

WHO nCOV DATABASE PLATFORM

**Instructions for OpenClinica Electronic Data Capture (EDC) System
(version 1.1)**

**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.



The screenshot shows the login page for the WHO OpenClinica system. At the top, there are logos for the World Health Organization and the Human Reproduction Programme (hrp). The main content area is divided into two sections: 'Login' and 'News'.

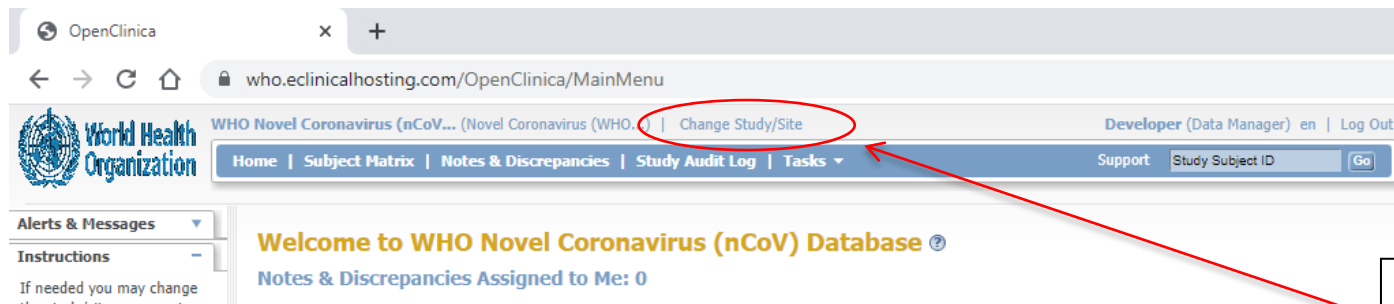
Login Section:

- Header: **Login**
- Form fields: **User Name** and **Password**, each with a corresponding input box.
- Buttons: A blue **Login** button and a **Forgot Password?** link.

News Section:

- Header: **News**
- List of news items:
 - 12/09 - To counter bias, counterbalance - On a scale from 1 to 10, with 10 representing ...
 - 10/09 - Just 4 weeks until OC19. Get your boarding pass! - It's not too late to register for Super User ...
 - 10/07 - Souvenirs from Baltimore (SCDM 2019) - Thank you to everyone who helped make SCDM 2019 ...
 - 08/27 - Register now for OC19: All Hands on Data - Register now! This year, sail the seas of ...
- Link: [More...](#)

Step 3. Welcome Dashboard, change study/site if you are entering data to more than one site.



OpenClinica x +

who.eclinicalhosting.com/OpenClinica/MainMenu

WHO Novel Coronavirus (nCoV... (Novel Coronavirus (WHO. | **Change Study/Site** Developer (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks ▾ Support Study Subject ID Go

Alerts & Messages ▾

Instructions -

If needed you may change the study/site assignment

Welcome to WHO Novel Coronavirus (nCoV) Database ⓘ

Notes & Discrepancies Assigned to Me: 0

Click here to
change study if
entering data
for more than
one site

Follow these steps:

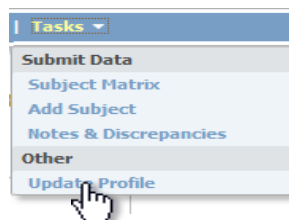
<input checked="" type="radio"/>	WHO Novel Coronavirus (nCoV) Database (Data Manager)
<input type="radio"/>	▶ ITALY SITE (Data Manager)
<input type="radio"/>	▶ WHO SITE (Data Manager)

<input type="button" value="Change Study"/> <input type="button" value="Cancel"/>

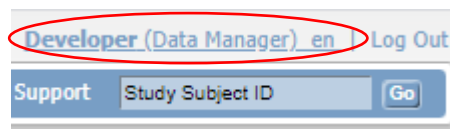
<p>Confirm Changing Study</p> <p>You are choosing to switch to the study: ITALY SITE with a role of Data Manager. The study/site status is available</p> <p><input type="button" value="Confirm"/></p>

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:



OR



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**.

