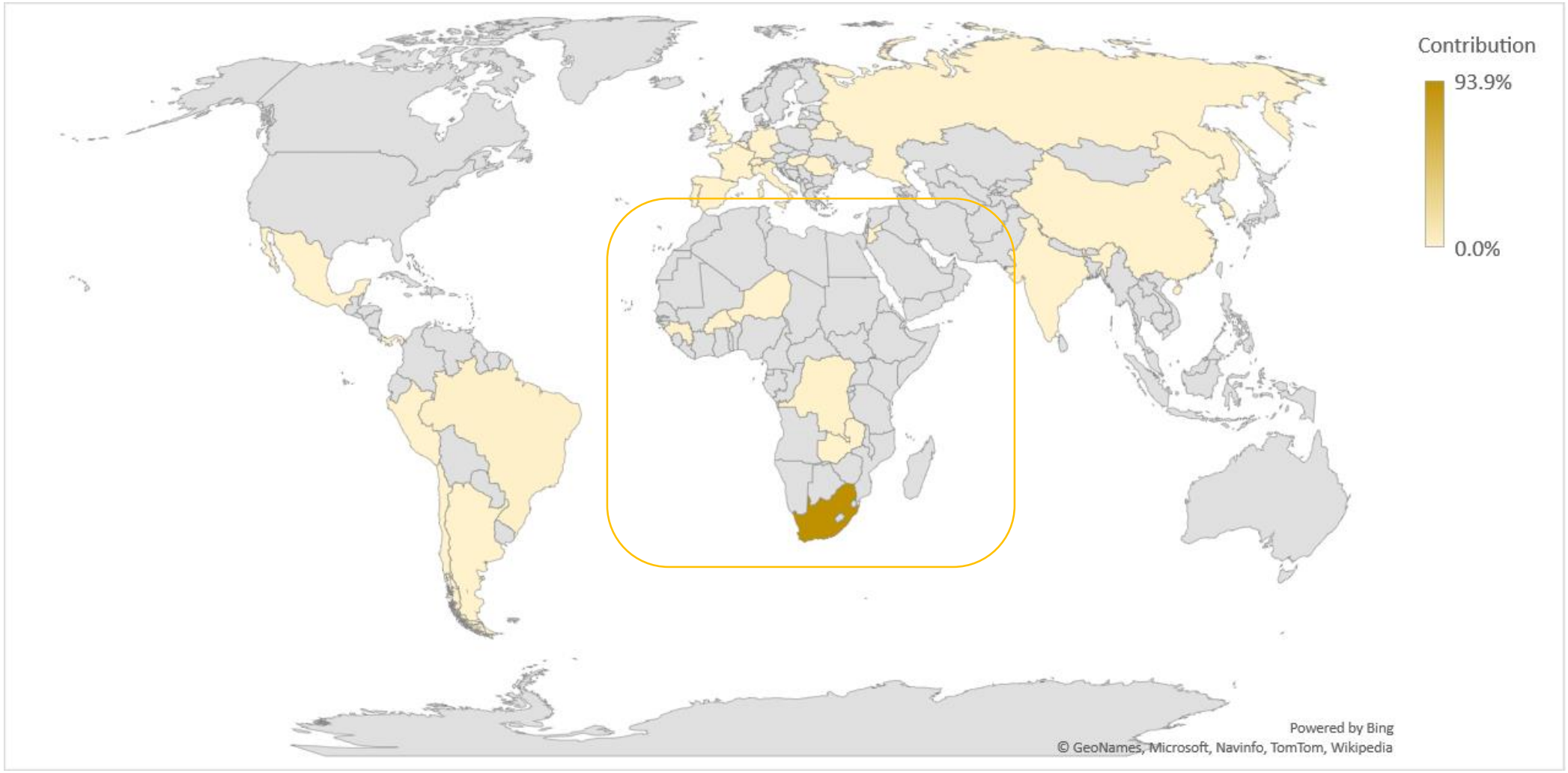
Except for the license and rights explicitly granted hereunder, nothing contained in these Terms of Use shall be construed as conveying to WHO any title, ownership or other rights in or to the Data, which remain the property of the Entity.

