

REDCap instructions for enrolment of participants in MISTRAL

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ACCESS TO REDCap

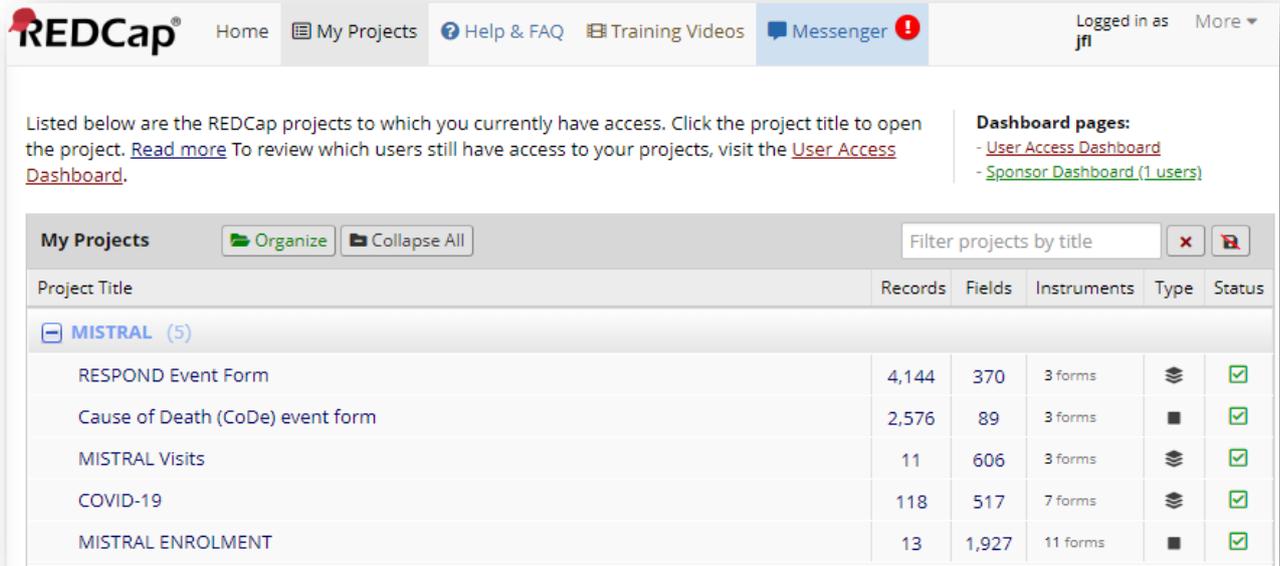
Enter the address: <https://chip-crf.info/redcap/> into your browser and log in with your username and password. If you have lost your username/password or if you have not received one yet, please write to the MISTRAL e-mail at: mistral.rigshospitalet@regionh.dk

The first time you log on you will be asked to change the password and set up a password recovery question. Please note that access is personal, and if more staff at your site needs access, please contact mistral.rigshospitalet@regionh.dk

FIND YOUR PROJECT

Go to **My Projects**

- **MISTRAL enrolment form: (for participants not already enrolled in EuroSIDA)** Enrolment forms for your patients should be completed in REDCap. The enrolment form contains several sections, which should all be reviewed and/or completed. Please note that all data items should be provided if available.
- **MISTRAL Visits:** Include 3 REDCap forms: Patient Baseline Data form (only Visit 1), Questionnaire form, Samples form
- **RESPOND Event Form** Please complete for patients who has experienced one or more of the following events:
 - Myocardial infarction (MI)
 - Stroke
 - Invasive cardiovascular procedure (ICP)
 - Cancer – AIDS and Non-AIDS defining
 - End stage liver disease and liver transplantation
 - End stage renal disease and kidney transplantation
 - Bone fracture
- **Cause of Death (CoDe event form):** Please complete for all patients who have died
- **COVID-19 form** Please complete the COVID-19 form in REDCap For patients who had a positive PCR test and have been admitted to hospital for treatment of COVID-19



