

# **WHO COVID-MISC DATABASE PLATFORM**

## **(Multisystem Inflammatory Syndrome in Children and Adolescents)**

**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](mailto:SIS@who.int)**



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

Step 2. Log in with Username and Password.

A screenshot of the WHO OpenClinica login page. The page has a light gray background with a subtle geometric pattern. At the top, there are two logos: the World Health Organization logo on the left and the Human Reproduction Programme (hrp) logo on the right. The hrp logo includes the text "human reproduction programme" and "research for impact" below it. Below the logos, there are two main white boxes. The left box is titled "Login" and contains two input fields: "User Name" and "Password". Below these fields is a blue "Login" button and a link "Forgot Password?". The right box is titled "News" and contains a list of four news items, each starting with a right-pointing arrow. The news items are dated 12/09, 10/09, 10/07, and 08/27. At the bottom right of the "News" box is a link "More...".

World Health Organization

human reproduction programme  
hrp  
research for impact  
UNDP · UNFPA · UNICEF · WHO · WORLD BANK

### Login

User Name

Password

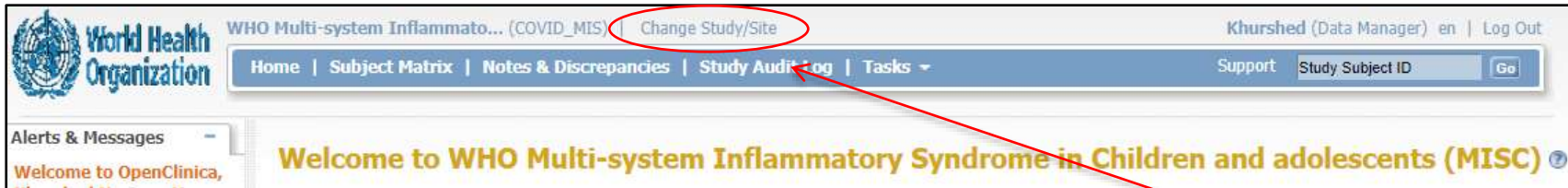
[Login](#) [Forgot Password?](#)

### News

- ▶ 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 ...

[More...](#)

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



WHO Multi-system Inflammatory Syndrome in Children and adolescents (MISC) (COVID\_MIS) **Change Study/Site** Khurshed (Data Manager) en | Log Out

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

Support Study Subject ID Go

Alerts & Messages  
Welcome to OpenClinica,

**Welcome to WHO Multi-system Inflammatory Syndrome in Children and adolescents (MISC)**

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

**Follow these steps:**

☐ **WHO Multi-system Inflammatory Syndrome in Children and adolescents (MISC) (Data Manager)**

▶ ☒ ITALY SITE (Data Manager)

▶ ☐ 99999-WHO Training SITE (Data Manager)

**Change Study** **Cancel**

**Confirm Changing Study**

You are choosing to switch to the study: ITALY SITE with a role of Data Manager. The study/site status is available

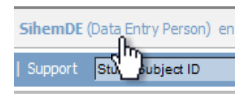
**Confirm**

#### 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 list of fields is shown, each with a required field indicator (an asterisk). The fields are: First Name (Sham Bani), Last Name (Lahoud), Email (lahouds@who.int), Institutional Affiliation (WHO/SHRS), Default Active Study (AG - The gentle Assisted Pyloric (GAP) study), Password Challenge Question (City of Birth), Password Challenge Answer (Makani), Old Password, New Password, Confirm New Password, and Phone (+41227914542). At the bottom, 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.



WHO Multi-system Inflammatory Syndrome in Children and adolescents (COVID\_MIS) | Change Study/Site

Khurshed (Data Manager) en | Log Out

[Home](#) | [Subject Matrix](#) | [Notes & Discrepancies](#) | [Study Audit Log](#) | [Tasks](#)

Support |

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 Multi-system Inflammatory Syndrome in Children and adolescents (MISC)

**Start Date:** 01-Jun-2020

**End Date:** N/A

**PI:** WHE

**Protocol Verification/IRB Approval Date:**

Icon Key

**Statuses**

Not Started

## Welcome to WHO Multi-system Inflammatory Syndrome in Children and adolescents (MISC)

Notes & Discrepancies Assigned to Me: 0

**Subject Enrollment By Site**

| Site                    | Enrolled | Expected Enrollment | Percentage |
|-------------------------|----------|---------------------|------------|
| 99999-WHO Training SITE | 0        | 1000                | 0%         |

**Subject Enrollment For Study**

| Study   | Enrolled | Expected Enrollment | Percentage |
|---|----------|---------------------|------------|
| WHO Multi-system Inflammatory Syndrome in Children and adolescents (MISC) | 0        | 1000                | 0%         |

