



Information Sheet Global Clinical Platform for COVID-19 for clinical characterization and management of 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 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 has developed a Global Clinical 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.

COVID-19 data collection is a surveillance activity of public health importance. The web-based electronic <u>WHO COVID-19 Clinical Platform</u> enables rapid and systematic collection of anonymized clinical data, and facilitate aggregation, tabulation and data analysis across different settings and subpopulations globally.

Hosted on REDcap, 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 <u>WHO Clinical Platform for COVID-19</u>, 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 patients with COVID-19 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 Clinical Platform for COVID-19.

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 four types of CRF:

- Core CRF: to record data relating to the general population of hospitalized patients with suspected or confirmed infection with COVID-19. The Core CRF also includes a pregnancy module record additional key information of hospitalized pregnant women with suspected or confirmed infection with COVID-19.
- **2. Multisystem inflammatory syndrome (MIS) CRF:** to record data relating to suspected cases of COVID-19 among children and adolescents with MIS.
- **3. Post COVID-19 Condition CRF:** to record data to assess the medium- and long-term sequelae of COVID-19 after an acute episode of COVID-19

The CORE and MIS-C 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. The Post COVID-19 Condition CRF should preferably be completed 4 to 8 weeks after hospital discharge from the acute ward or after acute illness due to COVID-19, and every 6 months thereafter

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 Clinical 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 Clinical Platform for COVID-19, there are 3 simple steps to follow:

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

STEP 2. REVIEW TERM OF USE and submit the form

STEP 3. After 1-2 days, you'll receive an email with log-in credentials for accessing the Global Clinical Platform for COVID-19 or, if you have an established database, other instructions for sharing data.

For more information on the Global Clinical Platform for COVID-19, 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 a Global Clinical Platform for COVID-19 (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.