4. Publications

4.1 Subject to the protection of the Entity's proprietary rights in the data and to the protection of the confidentiality of the Data, the findings and/or results obtained through use of the Data for and/or within the Purpose of Use (collectively, "Results") may be published or otherwise publicly disclosed by WHO.

4.2 In addition to, and without limiting, the foregoing, WHO shall also have the right to publish (including, without limitation, in the form of Public Health Reports on WHO's website) the Data provided by the Entity to WHO under the Platform; provided, however, that the Data shall be published in an anonymized fashion, and shall not be identified as

Implementation:
sites in 59 countries have confirmed interest and data from 57 932 cases have been shared from 29 countries, as of Aug 2020



N.B. Data contributors are changing daily

Implementation:

As of August 2020, Sites in 29 countries have contributed clinical data

7	AFRO	55449	Zambia, DRC, South Africa, Guinea, Burkina Faso, Nigeria, Niger
2	EMRO	364	Jordan, Saudi Arabia
13	EURO	1323	Belgium, Germany, Hungary, Italy, Spain, Armenia, Romania, Belarus, France, Portugal, Russian Federation, Switzerland, United Kingdom
7	PAHO	600	Brazil, Mexico, USA, Panama, Trinidad and Tobago, Argentina, Chile
2	SEARO	68	Bangladesh, India
2	WPRO	128	China, Republic of Korea
29		**57932**	

Who is invited to countribute?

- MoH
- Health facilities
- Clinical/research networks

Why contributing?

1. Upon submission of data to WHO, contributors will have access to their dataset in an *analyzable format*
2. WHO will develop country report to support national response to COVID19
3. Large size of the population studied = more robust estimates
4. Enable comparing disease presentation and outcome in different subpopulations (e.g children, HIV infected pts) with general population hospitalized with COVID
5. Facility-level information will not be identifiable, meaning that data contributors will still be able to publish their data elsewhere
6. Entered data will not be visible/accessible to other data contributors using the platform

Questions?

COVID-19 Clinical Platform Webpage

https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19/

30 September 2020

Global COVID-19 Clinical Data Platform

Soe Soe Thwin, MS, PhD
Manager - Biostatistics and Data Management
Dept of Sexual and Reproductive Health and Research, WHO

World Health Organization

human reproduction programme hrp
research for impact
UNDP · UNFPA · UNICEF · WHO · THE WORLD BANK

WHO Data Management Team

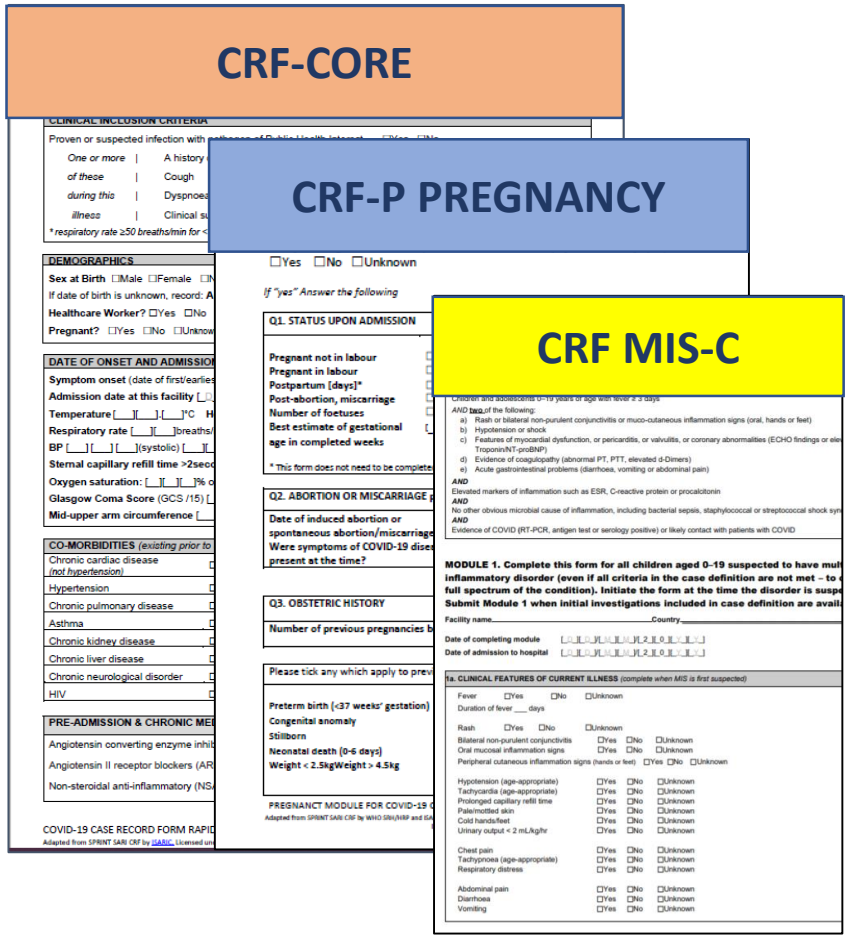
Soe Soe Thwin
Firdavs Kurbonov
Saidou Kouyate Mohamed
Ronaldo Silva