**Study Progress**

| Event Status       | # of Events | Percentage |
|--------------------|-------------|------------|
| scheduled          | 0           | 0%         |
| data entry started | 0           | 0%         |
| completed          | 0           | 0%         |
| signed             | 0           | 0%         |
| locked             | 0           | 0%         |
| skipped            | 0           | 0%         |
| stopped            | 0           | 0%         |

**Subject Status Count**

| Study Subject Status | # of Study Subjects | Percentage |
|----------------------|---------------------|------------|
| available            | 0                   | 0%         |
| signed               | 0                   | 0%         |
| removed              | 0                   | 0%         |

**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 Multi-system Inflammato... : 99999-WHO Training SITE (99999-WHO) | Change Study/Site | Khurshed (Data Manager) en | Log Out

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

Support | Study Subject ID | Go

### Subject Matrix for 99999-WHO Training SITE

15 | Show More | Select An Event | Add New Subject

| Study Subject ID | ADMISSION                           | OUTCOME | Actions                   |
|------------------|-------------------------------------|---------|---------------------------|
| 9999-0002        | <input checked="" type="checkbox"/> |         | Apply Filter Clear Filter |

Results 1 - 1 of 1.

Click here to start new patient

Existing pts

View subject info

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

**Add New Subject**

Study Subject ID: 9999-0001 \*

Enrollment Date: 29-May-2020 \*

Sex: Female ▼

Study Event: ADMISSION \*

Start Date: 29-May-2020 \*

**Add** **Cancel**

Participant ID

Date pt enrolled in study, on Case Report Form

CRFs to enter: 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 if not alphabetically sorted already. Click on icon shown to enter data for Subject.

WHO Multi-system Inflammato... : 99999-WHO Training SITE (99999-WHO) | Change Study/Site | Khurshed (Data Manager) en | Log Out

















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

Support Study Subject ID  Go

**View Subject: 9999-0001**

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)   |
|---------------------------|-------------|----------|-----------|--|--|
| ADMISSION                 | 29-May-2020 |          | scheduled |          | COVINFA V1.0     |
| OUTCOME                   | 29-May-2020 |          | scheduled |     | COVINFD V1.0     |

PT: WHE

Click here to enter data



## Step 9. Enter Data.

Scroll for more

**COVINFA V1.0**

CIIF Header Info

IDENTIF... (0/6) 1a. DEM... (0/5) 1b. DAT... (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:

**WORLD HEALTH ORGANIZATION**  
**Global COVID-19 Clinical Platform: Case Record Form for suspected cases of Multisystem inflammatory syndrome (MIS) in children and adolescents temporally related to COVID-19**

MODULE 1: Complete this module for all children aged 0-19 suspected to have multisystem inflammatory disorder (even if all criteria in the case definition are not met - to capture full spectrum of the condition).

Complete the module at the time the disorder is suspected. Submit module when initial investigations included in case definition are available.

Project ID: WHO\_nCoV\_MIS

**IDENTIFICATION**

Facility name: Facility 1

Country: Country 1

Participant ID: 9999-0001

1. Date of patient assessment: 29-May-2020 (dd-mm-YYYY)

2. Date of admission to hospital: 29-May-2020 (dd-mm-YYYY)

Return to top

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.

**COVINFA V1.0**
**9999-0001**

▼ CRF Header Info

1g. PRE...(0/16) 1h. LAB...(0/64) 1i. IMA...(0/11) -- Select to Jump --

**Title: 1i. IMAGING AND PATHOGEN TESTING**

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**

**1i. IMAGING AND PATHOGEN TESTING**  
*Complete when results of tests ordered at the time MIS is first suspected are available*

116. Chest X-Ray/CT performed: 2 - No If Yes, findings:

117. ECG performed: 2 - No On that ECG what were the findings?:

118. Echocardiography performed: 1 - Yes

If Yes, features of myocardial dysfunction: 2 - No If Yes, features of pericarditis: 1 - Yes