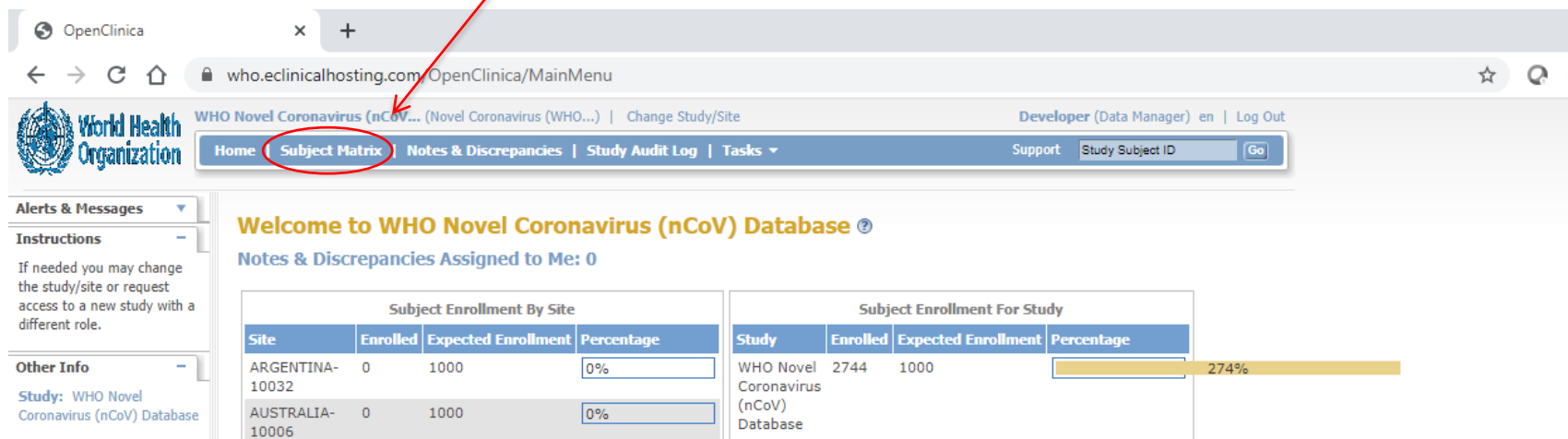


A screenshot of the 'Change User Profile' form. The form is titled 'Change User Profile' and includes a note: 'OpenClinica is currently being displayed in the English language.' Below this, a note states: '* indicates required field.' The form contains several input fields, each with a red asterisk indicating it is required:

- First Name: Sham Bant
- Last Name: Landoulsi
- Email: landoulsi@who.int
- Institutional Affiliation: WHO/RHS/SIS
- Default Active Study: AG - The gentle Assisted Pushing (GAP) study
- Password Challenge Question: City of Birth
- Password Challenge Answer: Maalen
- Old Password: (empty)
- New Password: (empty)
- Confirm New Password: (empty)
- Phone: +41227914542

At the bottom of the form, there are two buttons: 'Confirm Profile Changes' and 'Cancel'.

Step 5. From Welcome Dashboard, click on Subject Matrix option to start the data entry process.