REDCap® Home My Projects Help & FAQ Training Videos Messenger Logged in as jfi

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

Dashboard pages:
 - [User Access Dashboard](#)
 - [Sponsor Dashboard \(1 users\)](#)

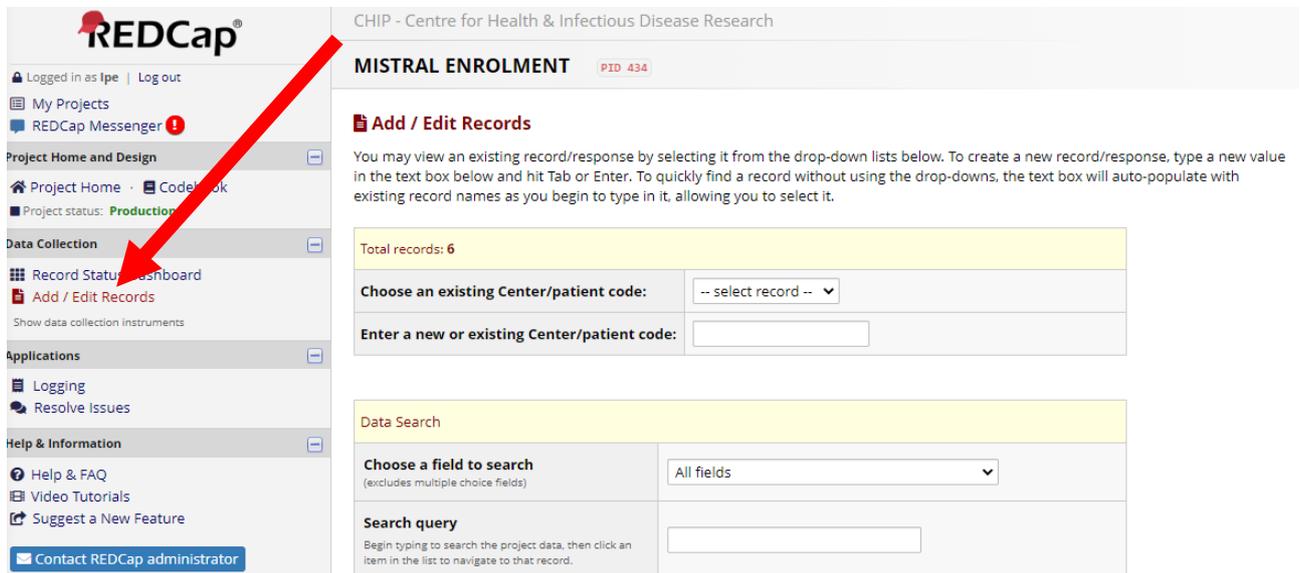
My Projects Organize Collapse All Filter projects by title

Project Title	Records	Fields	Instruments	Type	Status
MISTRAL (5)					
RESPOND Event Form	4,144	370	3 forms		✓
Cause of Death (CoDe) event form	2,576	89	3 forms		✓
MISTRAL Visits	11	606	3 forms		✓
COVID-19	118	517	7 forms		✓
MISTRAL ENROLMENT	13	1,927	11 forms		✓

ADD NEW PATIENT RECORD

To add a new record:

1. Click one of the projects. The project setup page will appear.
2. Click **Add/Edit Records** on the left-hand side under Data Collection.



REDCap® CHIP - Centre for Health & Infectious Disease Research

MISTRAL ENROLMENT PID 434

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 6

Choose an existing Center/patient code: -- select record --

Enter a new or existing Center/patient code:

Data Search

Choose a field to search (excludes multiple choice fields) All fields

Search query

Begin typing to search the project data, then click an item in the list to navigate to that record.

3. Type the EuroSIDA/MISTRAL Patient Identification code [centre code (3 digits) followed by patient code (4 digits) e.g. 1508001] and press ENTER.

