

Information Sheet

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

The World Health Organization (WHO) invites Member States, health facilities and other entities to contribute to WHO surveillance of clinical data of hospitalized cases of COVID-19 in order to improve global understanding of the clinical presentation of this disease.

The analysis of standardized and anonymized clinical data from across the globe is essential to the development of evidence-based guidelines on clinical management of COVID-19 and to support public health responses.

WHO had developed a Global COVID-19 Clinical Data Platform for the collection of COVID-19 clinical data which will inform:

- 1. Characterization of the key clinical features of hospitalized cases of suspected or confirmed COVID-19**, to increase understanding of the severity, spectrum, and impact of the disease in the hospitalized population globally, in different countries;
- 2. Characterization of clinical interventions**, to assist WHO with operational planning during the COVID-19 pandemic.

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

COVID-19 data collection is a surveillance activity of public health importance. The web-based electronic [WHO COVID-19 Clinical Data Platform](#) enables rapid and systematic collection of anonymized clinical data, and facilitate aggregation, tabulation and data analysis across different settings and sub-populations globally.

Hosted on OpenClinica, the WHO platform is a secure, limited-access, password-protected platform. WHO will:

- protect the confidentiality and prevent unauthorized disclosure of submitted data; and
- implement and maintain appropriate technical and organizational security measures to protect data stored on the WHO platform.

Note: Upon submission of their data to WHO, contributors will have access to their dataset in an analysable format.

Entities wishing to contribute anonymized (i.e., stripped of all personal identifiers) COVID-19 clinical data to the WHO COVID-19 Platform should email COVID_ClinPlatform@who.int. Provided they agree to the Terms of Use, they will receive log-in credentials. Data contributors are respectfully requested to ensure that they obtain any consent or approval needed before collecting and contributing any data to the platform, and that they take all necessary measures to protect their platform log-in credentials

and passwords. Data contributors will not have access to data from other facilities. The process for data sharing is further described in **Annex A**.

Data can be recorded directly into the electronic [WHO COVID-19 Clinical Data Platform](#), or into the local database of a facility or network, or on printed paper CRFs, with data entered into WHO Platform thereafter.

What if clinical data of hospitalized patients with COVID19 have been already collected using local databases? If clinical data have already been entered in local databases, the relevant datasets can be aligned and pooled with the WHO global dataset. WHO can work with data contributors from individual entities to transfer relevant variables from individual patients (i.e. not in aggregated fashion) from local databases to the WHO COVID-19 Clinical Data Platform.

Clinical characterization case report form

To facilitate standardization of collection and analysis of anonymized data, WHO has developed a standard **clinical characterization case report form (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 the general population of hospitalized patients 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.

The core and core/pregnancy CRFs each have three modules:

- Module 1: to be completed on the first day of admission to the health centre.
- Module 2: to be completed daily during the follow-up period of the stay in the health centre, for as many days as resources allow.
- Module 3: to be completed at discharge or death.

The CRF for multisystem inflammatory syndrome has two modules (admission and outcomes).

The CRFs should be completed and updated throughout the stay in the health centre – including if the patient is transferred from one ward to another, i.e. from the date of admission to the hospital, until the date of death or discharge from the hospital, or transfer to another hospital.

Data may be collected prospectively or retrospectively through examination and review of medical records. To ensure the high value of information generated by the WHO Global Platform, it is critical that contributors ensure the completeness and quality of reported data .

Clinical Advisory Group

WHO has established an independent Clinical Advisory Group (CAG) who meets regularly to advise WHO on global reporting and analysis of anonymized COVID-19 data.

Statistical analysis plan

- Data will be pooled and presented as aggregated global figures. Pending data availability, subnational, national or larger regional statistics may be reported.
- Descriptive analysis will be performed on clinical characteristics at hospital admission, during hospitalization, and on interventions and clinical outcomes (mortality, length of stay) at discharge.
- Analysis by subpopulations will be performed where possible (e.g. children, pregnant women, populations with co-infection).
- Other analysis will be guided by the CAG and data contributors.

Reporting and publication

WHO will analyse the data regularly and share a summary report with all contributors. The report will subsequently be made publicly available on the WHO website.

Where possible and appropriate, data will be reported in an aggregated fashion with other data provided to WHO by third parties. As such, facility-level information will not be identifiable, meaning that data contributors will still be able to publish their data elsewhere. Indeed, while publication in a peer-reviewed scientific journal is not the primary purpose of WHO repository, data contributors are encouraged to analyse and publish results from their own datasets.

Data contributors of COVID-19 will be acknowledged in the reports, as appropriate.

To contribute anonymized COVID-19 Data to Global COVID-19 Clinical Data Platform, there are 4 simple steps to follow:

STEP 1. Go to the webpage for more information: <https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19/data-platform>

STEP 2. CREATE YOUR PROFILE

STEP 2. REVIEW TERM OF USE

STEP 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 WHO at: COVID_ClinPlatform@who.int

Annex A – Data sharing with WHO

In response to COVID-19, the World Health Organization has launched a Global COVID-19 Anonymized Clinical Data Platform (the “COVID-19 Data Platform”) to enable State Parties to the International Health Regulations (IHR) (2005) and other entities to share with WHO anonymized clinical data and information relating to patients suspected or confirmed to have COVID-19 (collectively, the “Anonymized COVID-19 Data”).

State Parties to the IHR are invited to contribute Anonymized COVID-19 Data collected by such State Parties (including, without limitation, by their ministries of health or public health agencies or institutions) through the WHO COVID-19 Clinical Data Platform, pursuant to and in line with the requirements of the IHR (2005).

Other entities (such as healthcare facilities, universities, research networks) are invited to contribute their anonymized COVID-19 data to the WHO COVID-19 Clinical Data Platform subject to and in accordance with the Terms of Use .

The Anonymized COVID-19 data received from State Parties to the IHR and/or entities through the COVID-19 Data Platform will remain property of the contributing State Party or entity, as applicable, and will be used by WHO to inform appropriate public health response and the development of clinical guidance concerning COVID-19.

State Parties to the IHR and/or other entities wishing to contribute Anonymized COVID-19 Data to the WHO COVID-19 Platform should email COVID_ClinPlatform@who.int to view the Terms of Use and obtain log-in credentials for the COVID-19 Platform.

In accordance with Article 11(4) of the IHR (2005), WHO will not make the individual dataset of Anonymized COVID-19 Data generally available to other State Parties or third parties until such time as any of the conditions set forth in paragraph 2 of such Article 11 are first met and following consultation with the affected countries.

Pursuant to that same Article 11, WHO will not make Anonymized COVID-19 data available to the public, unless and until Anonymized COVID-19 data has already been made available to State Parties, and provided that other information about the COVID-19 epidemic has already become publicly available and there is a need for the dissemination of authoritative and independent information.