- -

Khurshed Nosirov
Sihem Landoulsi

Data platform
Data Curation
Data Analytics (EPI team)

Case Report Forms (CRFs)



Core CRF: hospitalized children and adults with COVID19

Pregnancy CRF: core CRF + specific sections/variables in hospitalized pregnant women

Multisystem inflammatory syndrome (MIS): Children and Adolescents

MODULE 1
Admission

- Clinical inclusion criteria
- Demographics
- Date of onset and admission vital signs
- Co-morbidities
- Medication
- Signs and symptoms on admission
- Supportive care received
- Lab results
- _____
- Pregnancy Status upon Admission

MODULE 2
Inpatient stay (Daily Follow Up)

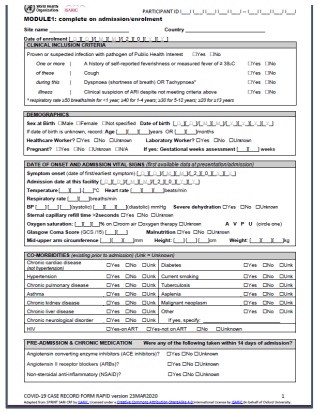
- Vital signs
- Daily clinical features
- Lab results
- Medication
- Supportive care received
- _____
- Fetal Heart Rate

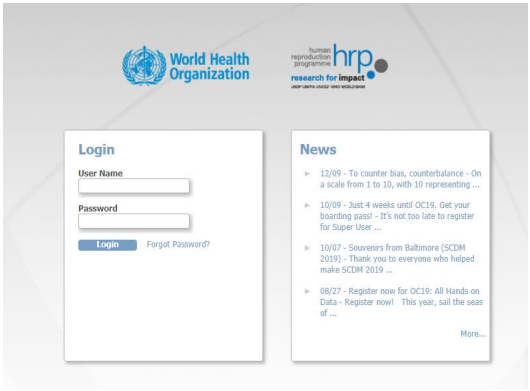
MODULE 3
Discharge or death (Outcome)

- Diagnostic/ pathogen testing
- Complications
- Medication
- Supportive care received
- Outcome
- _____
- Pregnancy Outcomes

2 options for contributing data to WHO Platform

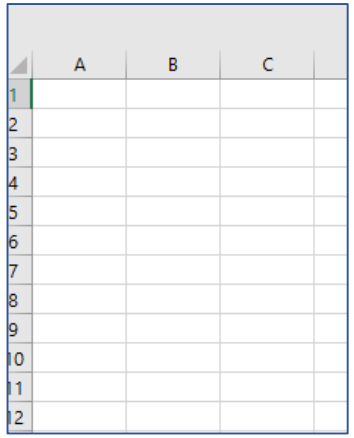
1) WHO CRF used to collect data (paper based or electronic)