MISTRAL Enrolment codes for new participants start from 8001 following the centre code. Please enroll consecutively as e.g. 1508001, 1508002, 1508003 and so on. Existing EuroSIDA participants, enrolled in MISTRAL, maintain their EuroSIDA PID.

MISTRAL ENROLMENT

PID 434

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 6	
Choose an existing Center/patient code:	-- select record -- ▾
Enter a new or existing Center/patient code:	1508001

Data Search	
Choose a field to search <small>(excludes multiple choice fields)</small>	All fields ▾
Search query <small>Begin typing to search the project data, then click an item in the list to navigate to that record.</small>	<input type="text"/>

4. To access specific sections press on any of the round buttons on the right from the section list:

MISTRAL ENROLMENT PID 434

Record Home Page

Record "1508001" is a new Center/patient code. To create the record and begin entering data for it, click any gray status icon below.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Legend for status icons:

● Incomplete ? Incomplete (no data saved)

● Unverified

● Complete

NEW Center/patient code: 1508001

Data Collection Instrument	Status
Section A1 - Demography and HIV-status	?
Section A2 - Basic Clinical Information	?
Section B1 - Laboratory Values	?
Section B2 - CD4, CD8 and HIV-RNA	?
Section B3 - Hepatitis Virology and Fibrosis Screening	?
Section B4 - COVID-19	?
Section C1 - Antiretroviral Treatment	?
Section C2 - Risk of Cardiovascular Disease and Diabetes	?
Section C3 - Treatment Against Hepatitis C	?
Section D - Severe Opportunistic Infections and Sexually Transmitted Infections	?
Section E - Clinical Events	?
Status	?

ENTER DATA INTO THE PATIENT RECORD

1. The MISTRAL enrolment form contains a form for each section. You can navigate between the different sections using the links on the left-hand side:



Data Collection

- Record Status Dashboard
- Add / Edit Records
- Center/patient code: **1508001** [Select other record](#)
- Data Collection Instruments:
 - Section A1 - Demography and HIV-status**
 - Section A2 - Basic Clinical Information
 - Section B1 - Laboratory Values
 - Section B2 - CD4, CD8 and HIV-RNA
 - Section B3 - Hepatitis Virology and Fibrosis Screening
 - Section B4 - COVID-19
 - Section C1 - Antiretroviral Treatment
 - Section C2 - Risk of Cardiovascular Disease and Diabetes
 - Section C3 - Treatment Against Hepatitis C
 - Section D - Severe Opportunistic Infections and Sexually Transmitted Infections
 - Section E - Clinical Events
 - Status

Adding new Center/patient code: **1508001**

Center/patient code:

Data Entry Instructions

Comma vs. full stop in numbers e.g. 2.5/2.5:
You have to use full stop instead of comma, otherwise ar

Test/measurement not performed:
Leave the field(s) blank.

or the Record Status Dashboard:

Center/patient code:	Section A1 - Demography and HIV-status	Section A2 - Basic Clinical Information	Section B1 - Laboratory Values	Section B2 - CD4, CD8 and HIV-RNA	Section B3 - Hepatitis Virology and Fibrosis Screening	Section B4 - COVID-19	Section C1 - Antiretroviral Treatment	Section C2 - Risk of Cardiovascular Disease and Diabetes	Section C3 - Treatment Against Hepatitis C	Section D - Severe Opportunistic Infections and Sexually Transmitted Infections	Section E - Clinical Events	Status
9999991	●	●	●	●	●	●	●	●	●	●	●	●
9999992	●	●	●	●	●	●	●	●	●	●	●	●
9999993	●	●	●	●	●	●	●	●	●	●	●	●
9999994	●	●	●	●	●	●	●	●	●	●	●	●
9999998	●	●	●	●	●	●	●	●	●	●	●	●
9999999	●	●	●	●	●	●	●	●	●	●	●	●

The colored icon in front of the form denotes the status, i.e.:

- **Green** (complete) = The form/section is complete.
- **Yellow** (unverified) = The form/section has been edited but is incomplete.
- **Red** (incomplete) = The form/section contains preloaded data and has not been reviewed and/or the form/section has been saved, but data is incomplete and will be completed/reviewed later.
- **Grey** (incomplete) = No data has been entered/saved.

