

REDCap instructions for enrollment of patients in the CARE Study (WP5-WP6)

Autumn 2019

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ACCESS TO REDCap

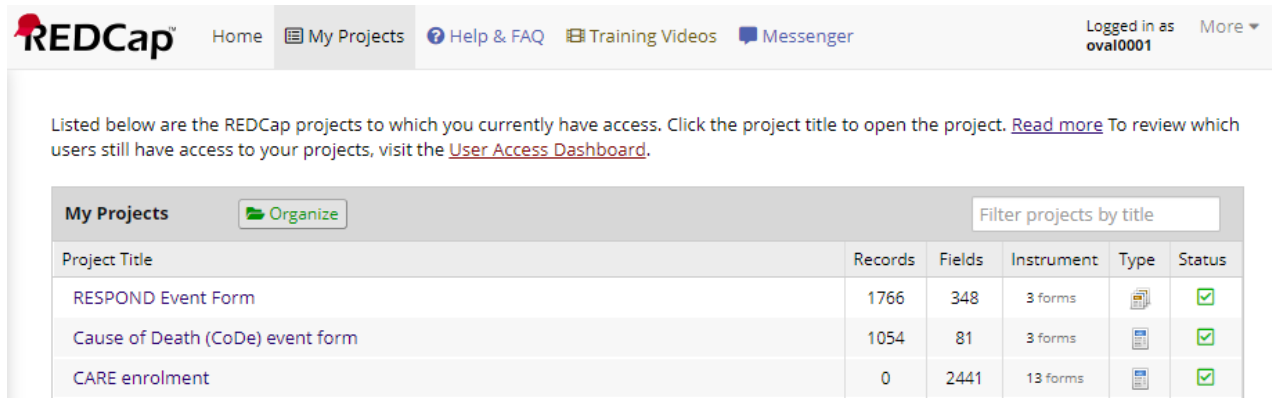
Enter the address: <https://chip-crf.info/redcap/> into your browser and log in with your username and password. If you have lost your username/password or if you have not received one yet, please write to the CARE e-mail at CHIP/RegionH: care.rigshospitalet@regionh.dk

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 care.rigshospitalet@regionh.dk

FIND YOUR PROJECT

Go to **My Projects** tab – Here you will find access to some or all of these projects:

- **CARE enrolment form:** Enrollment forms for all 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 'Must Provide Values' must be completed (marked in the form with ***must provide value**), unless the patient is dead, lost to follow-up, indicated in Section A. If there are no new values to enter in a given field, you should mark this with a 'No', and not leave the field blank.
Reimbursement will be based on completeness of 'Must Provide Values'.
- **RESPOND Event Form**
- **Cause of Death (CoDe Event Form)**



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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](#).

Project Title	Records	Fields	Instrument	Type	Status
RESPOND Event Form	1766	348	3 forms		
Cause of Death (CoDe) event form	1054	81	3 forms		
CARE enrolment	0	2441	13 forms		