Web-based System

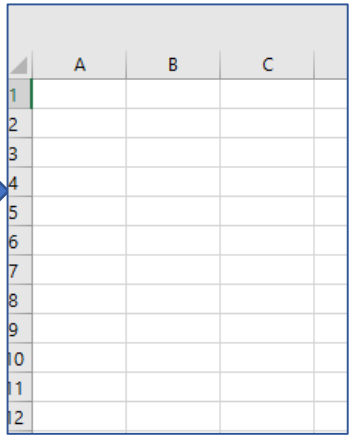
2) Data entered in local system

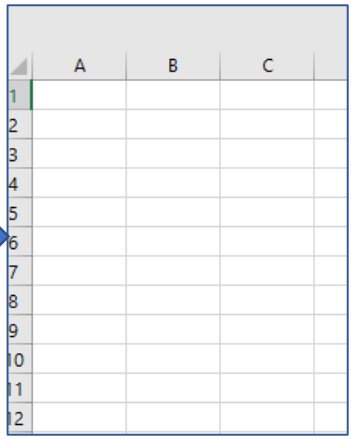


Variables aligned and transferred to WHO

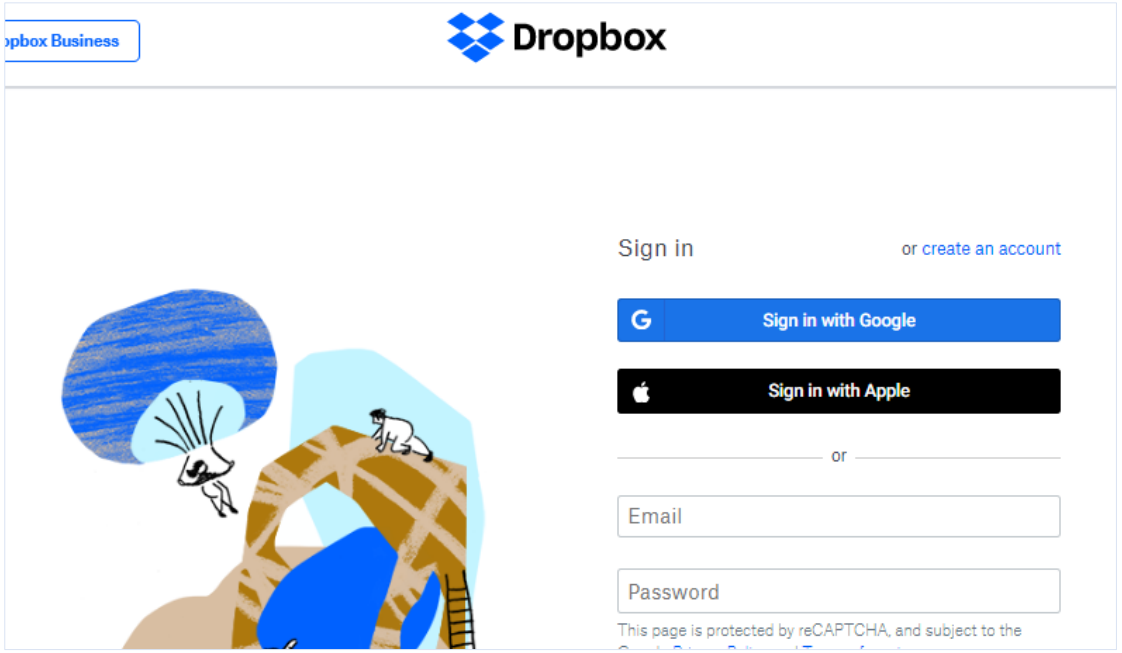
WHO work with data contributors to transfer relevant variables from local databases to the WHO COVID-19 Clinical Data Platform