- If treatment is ongoing, please leave stop date **blank**. This applies to all variables mentioned under **Treatment**.

Treatment	
Antibiotics	
Have you taken antibiotics within the last three months (excluding topical treatment (e.g., applied to the skin)):	<input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown
reset	
Please report all antibiotics three months from stool sample collection date:	
Antibiotic (1):	Amikacin
Start date Antibiotic (1):	2021-05-31 31 Today Y-M-D
On drug at most recent visit (1):	<input checked="" type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
reset	
Stop date Antibiotic (1):	<input type="text"/> 31 Today Y-M-D

Comma vs. full stop

You must use full stop instead of comma. Otherwise you will receive this error:



2. Select status at the bottom of the form/section.

Incomplete: The form/section contains incomplete data and will be completed later.

Unverified: The form/section contains incomplete data and will be completed later. Please use this status if you are interrupted and need to come back to it later. Using this status will make it easy to find the form again via the Record Status Dashboard.

Complete: The form/section contains all available data.

Form Status

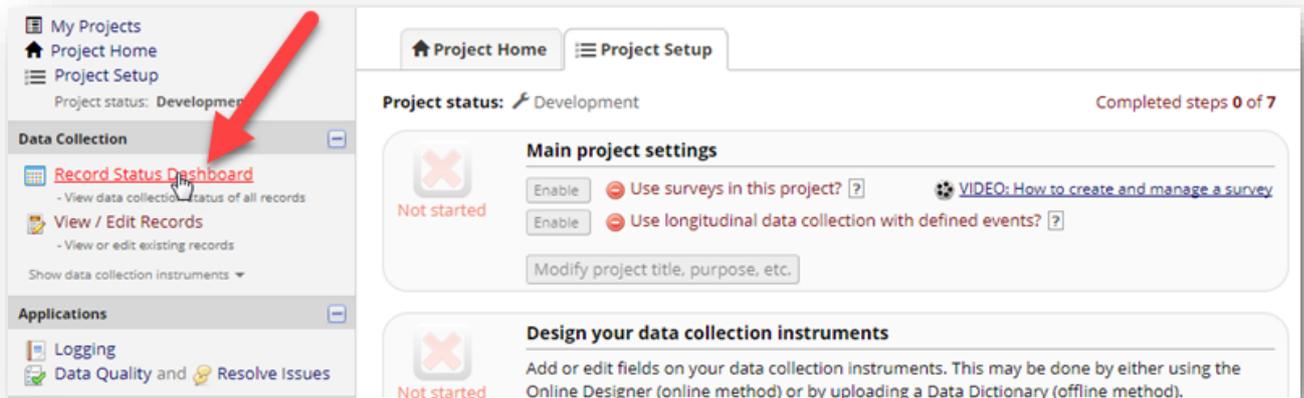
Complete? Incomplete

Lock this record for this form?
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

3. Click **Save & Exit Form**, **Save & Stay** or **Save and go to Next Form**.

FIND A PATIENT RECORD

1A. Click **Record Status Dashboard** on the left-hand side under Data Collection