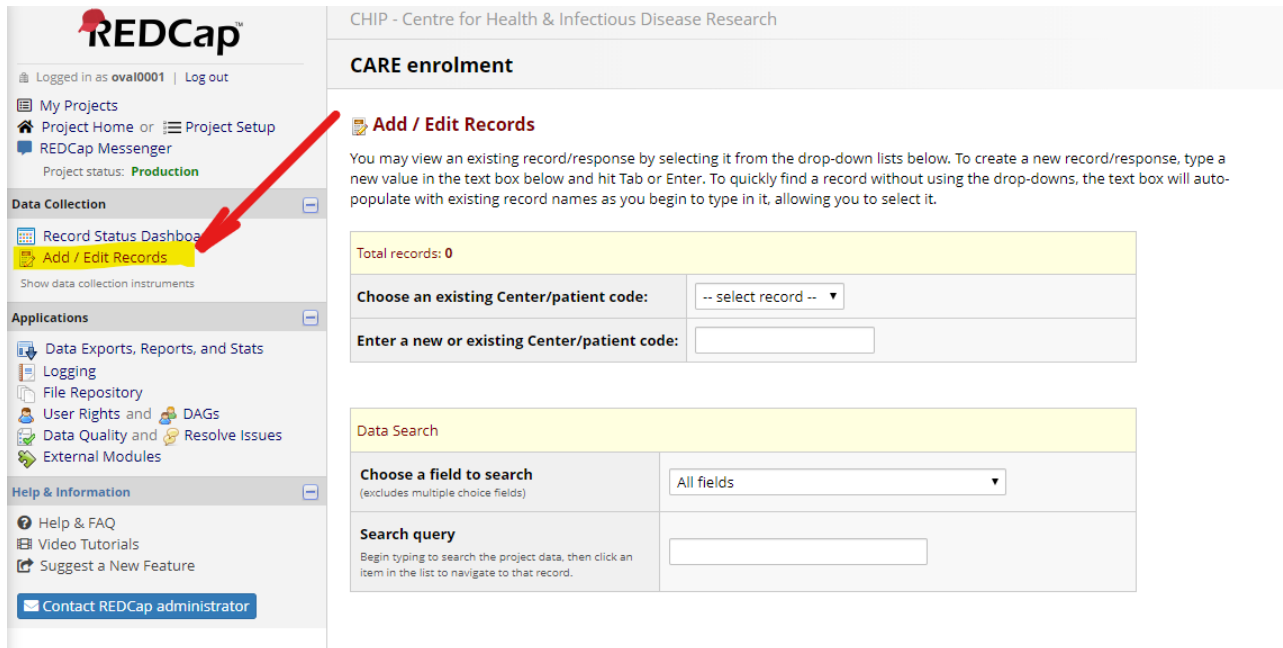
ADD NEW PATIENT RECORD

To add a new record:

1. Click one of the projects (i.e. CARE enrolment form, Respond Event form or CoDe form). The project setup page will appear.



2. Click **Add/Edit Records** on the left-hand side under Data Collection.



CHIP - Centre for Health & Infectious Disease Research

CARE enrolment

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: 0

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 CARE Patient Identification code [centre code (3 digits) followed by patient code (7 digits) e.g. 1300000001] and press ENTER.

- Ukrainian sites will be marked from 130 [format of PID 130AAAAAAA]
- Russian sites will be marked from 131 [format of PID 131AAAAAAA]

NB!: For the HIV+ patients that will also have whole blood samples collected, patient identification code should match the code indicated on the blood samples!

CARE enrolment

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: 0

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

Enter a new or existing Center/patient code: 1300000001



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

CARE enrolment

Record Home Page

Record "1300000001" 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: 1300000001




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 - Plasma Samples Resistance and Screening	●
Section C1 - Antiretroviral Treatment	●
Section C2 - Risk of Cardiovascular Disease and Diabetes	●
Section C3 - Treatment Against Hepatitis C	●
Section C4 - Tuberculosis	●
Section D - Severe Opportunistic Infections and Sexually Transmitted Infections	●
Section E - Clinical Events	●
Status	●




CHANGE LANGUAGE


Once you have created patient record, you can switch between English and Russian version. Press Blue button in the top right corner of the section.

CARE enrolment

Actions:  Download PDF of instrument(s)  Share instrument in the Library  VIDEO: Basic data entry

 **Section A1 - Demography and HIV-status**

Assign record to a Data Access Group? -- select a group -- **English**

 Adding new Center/patient code: 1300000001

Center/patient code: 1300000001




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 an error will be displayed and you will not be allowed to continue.

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


Unknown dates:
(yyyy-mm-??) If only the day is unknown, use the 15th and then the known month and year. (yyyy-mm-15) For example unknown day in September 2007: 2007-09-15.
(yyyy-??-??) If both day and month are unknown, use the 1st July and then the known year. (yyyy-07-01) For example unknown day and month in 2011: 2011-07-01.
(????-??-??) If both day, month and year are unknown, use the 11th November 1911. i.e. 1911-11-11.