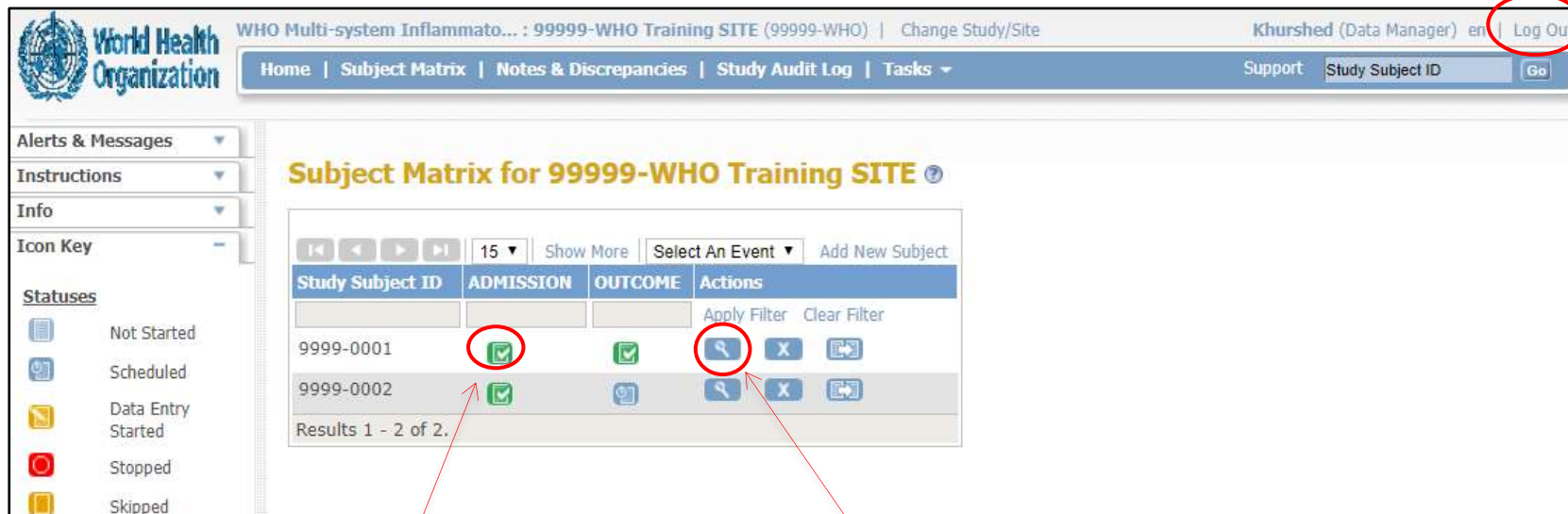
If Yes, features of valvulitis: 1 - Yes If Yes, coronary abnormalities: 2 - No

119. Other cardiac imaging performed: 2 - No If Yes, specify name of imaging and results:

Return to top ☒ **Mark CRF Complete** **Save** **Exit**

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

Step 11. When data entry is done, go back to Subject Matrix and select to view subject or to log out.



WHO Multi-system Inflammato... : 99999-WHO Training SITE (99999-WHO) | Change Study/Site

Khurshed (Data Manager) en | Log Out

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

Support: Study Subject ID Go

### Subject Matrix for 99999-WHO Training SITE

15 Show More Select An Event Add New Subject

| Study Subject ID | ADMISSION | OUTCOME | Actions |
|------------------|-----------|---------|---------|
| 9999-0001        |           |         |         |
| 9999-0002        |           |         |         |

Results 1 - 2 of 2.