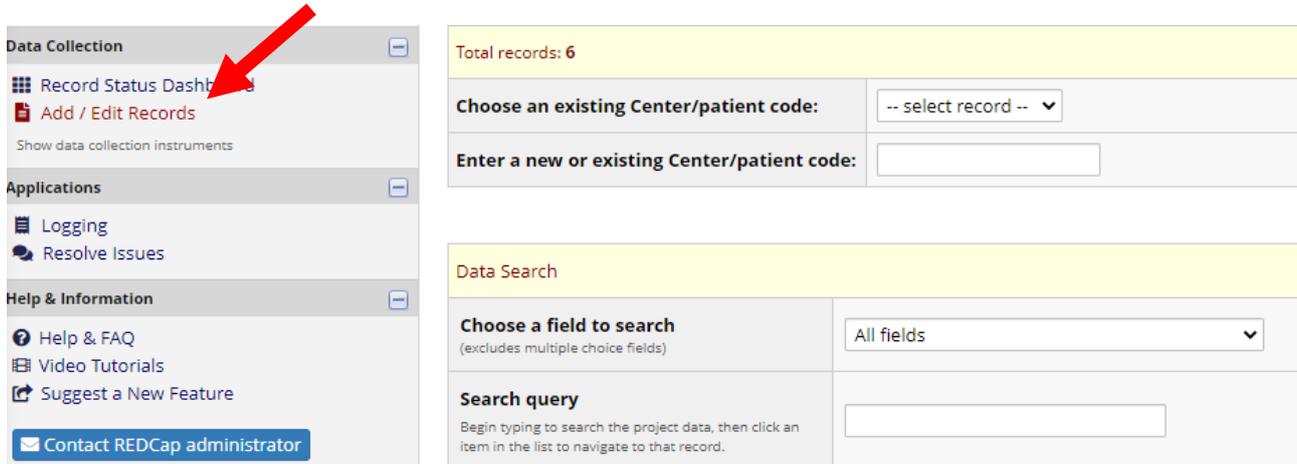


The screenshot shows the 'Record Status Dashboard' interface. On the left, a navigation menu includes 'My Projects', 'Project Home', 'Project Setup', 'Data Collection', and 'Applications'. Under 'Data Collection', 'Record Status Dashboard' is highlighted with a red arrow. The main content area shows 'Project status: Development' and 'Completed steps 0 of 7'. It contains sections for 'Main project settings' and 'Design your data collection instruments', both marked as 'Not started'.

and then click the status icon for the patient and section you wish to edit.

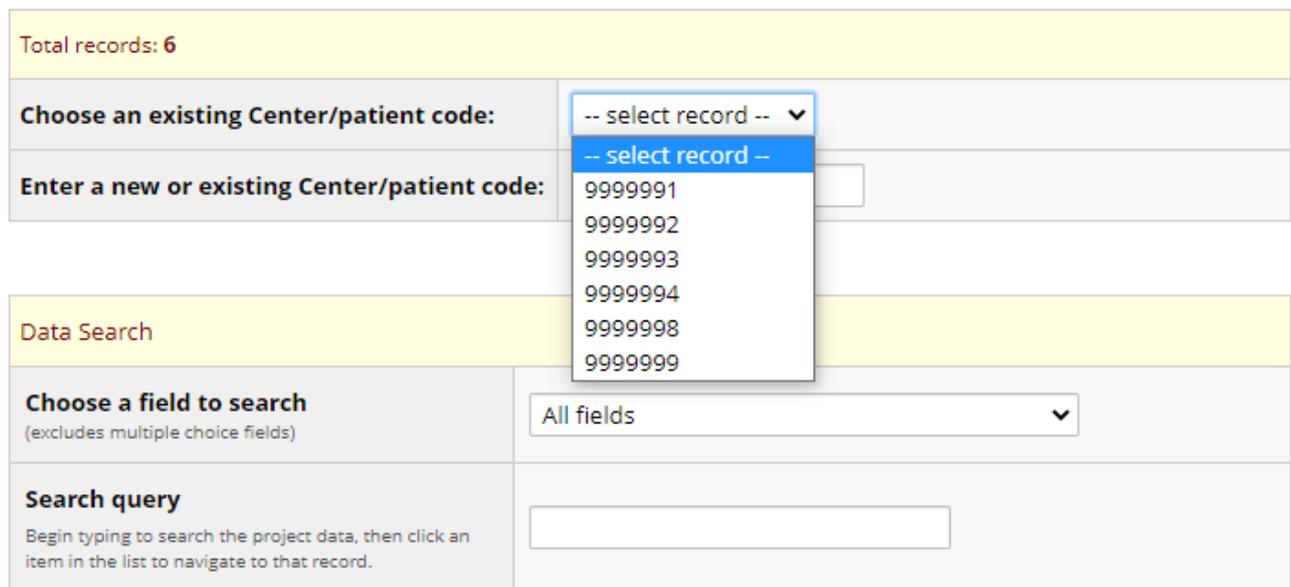
Center/patient code:	Section A1 - Demography and HIV-status	Section A2 - Basic Clinical Information	Section B1 - Laboratory Values	Section B2 - CD4, CD8 and HIV-RNA	Section B3 - Hepatitis a Virus screening	Section B4 - COVID-19	Section C1 - Antiretroviral Treatment	Section C2 - Risk of Cardiovascular Disease and Diabetes	Section C3 - Treatment Against Hepatitis C	Section D - Severe Opportunistic Infections and Sexually Transmitted Infections	Section E - Clinical Events	Status
9999991	●	●	●	●	●	●	●	●	●	●	●	●
9999992	●	●	●	●	●	●	●	●	●	●	●	●
9999993	●	●	●	●	●	●	●	●	●	●	●	●
9999994	●	●	●	●	●	●	●	●	●	●	●	●
9999998	●	●	●	●	●	●	●	●	●	●	●	●
9999999	●	●	●	●	●	●	●	●	●	●	●	●