CARE enrolment

Actions:  Download PDF of instrument(s)  Share instrument in the Library  VIDEO: Basic data entry

 **Section A1 - Demography and HIV-status**

Assign record to a Data Access Group? -- select a group -- **Russian**

 Adding new Center/patient code: 1300000001

Center/patient code: 1300000001

Инструкции по вводу данных

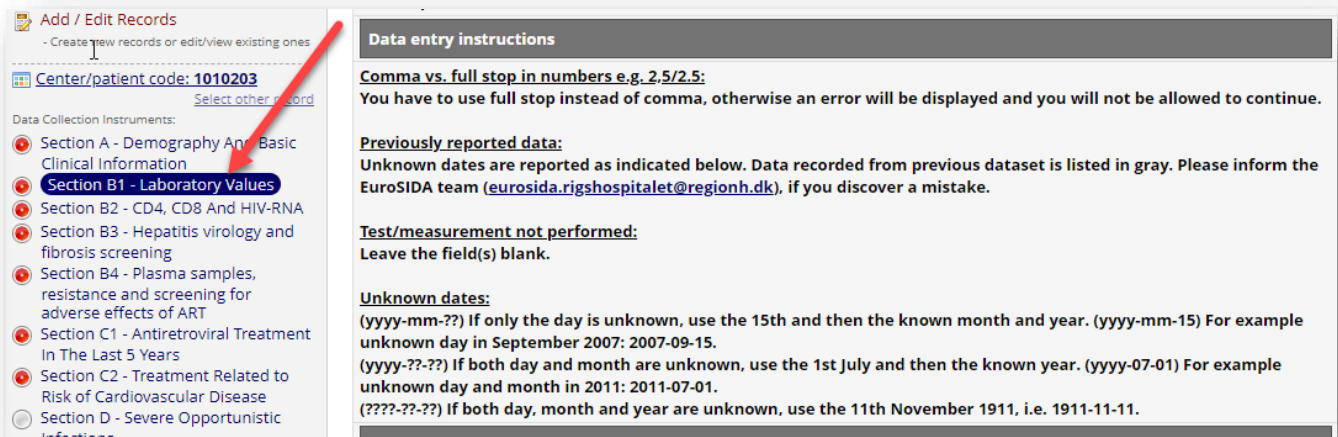
Запятая или точка в числах, напр. 2,5/2.5:
Вы должны использовать точку вместо запятой, в противном случае появится сообщение об ошибке, и вы не сможете продолжить заполнять форму.

Тест/измерение не выполнено:
Оставьте поле/поля незаполненными.



ENTER DATA INTO THE PATIENT RECORD

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



Add / Edit Records
- Create new records or edit/view existing ones

Center/patient code: **1010203**
[Select other record](#)

Data Collection Instruments:

- Section A - Demography And Basic Clinical Information
- Section B1 - Laboratory Values**
- Section B2 - CD4, CD8 And HIV-RNA
- Section B3 - Hepatitis virology and fibrosis screening
- Section B4 - Plasma samples, resistance and screening for adverse effects of ART
- Section C1 - Antiretroviral Treatment In The Last 5 Years
- Section C2 - Treatment Related to Risk of Cardiovascular Disease
- Section D - Severe Opportunistic Infections

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 an error will be displayed and you will not be allowed to continue.

Previously reported data:
Unknown dates are reported as indicated below. Data recorded from previous dataset is listed in gray. Please inform the EuroSIDA team (eurosida.rigshospitalet@regionh.dk), if you discover a mistake.