OpenClinica

who.eclinicalhosting.com OpenClinica/MainMenu

WHO Novel Coronavirus (nCoV) Database | Change Study/Site

Developer (Data Manager) en | Log Out

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

Support Study Subject ID Go

Alerts & Messages

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

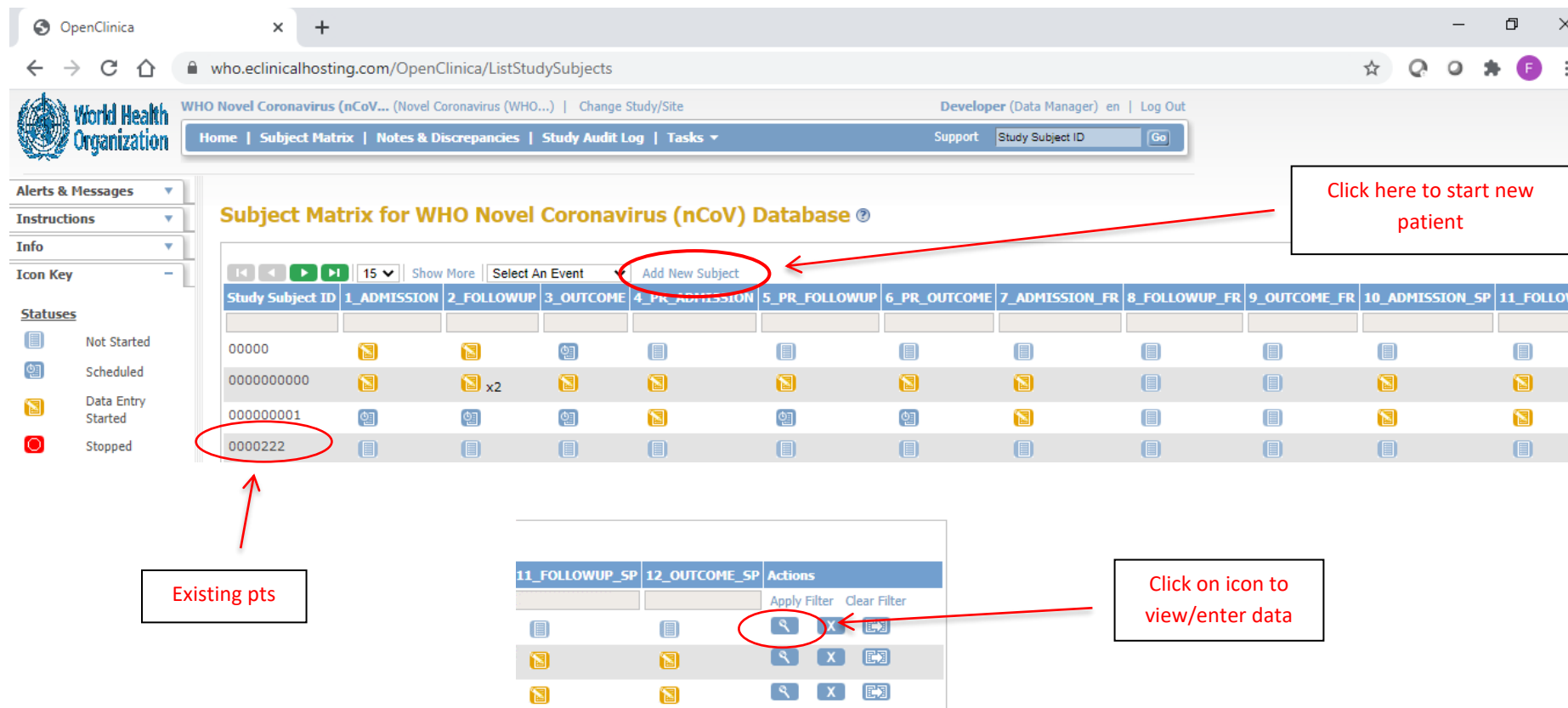
Welcome to WHO Novel Coronavirus (nCoV) Database

Notes & Discrepancies Assigned to Me: 0

Subject Enrollment By Site			
Site	Enrolled	Expected Enrollment	Percentage
ARGENTINA-10032	0	1000	0%
AUSTRALIA-10006	0	1000	0%

Subject Enrollment For Study			
Study	Enrolled	Expected Enrollment	Percentage
WHO Novel Coronavirus (nCoV) Database	2744	1000	274%

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.



WHO Novel Coronavirus (nCoV) Database

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

Developer (Data Manager) en | Log Out

Support Study Subject ID Go

Subject Matrix for WHO Novel Coronavirus (nCoV) Database

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_ADMISSION_SP	11_FOLLOWUP_SP	12_OUTCOME_SP	Actions
00000	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]
0000000000	[icon]	[icon] x2	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]
000000001	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]
0000222	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]	[icon]

Existing pts

Click on icon to view/enter data

Click here to start new patient

Step 7. To add new subject, complete and press Add.

