

Information sheet

Global COVID-19 Clinical Data Platform for clinical characterization and management of patients hospitalized 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 from persons hospitalized with 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 for public health responses.

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

- characterization of the key clinical features of patients hospitalized with suspected or confirmed COVID-19, to increase understanding of the severity, spectrum and impact of the disease in the hospitalized population in various countries throughout the world;
- **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 patients hospitalized with suspected or confirmed COVID-19

COVID-19 data collection is a surveillance activity of public health importance. The web-based electronic www.web-based electronic wwww.web-based</a

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

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

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

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

Data can be recorded directly on the electronic <u>COVID-19 Data Platform</u>, or in the local database of a facility or network, or printed on paper case report forms (CRFs), with the data being entered on the WHO platform afterwards.

What if clinical data from patients hospitalized 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 form) from local databases to the COVID-19 Data Platform.

Clinical characterization case report form

To facilitate standardization of collection and analysis of anonymized data, WHO has developed a standard **clinical characterization CRF.** This contains a minimum set of key variables and forms the basis of three types of CRF:

- **1. core CRF**: to record data relating to the general population of patients hospitalized 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** in children and adolescents, temporally related to the 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 stay in the health centre, for as many days as resources allow;
- module 3: to be completed at discharge or on 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 points where 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 the examination and review of medical records. To ensure the high value of information generated by the WHO platform, it is critical that contributors ensure that reported data are complete and of high quality.



Clinical Advisory Group

WHO has established an independent Clinical Advisory Group (CAG), which 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. Depending on data availability, subnational, national or broader regional statistics may be reported.
- Descriptive analysis will be performed on clinical characteristics at the point of hospital admission and 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 coinfection).
- 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 supplied 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 the WHO repository, data contributors are encouraged to analyse and publish results from their own datasets.

Contributors of COVID-19 data will be acknowledged in the reports, as appropriate.

To contribute anonymized COVID-19 data to the WHO Global COVID-19 Clinical Data Platform, follow these three simple steps:

STEP 1. CREATE YOUR PROFILE by clicking on the following web link: https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19/data-platform/form.

STEP 2. REVIEW TERMS OF USE and submit the form.

STEP 3. After 1–2 days, you will receive an email with login credentials for accessing the COVID-19 Data Platform or, if you have an established database, other instructions for sharing data.

For more information on the COVID-19 Data Platform, visit the webpage

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

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 the WHO Global COVID-19 Clinical Data Platform (the "COVID-19 Data Platform") to enable States 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 referred to as "anonymized COVID-19 data").

States Parties to IHR (2005) are invited to contribute anonymized COVID-19 data (including, but not limited to, data collected by their ministries of health or public health agencies or institutions) through the COVID-19 Data Platform, pursuant to and in line with the requirements of IHR (2005).

Other entities (e.g. health-care facilities, universities, research networks) are invited to contribute their anonymized COVID-19 data to the COVID-19 Data Platform, subject to and in accordance with the Terms of Use.

The anonymized COVID-19 data received from States Parties to IHR (2005) and/or other 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 an appropriate public health response and the development of clinical guidance concerning COVID-19.

States Parties to IHR (2005) and/or other entities wishing to contribute anonymized COVID-19 data to the COVID-19 Data Platform should email covid_clinplatform@who.int to view the Terms of Use and obtain login credentials for the platform.

In accordance with Article 11(4) of IHR (2005), WHO will not make the individual dataset of anonymized COVID-19 data generally available to other States Parties or third parties, until such time as any of the conditions set forth in Article 11(2) are 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 have been made available to States 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.