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

Unknown dates:
(yyyy-mm-??) If only the day is unknown, use the 15th and then the known month and year. (yyyy-mm-15) For example unknown day in September 2007: 2007-09-15.
(yyyy-??-??) If both day and month are unknown, use the 1st July and then the known year. (yyyy-07-01) For example unknown day and month in 2011: 2011-07-01.
(????-??-??) If both day, month and year are unknown, use the 11th November 1911, i.e. 1911-11-11.

or the Record Status Dashboard:

Center/patient code:	Section A - Demography And Basic Clinical Information	Section B1 - Laboratory Values	Section B2 - CD4, CD8 And HIV-RNA	Section B3 - Hepatitis virology and fibrosis screening	Section B4 - Plasma samples, resistance and screening for adverse effects of ART	Section C1 - Antiretroviral Treatment In The Last 5 Years	Section C2 - Treatment Related to Risk of Cardiovascular Disease	Section D - Severe Opportunistic Infections	Section E - Events	Status
1010201										
1010203										
1010204										
1010206										
1010207										
1010208										

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.



Comma vs. full stop

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

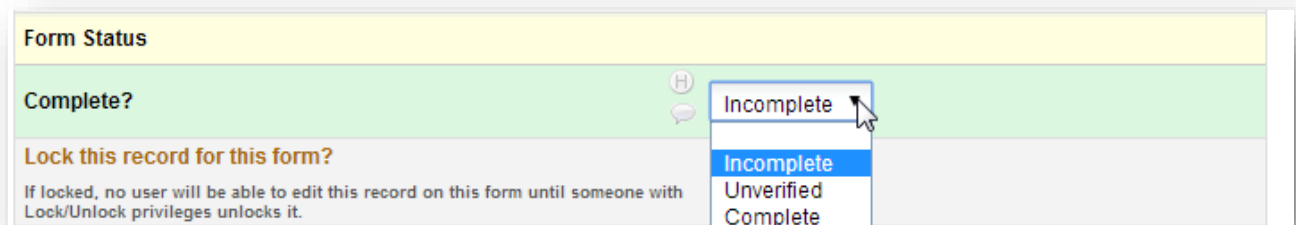


2. Select status at the bottom of the form/section.

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.

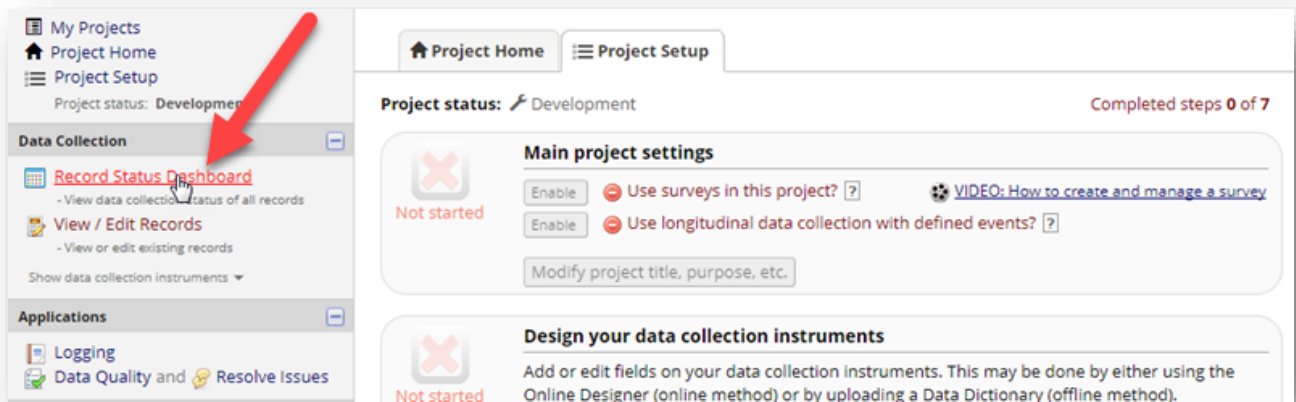
Complete: The form/section contains all available data.