Add New Subject

Study Subject ID: 9999-0001 *

Enrollment Date: 30-Sep-2020 *

Sex: -Select- ▼

Study Event: 1_ADMISSION *

Start Date: 30-Sep-2020 *

Add

Cancel

Participant ID

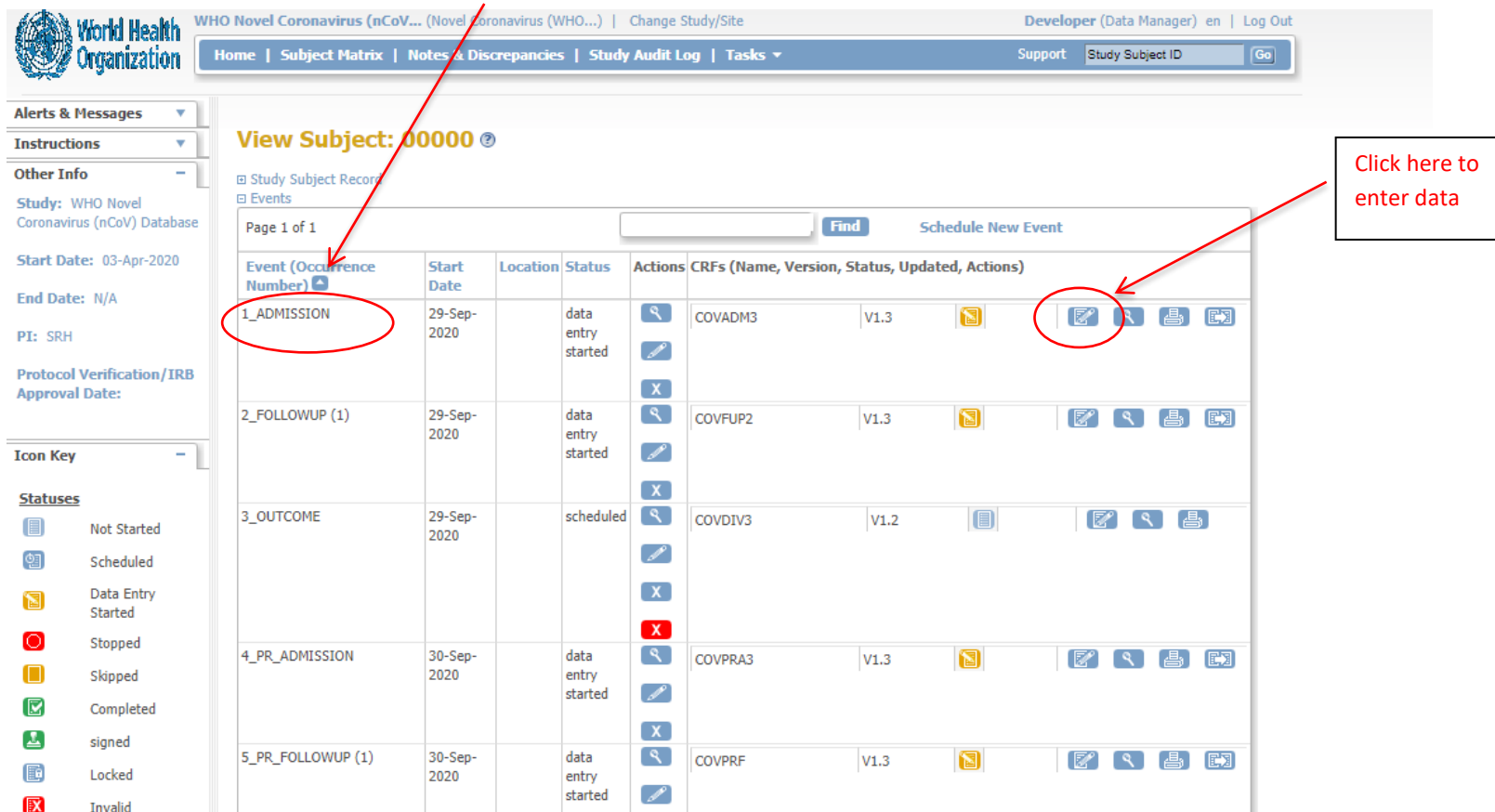
Date pt enrolled in study, on Case Report Form

CRFs to enter: 1_ADMISSION

Date pt is added to OpenClinica, Default to today's date

Press to Add new subject

Step 8. On Subject-specific Dashboard Click on Event (Occurrence Number) to sort. Click on icon shown to enter data for Subject.























WHO Novel Coronavirus (nCoV) Database | Change Study/Site | Developer (Data Manager) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks | Support | Study Subject ID | Go

View Subject: 00000

Study Subject Record | Events

Page 1 of 1 | Find | Schedule New Event

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
1_ADMISSION	29-Sep-2020		data entry started	                   	

Step 9. Enter Data.

COVADM3 V1.3

CRF Header Info

IDENTIF...(0/5) INCLUSI...(0/5) DEMOGRA...(0/9) ▶ - Select to Jump --

Scroll for more

000000001

Title: IDENTIFICATION

Instructions:
Once you click "Save", wait for the confirmation message
Do not use "Back" button in your browser, always click on "Exit" to go back to main menu.