Pool Data

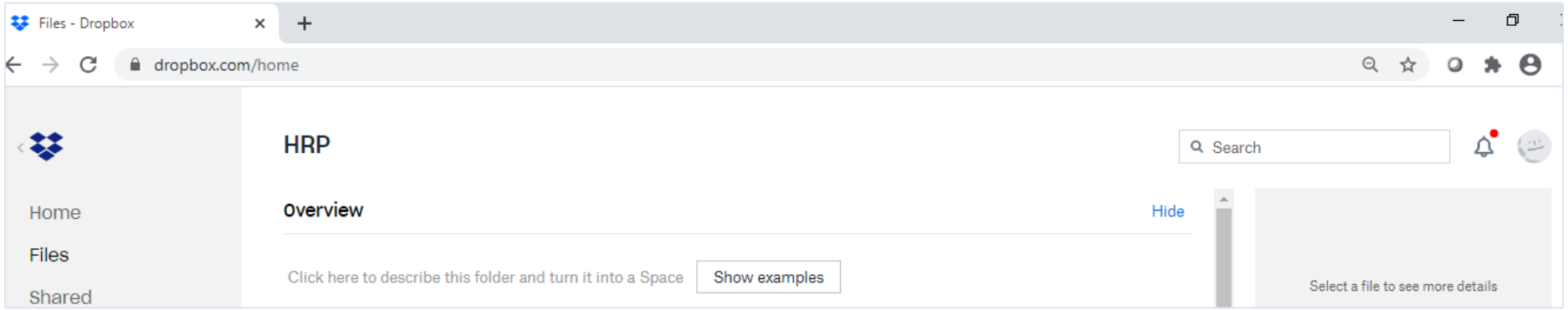




WHO/HRP DropBox



- Access Controlled
- Data Upload and Download



DATABASE-X VARIABLE NAME	DATA TYPE (if different)	RESPONSE OPTIONS (if different)	OC-DATABASE VARIABLES	Data Type	UNITS	DESCRIPTION	RESPONSE OPTIONS
			dispro	character string		Project ID:	text
			dissit	character string		Facility name:	text
			discou	character string		Country:	text
			diapar	character string		Participant ID:	text
			dis01	integer		Chest X-Ray /CT performed:	1 - Yes, 2 - No, 3 - Unknown
			dis01s	integer		If Yes , Infiltrates present:	1 - Yes, 2 - No, 3 - Unknown
			dis02	integer		Was pathogen testing done during this illnes	1 - Yes, 2 - No, 3 - Unknown
			dis03	integer		Influenza virus:	1 - Positive, 2 - Negative, 3 -
			dis03s	character string		If Positive, specify type:	text
			dis04	integer		Coronavirus:	1 - Positive, 2 - Negative, 3 -
			dis04s1	integer		If Positive, specify type:	1 - MERS-CoV, 2 - SARS-CoV-2
			dis04s2	character string		If Other , specify:	text
			dis05	integer		Other respiratory pathogen:	1 - Positive, 2 - Negative, 3 -
			dis05s	character string		If Positive, specify type:	text
			dis06	integer		Viral haemorrhagic fever:	1 - Positive, 2 - Negative, 3 -
			dis06s	character string		If Positive, specify virus:	text
			dis07	integer		Other pathogen of public health interest det	1 - Yes, 2 - No, 3 - Unknown
			dis07s	character string		If Yes, specify:	text
			dis08	integer		Falciparum malaria:	1 - Positive, 2 - Negative, 3 -

Electronic Data Capture (EDC) Platform

- EDC platform, web based
- Regulatory Compliant
- Access controlled
- System commands in English
- eCRFs interface in English, French, Spanish

https://who.eclinicalhosting.com/OpenClinica/pages/login/login

PLATFORM	__X__ COVID-MISC __X__ CORE/PREGNANCY
User Name	
Email	
Site Name	
City	
Country	
Additional Users	

Alerts & Messages

Your current active study has been changed successfully.

Instructions

If needed you may change the study/site or request access to a new study with a different role.