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



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

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Legend for status icons:

- Incomplete
- Incomplete (no data saved) ?
- Unverified
- Complete

Dashboard displayed: [Default dashboard] [Create custom dashboard](#)

Displaying Data Access Group: -- ALL --

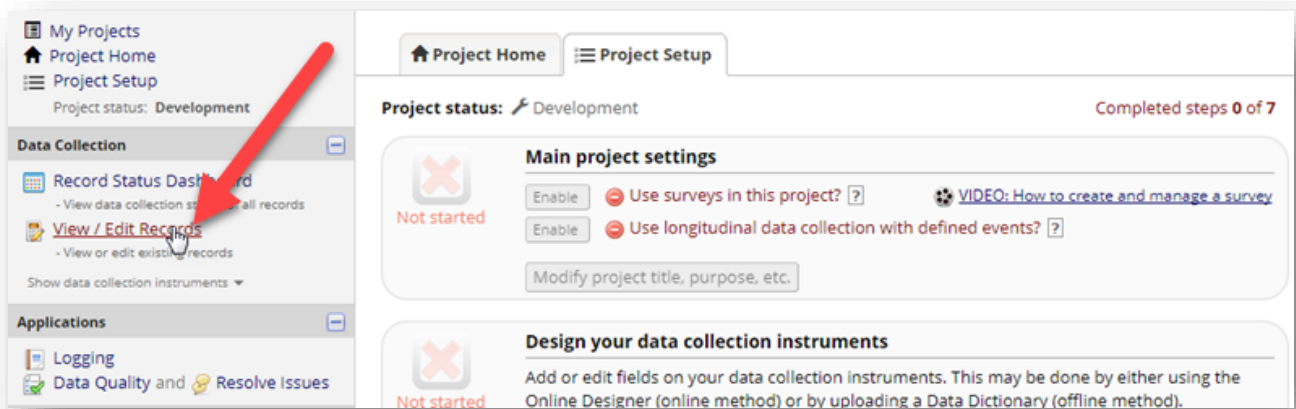
Displaying record: Page 1 of 118: "1010201" through "1011013" of **11,753** records

100 records per page

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#) Table not displaying properly ?

Center/patient code:	Section A - Demography And Basic Clinical Information	Section B1 - Laboratory Values	Section B2 - CD4, CD8 And HIV-RNA	Section B3 - Hepatitis virology and fibrosis screening	Section B4 - Plasma samples, resistance and screening for adverse effects of ART	Section C1 - Antiretroviral Treatment In The Last 5 Years	Section C2 - Treatment Related to Risk of Cardiovascular Disease	Section D - Severe Opportunistic Infections	Section E - Events	Status
1010201	●	●	●	●	●	●	●	●	●	●
1010203	●	●	●	●	●	●	●	●	●	●

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



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

Total records: **11,535**

Incomplete Records (11535)	-- select record --
Complete Records (0)	-- select record --

Enter a new or existing Center/patient code:

Data Search

Choose a field to search
(excludes multiple choice fields)

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

1010201
1010203
1010204
1010206
1010207
1010208
1010210
1010212
1010213
1010214
1010215
1010217
1010218
1010219
1010221
1010223
1010226
1010227
1010228

Show Unverified Records above

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

Total records: **11,535**

Incomplete Records (11535)	-- select record --
Complete Records (0)	-- select record --

Enter a new or existing Center/patient code:

9999999

Show Unverified Records above

SAVE OR PRINT RECORD FOR YOUR OWN USE.

If you wish to download your reported data from REDCap, please contact the coordinating centre at : care.rigshospitalet@regionh.dk, detailing which forms or data you wish to download.

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

Лабораторные данные

Сдавал ли пациент анализы на содержание протеинурии, АЛТ, АСТ, альбумина, билирубина, тромбоцитов, сывороточного креатинина, общего холестерина, ЛПВП, ЛПНП, триглицеридов в сыворотке крови, гликогемоглобина, глюкозы плазмы, гемоглобина и/или МНО?

***обязательное значение**

☒ Нет
☐ Да
☐ Неизвестно

reset

- If the patient has died and no new data is available, please indicate this in Section A of the CARE enrolment form and complete the final Status Section.
- 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.