Page: Save Exit

WORLD HEALTH ORGANIZATION
Global COVID-19 Clinical Platform
NOVEL CORONAVIRUS (COVID-19) - RAPID CORE CRF
MODULE1: Complete on hospital admission

Project ID: WHO_nCoV

IDENTIFICATION

Facility name:

Country:

Participant ID:

1. Date of enrolment: (dd-mm-yyyy)

Return to top


Save Exit

Need to be same

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


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




Do not use "Back" button in your browser, always click on "Exit" to go back to main menu.





Page: ☐ Mark CRF Complete 



2e. SUPPORTIVE CARE



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


59. ICU or High Dependency Unit admission: (select one) 


Date of ICU/HDU admission:  (dd-mmm-yyyy)  Check box if *Date of ICU/HDU admission - Unknown:* ☐ 

ICU/HDU discharge date:  (dd-mmm-yyyy)  Check box if *ICU/HDU discharge date - Not yet discharged:* ☐  Check box if *ICU/HDU discharge date - Unknown:* ☐ 



60. Oxygen therapy: (select one)  If *Yes*, O2 flow: (select one) 




If *Yes*, Source of oxygen: (select one)  If *Yes*, Interface: (select one) 


61. Non-invasive ventilation (e.g. BIPAP, CPAP)? (select one) 


62. Invasive ventilation (*Any*): (select one) 


If *Yes*, what were the following values closest to 0800


PEEP (cm H2O):  FIO2 (%): 

Plateau pressure (cm H2O):  PaCO2:  PaO2: 


63. Extracorporeal (ECMO) support: (select one) 

64. Prone Position: (select one) 

65. Inotropes/vasopressors: (select one) 

66. Renal replacement therapy (RRT) or dialysis: (select one) 

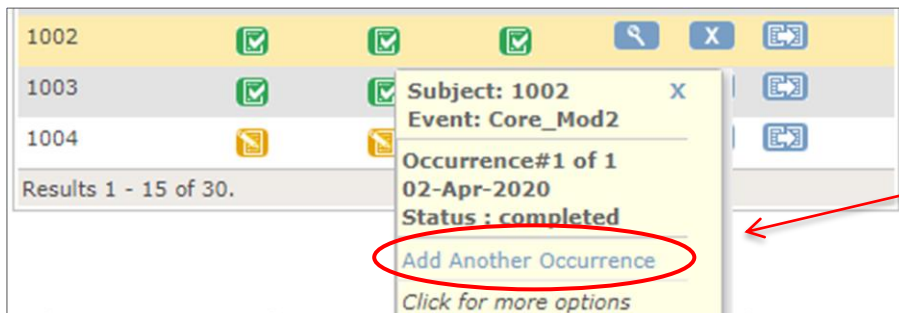
[Return to top](#)

☐ Mark CRF Complete 

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

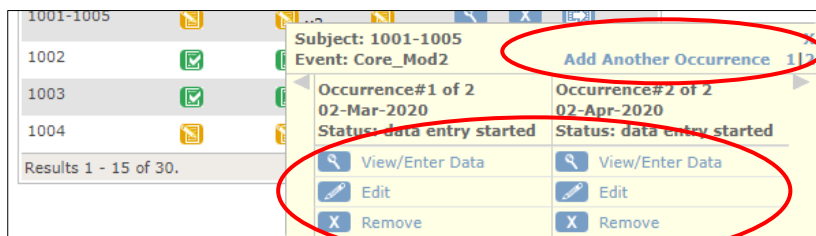
Step 11. Entering Data into a Repeated MODULE 2: FOLLOW UP Form.

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.

OpenClinica

who.eclinicalhosting.com/OpenClinica/ListStudySubjects?module=admin&maxRows=15&showMoreLink=true&findSubjects_tr=true&findSubjects_p=...

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

Developer (Data Manager) en | Log Out

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

Support Study Subject ID

Log out to exit

Subject Matrix for WHO Novel Coronavirus (nCoV) Database

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_ADMISSION_SP	11_FOLLOWUP_SP	12_OUTCOME_SP	Actions
10026-0018	✓	✓	✓	📄	📄	📄	📄	📄	📄	📄	📄	📄	🔍 X 📄
10026-0019	✓	🟡 x2	🟡	📄	📄	📄	📄	📄	📄	📄	📄	📄	🔍 X 📄
10026-0020	✓	✓	✓	📄	📄	📄	📄	📄	📄	📄	📄	📄	🔍 X 📄
10026-0021	✓	✓	✓	📄	📄	📄	📄	📄	📄	📄	📄	📄	🔍 X 📄
10026-0022	✓	✓	✓	📄	📄	📄	📄	📄	📄	📄	📄	📄	🔍 X 📄
10026-0023	✓	✓	✓	📄	📄	📄	📄	📄	📄	📄	📄	📄	🔍 X 📄