Log out to exit

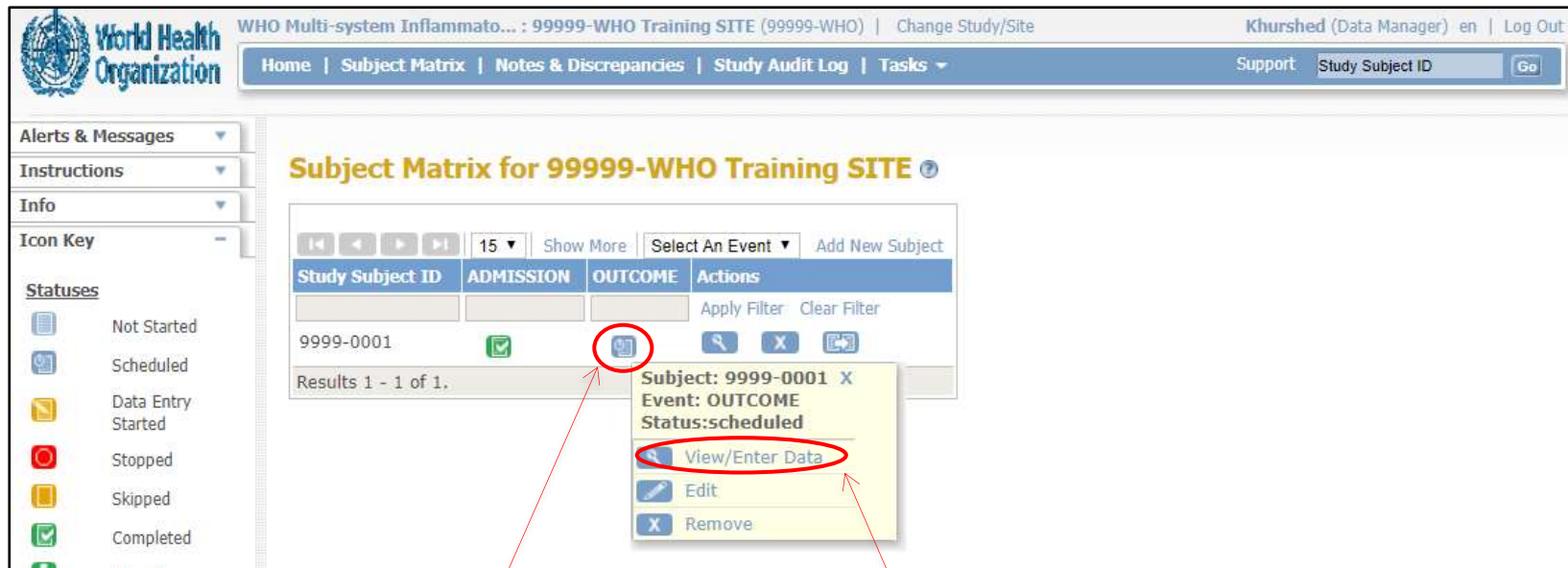
Green if completed

Yellow if saved but  
not completed yet

Click on icon to  
view subject

**Step 12. If participant discharged or dead, complete the Outcome form.**

**Go to Subject Matrix and click on the View/Enter Data for Outcome form.**



WHO Multi-system Inflammato... : 99999-WHO Training SITE (99999-WHO) | Change Study/Site


Khurshed (Data Manager) en | Log Out

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

Support: Study Subject ID [Go]

### Subject Matrix for 99999-WHO Training SITE

15 Show More Select An Event Add New Subject

| Study Subject ID | ADMISSION                           | OUTCOME   | Actions                   |
|------------------|-------------------------------------|---|---------------------------|
| 9999-0001        | <input checked="" type="checkbox"/> |  | Apply Filter Clear Filter |

Results 1 - 1 of 1.

Subject: 9999-0001 X  
Event: OUTCOME  
Status:scheduled

View/Enter Data  
Edit  
Remove

Click on icon to open popup  
menu

Click on icon to start data entry  
for Outcome

**Step 13. Press Enter Data to start the data entry for Outcome form.**

WHO Multi-system Inflammato... : 99999-WHO Training SITE (99999-WHO) | Change Study/Site | Khurshed (Data Manager) en | Log Out

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

Alerts & Messages ▾  
Instructions ▾  
Info ▾  
Study Events ▾




Study Events: (2)  
ADMISSION  
OUTCOME  
Status: scheduled  
COVINFD

### Enter or Validate Data for CRFs in OUTCOME

Edit Study Event

|                      |                  |
|----------------------|------------------|
| Study Subject ID     | 9999-0001        |
| Study Event          | OUTCOME          |
| Location             | N/A              |
| Study Subject OID    | SS_99990001_3626 |
| Start Date           | 29-May-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   |
|----------|---------|--------|--------------------|-------------------|---|
| COVINFD  | V1.0    |        |                    |                   |    |

View this Subject's Record | Exit

Workflow

```

graph LR
    A[Study Event Overview] --> B[Data Entry]
    B --> C[Mark Event CRF Complete]
  
```

Click on icon to Enter Data

Step 14. Enter Data.

COVINFD V1.0

CRF Header Info

IDENTIF...(0/4) 2a. SUM...(0/24) 2b. LAB...(0/64) -- Select to Jump --

Scroll for more

9999-0001

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 - Rapid version  
Multisystem Inflammatory Syndrome in Children and adolescents temporally related to COVID  
(MODULE 2: Complete and submit this module at the time of discharge or death)  
18MAY2020

Project ID: WHO\_nCoV\_MIS

IDENTIFICATION

Facility name: Facility 1

Country: Country 1


Participant ID: 9999-0001

Need to be same

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

Save Exit

**Step 15. Mark the form complete.**


**COVINFD V1.0**  **9999-0001**

▼ CRF Header Info

2d. TRE...(0/78) 2e. SUP...(0/27) 2f. OUT...(0/12) -- Select to Jump --


**Title: 2f. OUTCOME**



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** 


**2f. OUTCOME**

*Complete at the time of discharge/death*


88. Outcome: 1 - Discharged alive 


89. Outcome date: 31-May-2020  (dd-mmm-yyyy) Check box if *Unknown*: ☐ Unknown 


*If discharged alive,*


90. Care needs at discharge versus before illness: 3 - Better 



*What was the physicians impression of the final diagnosis?*



91. Multisystem inflammatory syndrome: 1 - Yes 


92. Kawaksaki disease: 2 - No 

93. Atypical Kawasaki disease: 2 - No 

94. Toxic shock syndrome: 2 - No 

95. Other: 2 - No  If *Other*, specify name:  

96. Were there any sequale present at the time of discharge: 2 - No  If *Yes*, specify:  

[Return to top](#) ☒ Mark CRF Complete **Save** **Exit** 

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

**END.**

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