Other Info

Study: WHO Novel Coronavirus (nCoV) Database

Site: WHO Training SITE

Start Date: N/A

End Date: N/A

PI: SRH

Protocol Verification/IRB Approval Date:

Welcome to WHO Novel Coronavirus (nCoV) Database

Notes & Discrepancies Assigned to Me: 0

Subject Enrollment By Site

Site	Enrolled	Expected Enrollment	Percentage
WHO Training SITE	83	1000	8%

Study Progress

Event Status	# of Events	Percentage
scheduled	165	59%
data entry started	80	29%
completed	33	12%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

Subject Status Count

Study Subject Status	# of Study Subjects	Percentage
available	81	98%
signed	0	0%
removed	2	2%

Files - Dropbox | OpenClinica

who.eclinicalhosting.com/OpenClinica/ListStudySubjects

World Health Organization

WHO Novel Coronavirus (nCoV... : WHO Training SITE (WHO Training SITE) | Change Study/Site

Soesoe (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Support | Study Subject ID | Go

Alerts & Messages

Instructions

Info

Icon Key

Statuses

- Not Started
- Scheduled
- Data Entry Started
- Stopped
- Skipped
- Completed
- signed
- Locked
- Invalid

Actions

- View
- Edit
- Remove
- Restore
- Reassign

Subject Matrix for WHO Training SITE

15 | Show More | Select An Event | Add New Subject

Study Subject ID	1_ADMISSION	2_FOLLOWUP	3_OUTCOME	4_PR_ADMISSION	5_PR_FOLLOWUP	6_PR_OUTCOME	7_ADMISSION_FR	8_FOLLOWUP_FR	9_OUTCOME_FR	10_ADMISS
0000000000		x2								
000000001										
0000222										
000032								x4		
00006										
000072										
0001										
00015										
0002										
001993										
0033										
00921										
00972								x2		
01010-01012								x10		

7:58 PM 9/29/2020

Data Curation

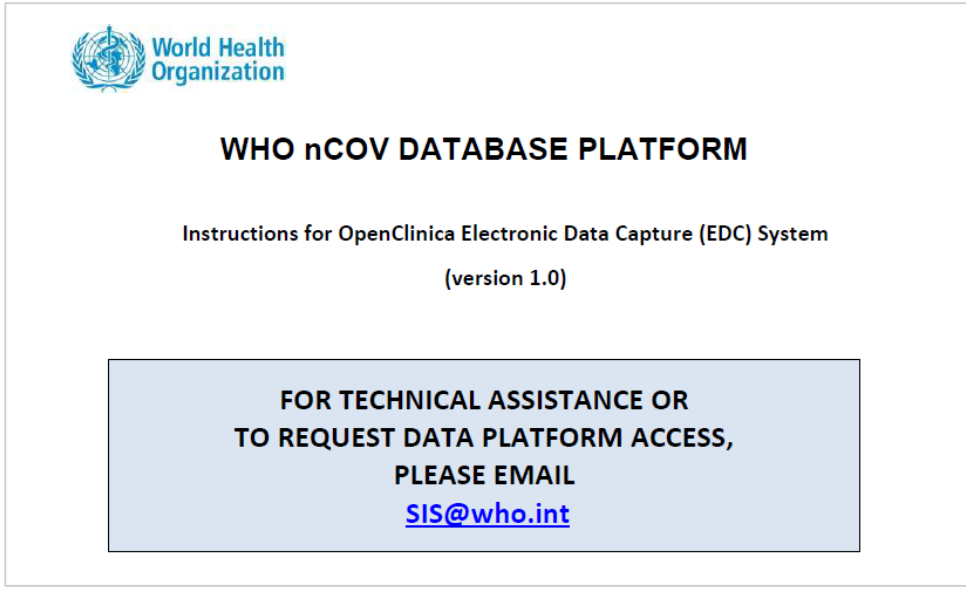
- Identify missing key variables (Admission date, Age/DOB)
- Identify outliers (lab values)
- Identify logic discrepancies (parent/child questions, xtabulation)

Data Aggregation and Analysis

- Algorithms developed in SAS and R for data aggregation and visualization (Global and Country Report)
- Statistical Analysis Plan