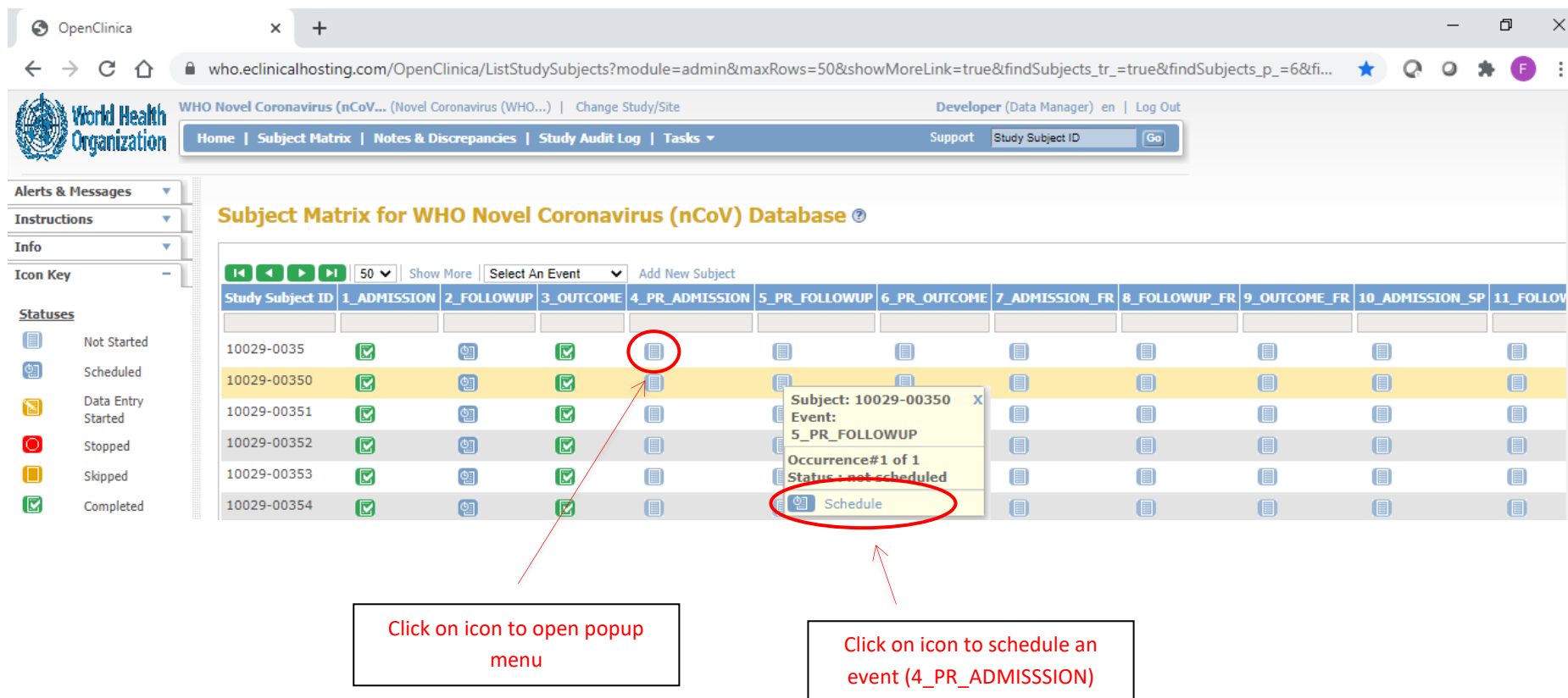
Green if completed

Yellow if saved but not completed yet

Click on icon to view subject

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.



OpenClinica

who.eclinicalhosting.com/OpenClinica/ListStudySubjects?module=admin&maxRows=50&showMoreLink=true&findSubjects_tr=true&findSubjects_p=6&fi...

