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
Step 1. Go to https://who.eclinicalhosting.com/OpenClinica/pages/login/login

Step 2. Log in with Username and Password.
Step 3. Welcome Dashboard, change study/site if you are entering data to more than one site.

Follow these steps:

Click here to change study if entering data for more than one site.
Step 4. Change password and set security question (mandatory at first login).

1. Click on menu item "Tasks" - "Update profile", OR on your name in top right corner:

2. "Change User Profile" page will open.

3. Check and/or fill in the following items:
   - “Email”: should be your valid email address
   - “Password Challenge Question and Answer”: You can use it to reset your own password.
   - “Old password”: password you used to log into the system.
   - “New password”: A password of your choice, something you can easily remember. The new password should be at least 8 characters long, with one capital letter, one number and one special character (!@#$%^&).
   - “Confirm new password”: Retype the new password.

4. Click the button "Confirm Profile Changes".
   From now on use the new password for logging into the system. Keep it in a safe place and do not share it with anyone else.
Step 5. From Welcome Dashboard, click on Subject Matrix option to start the data entry process.
Step 6. On Subject Matrix, Click on Add New Subject to create a new record or click on icon to view/enter data for an existing pt.

Click here to start new patient

Existing pts

Click on icon to view/enter data
Step 7. To add new subject, complete and press Add.

Press to Add new subject

Participant ID

Date pt enrolled in study, on Case Report Form

CRFs to enter: 1_ADMISSION

Date pt is added to OpenClinica, Default to today’s date
Step 8. On Subject-specific Dashboard Click on Event (Occurrence Number) to sort. Click on icon shown to enter data for Subject.

<table>
<thead>
<tr>
<th>Event (Occurrence Number)</th>
<th>Start Date</th>
<th>Location</th>
<th>Status</th>
<th>Actions</th>
<th>CRF's (Name, Version, Status, Updated, Actions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1_ADMISSION</td>
<td>06-Apr-2020</td>
<td></td>
<td>scheduled</td>
<td></td>
<td>COVAD3 V1.1</td>
</tr>
<tr>
<td>2_FOLLOWUP (1)</td>
<td>07-Apr-2020</td>
<td></td>
<td>scheduled</td>
<td>X</td>
<td>k_COVFUP2 V1.1</td>
</tr>
<tr>
<td>3_OUTCOME</td>
<td>07-Apr-2020</td>
<td></td>
<td>scheduled</td>
<td>X</td>
<td>COVID3 V1.1</td>
</tr>
</tbody>
</table>

Click here to enter data
Step 9. Enter Data.

Scroll for more

90009

Need to be same

Press Save to move to next tab (can save and come back later)

World Health Organization

COAD1 V0.4

CRF Header Info

IDENTIF...(0/5) INCLUSE...(0/5) DEMOGR...(0/3)

Select to Jump –

WORLD HEALTH ORGANIZATION GLOBAL COVID-19 CLINICAL PLATFORM

NOVEL CORONAVIRUS (COVID-19) - RAPID VERSION Data Tool - ADMISSION FORM version 23MAR2020

Project ID: WHO_nCoV

IDENTIFICATION

Site name:

Country:

Participant ID:

Date of enrolment:

Save Exit

Return to top

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Step 10. When data entry is complete, check box to mark complete and press save to submit data.

Check here and press Save when complete. That will submit the form.
Step 11. Entering Data into a Repeated MODULE 2: FOLLOW UP Form.

Case when you have one or no occurrence.

Click on Add Another Occurrence to add another occurrence

Case when you have more than one occurrence.

Click on Add Another Occurrence to add another occurrence

Click on any occurrence to enter or view data for that occurrence.
Step 12. When data entry is done, go back to Subject Matrix and select to view subject or to log out.

- Green if completed
- Yellow if saved but not completed yet
- Click on icon to view subject
- Log out to exit
Step 13. If participant is pregnant or delivered within 21 days from onset of symptoms, complete the Pregnancy Module.

Go to Subject Matrix and schedule Pregnancy Admission (4_PR_ADMISSION) form.
Step 14. Press Proceed to Enter Data button to schedule Pregnancy Module Admission form.

By default, Study Event is 4_PR_ADMISSION. Do not change it.
Step 15. Click on icon to start data entry.
Step 16. Enter Data.

Click on the Save button to save data and you will be directed to the next section automatically.

Need to be the same.
Step 17. Mark the form complete.

Check here and press Save when complete. That will submit the form.

Red icon signals data have been modified but not saved yet.
Step 18. Schedule Follow up module.

Check on scheduled label to open study event overview (Follow up form). The remaining steps are similar starting from Step 14.

Check on scheduled label to open study event overview (Outcome form). The remaining steps are similar starting from Step 14.
Step 19. Enter Data into PREGNANCY Follow Up form, press Save, or press Mark Complete and Save, and go back to Subject Matrix.
Step 20. Enter Data into PREGNANCY Outcome form, press Save, or press Mark Complete and Save, and go back to Subject Matrix.

END.