Training & Technical Support

- Instruction Manual for Data Platform
- Instruction Manual for Data Extraction
- Training Video
- End-User training via Zoom / Q&A via phone or email

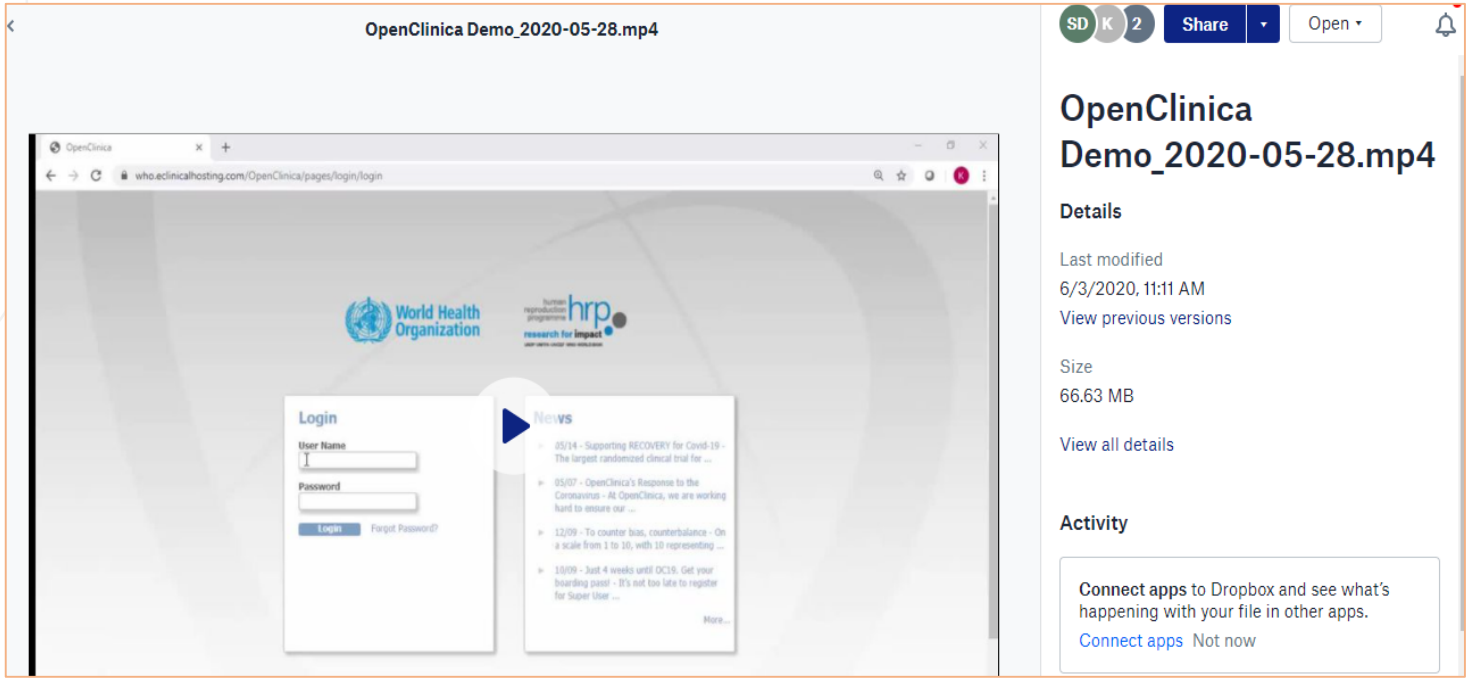

World Health Organization

WHO nCOV DATABASE PLATFORM

Instructions for OpenClinica Electronic Data Capture (EDC) System

(version 1.0)

FOR TECHNICAL ASSISTANCE OR
TO REQUEST DATA PLATFORM ACCESS,
PLEASE EMAIL
SIS@who.int



WHO Website Link:

https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19/data-platform

OpenClinica Logon Link:

https://who.eclinicalhosting.com/OpenClinica/pages/login/login

Thank you.