1B. Or click **Add/Edit Records** on the left-hand side under Data Collection



The screenshot shows the REDCap interface. On the left-hand side, under the 'Data Collection' section, the 'Add / Edit Records' button is highlighted with a red arrow. The main content area shows a summary of 6 total records and a search interface. The search interface includes a dropdown menu for 'Choose an existing Center/patient code' (currently set to '-- select record --'), a text input field for 'Enter a new or existing Center/patient code:', a dropdown menu for 'Choose a field to search' (set to 'All fields'), and a text input field for 'Search query'.

and find the record using the **Incomplete Records** drop down box.



This screenshot shows a closer view of the search interface. The 'Choose an existing Center/patient code:' dropdown menu is open, displaying a list of record IDs: 9999991, 9999992, 9999993, 9999994, 9999998, and 9999999. The 'Enter a new or existing Center/patient code:' field is empty. The 'Data Search' section below shows the 'Choose a field to search' dropdown set to 'All fields' and the 'Search query' field empty.

Or by entering the PID in **Enter a new or existing Center/patient code:**



This screenshot shows the search interface with the record ID '9999991' entered in the 'Enter a new or existing Center/patient code:' text input field. The 'Choose an existing Center/patient code:' dropdown menu is still set to '-- select record --'.

FINALIZE EACH PATIENT RECORD

Before finalizing a patient record, please make sure that you have

- entered all data available for the patient
- if no data is available, please make sure that “no data” information is provided, e.g.:

Laboratory values

Has the patient had proteinuria, ALT, AST, albumin, bilirubin, platelets, serum creatinine, total cholesterol, HDL, LDL, serum triglycerides, HbA1C, plasma glucose, haemoglobin and/or INR been measured?

***must provide value**

No
 Yes
 Unknown

reset

- completed all sections in all applicable forms

Please click “Status” in the left side menu and confirm that you have finalized your data collection by choosing “complete” in the dropdown menu. By changing the status of this form to "**complete**" you confirm that there is no more available data for the patient during the current follow-up period.

Center/patient code: 9999991

By changing the status of this form to "complete" you confirm that there is no more available data for the patient.

Form Status

Complete?