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

Developer (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

Not Started

Scheduled

Data Entry Started

Stopped

Skipped

Completed

Subject Matrix for WHO Novel Coronavirus (nCoV) Database

50 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_ADMISSION_SP	11_FOLLOWUP
10029-0035	✓		✓								
10029-00350	✓		✓								
10029-00351	✓		✓								
10029-00352	✓		✓								
10029-00353	✓		✓								
10029-00354	✓		✓								

Subject: 10029-00350 X

Event: 5_PR_FOLLOWUP

Occurrence#1 of 1

Status: not scheduled

Schedule

Click on icon to open popup menu

Click on icon to schedule an event (4_PR_ADMISSION)

Step 14. Press Proceed to Enter Data button to schedule Pregnancy Module Admission form.

OpenClinica

who.eclinicalhosting.com/OpenClinica/CreateNewStudyEvent?studySubjectId=74550&studyEventDefinition=271

WHO Novel Coronavirus (nCoV... : WHO Training SITE (WHO Training SITE) | Change Study/Site Developer (Data Manager) en | Log Out

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

Alerts & Messages

Instructions

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:

Schedule Study Event for 00972

* indicates required field.

Study Subject ID: 00972

Study Event Definition: 4_PR_ADMISSION (Non-repeating)

Start Date/Time: 30-Sep-2020 : (DD-MMM-YYYY HH:MM) *

End Date/Time: : (DD-MMM-YYYY HH:MM) *

Leave this field blank if the end date/time is not applicable.

☐ Schedule Another Event: (optional)

☐ Schedule Another Event: (optional)

☐ Schedule Another Event: (optional)

☐ Schedule Another Event: (optional)

Proceed to Enter Data Cancel

By default, Study Event is 4_PR_ADMISSION. Do not change it.

Click on Proceed to Enter Data

Step 15. Click on icon to start data entry.

OpenClinica

who.eclinicalhosting.com/OpenClinica/EnterDataForStudyEvent?eventId=216518&alertmessage=The+study+event

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

Developer (Da

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

Support Study

Alerts & Messages

The study event with definition '4_PR_ADMISSION' and subject '00015' was created successfully.

Instructions

Info

Study Events

Study Events: (5)

4_PR_ADM
ISSION

Status: scheduled

COVPRA3

5_PR_FOLL
OWUP

6_PR_OUT
COME




7_PR_OUTCOM

Enter or Validate Data for CRFs in 4_PR_ADMISSION

Edit Study Event

Study Subject ID	00015
Study Event	4_PR_ADMISSION
Location	N/A
Study Subject OID	SS_00015
Start Date	30-Sep-2020
End Date/Time	
Subject Event Status	scheduled
Last Updated by	()

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
COVPRA3	V1.3				  

View this Subject's Record

Exit

Click on this icon to start
data entry

Step 16. Enter Data.

COVPRA3 V1.3

▼ CRF Header Info

00000

IDENTIF...(0/5) INCLUSI...(0/5) DEMOGRA...(0/9) -- Select to Jump --

Title: IDENTIFICATION

Instructions:
Once you click "Save", wait for the confirmation message
Do not use "Back" button in your browser, always click on "Exit" to go back to main menu.

Page: Save Exit

WORLD HEALTH ORGANIZATION
Global COVID-19 Clinical Platform
WITH PREGNANCY MODULE – CRF-P
MODULE1: Complete on hospital admission

Project ID: WHO_nCoV

IDENTIFICATION

Facility name:

Country:

Participant ID:

1. Date of enrolment: (dd-mmm-yyyy)

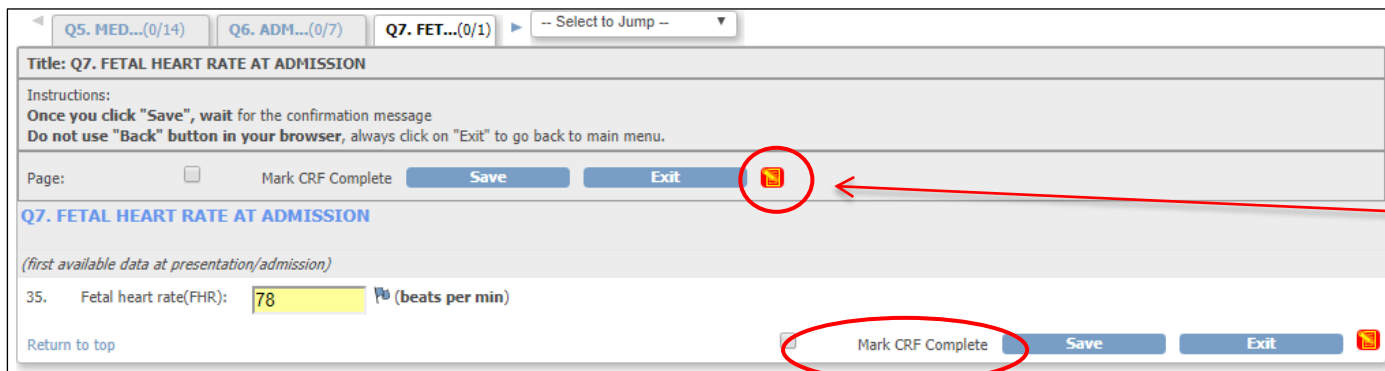
Return to top Save Exit

Scroll for more

Need to be same

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


Step 17. Mark the form complete.



Q5. MED...(0/14) Q6. ADM...(0/7) Q7. FET...(0/1) -- Select to Jump --

Title: Q7. FETAL HEART RATE AT ADMISSION


Instructions:
Once you click "Save", wait for the confirmation message
Do not use "Back" button in your browser, always click on "Exit" to go back to main menu.

Page: ☐ Mark CRF Complete Save Exit 

Q7. FETAL HEART RATE AT ADMISSION

(first available data at presentation/admission)

35. Fetal heart rate(FHR): 78 (beats per min)

Return to top ☐ Mark CRF Complete Save Exit 

Red icon signals data have been modified but not saved yet.

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

Step 18. Schedule Follow up module.

OpenClinica

who.eclinicalhosting.com/OpenClinica/EnterDataForStudyEvent?eventId=216518&alertmessage=The+study+event+with+definition+%274_PR_ADMISSION%27+and+subject+%2700015%27+was+created+successfully.

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

Developer (Data Manager) en | Log Out

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

Support Study Subject ID Go

Alerts & Messages

The study event with definition '4_PR_ADMISSION' and subject '00015' was created successfully.

Instructions

Info

Study Events

Study Events: (5)

4_PR_ADMISSION

Status: scheduled

COVPRA3

5_PR_FOLLOWUP

Status: scheduled

COVPRF

6_PR_OUTCOME

Status: scheduled

COVPRD

Enter or Validate Data for CRFs in 4_PR_ADMISSION

Edit Study Event

Study Subject ID	00015
Study Event	4_PR_ADMISSION
Location	N/A
Study Subject OID	SS_00015
Start Date	30-Sep-2020
End Date/Time	
Subject Event Status	scheduled
Last Updated by	()

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
COVPRA3	V1.3				

View this Subject's Record Exit

Workflow

Study Event Overview → Data Entry → Mark Event CRF Complete

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.

COVPRF V1.3 

00000

▼ CRF Header Info

IDENTIF...(0/5)

VITAL S...(0/11)

DAILY C...(0/15)

-- Select to Jump --

Title: IDENTIFICATION

Instructions:


Once you click "Save", wait for the confirmation message

Do not use "Back" button in your browser, always click on "Exit" to go back to main menu.

Page:

Save

Exit



WORLD HEALTH ORGANIZATION

Global COVID-19 Clinical Platform


WITH PREGNANCY MODULE – CRF-P

MODULE2: Daily follow up during hospital stay (daily or as frequent as possible based on feasibility)

Project ID:

WHO_nCoV


*



IDENTIFICATION


Facility name:

*




Country:

*




Participant ID:


*



1. Date of follow-up:



*




(dd-mmm-yyyy)

Return to top

Save

Exit



Step 20. Enter Data into PREGNANCY Outcome form, press Save, or press Mark Complete and Save, and go back to Subject Matrix.

COVPRD V1.4

00000

▼ CRF Header Info

IDENTIF...(0/4)


DIAGNOS...(0/17)

COMPLIC...(0/21)


-- Select to Jump --

Title: IDENTIFICATION


Instructions:
Once you click "Save", wait for the confirmation message
Do not use "Back" button in your browser, always click on "Exit" to go back to main menu.


Page: Save Exit 


WORLD HEALTH ORGANIZATION
Global COVID-19 Clinical Platform
WITH PREGNANCY MODULE – CRF-P
MODULE 3: complete at discharge/death


Project ID: * 

IDENTIFICATION

Facility name: * 

Country: * 

Participant ID: * 

Return to top Save Exit 

END.