



Rigshospitalet



PreVent-ACaLL

REDCap Guide

Version 3.0

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1 Introduction

REDCap is a secure web platform for building and managing online databases. In the PreVent-ACaLL study, each site must use REDCap to enter study data and report serious adverse events and protocol deviations to sponsor. The two projects available in REDCap are:

1. PreVent-ACaLL – pre-screening
2. PreVent-ACaLL – low risk/observation/treatment

In the first project, pre-screening data must be entered for each participant who has signed the pre-screening informed consent. It is also in this project the CLL-TIM algorithm is run and the participants are randomized if screening result is high risk/high confidence and the patient has signed the informed consent to the main part of the study. The second project is developed to report study data for the enrolled participants incl. those in the low risk category (screen failures).





2 REDCap Access

To request REDCap access, you must write to: chip-prevent.rigshospitalet@regionh.dk. Remember to include name, role in the study, email address and site of the person who requires access. Once access has been granted the user will receive an email with username and a link to set password. The login details for REDCap are personal and must not be shared. Below you find the study specific REDCap link.

REDCap Log In webpage: <https://www.chip-crf.info/redcap/index.php>

REDCap®

Log In

Please log in with your user name and password. If you are having trouble logging in, please contact [CHIP - Centre for Health & Infectious Disease Research](#).

Username:

Password:

[Forgot your password?](#)

Welcome to REDCap!

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Learn more about REDCap by watching a [brief summary video \(4 min\)](#). If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the [Training Resources](#) page.

NOTICE: If you are collecting data for the purposes of human subjects research, review and approval of the project is required by your Institutional Review Board.

If you require assistance or have any questions about REDCap, please contact [CHIP - Centre for Health & Infectious Disease Research](#).

REDCap Features

Build online surveys and databases quickly and securely in your browser - Create and design your project using a secure login from any device. No extra software required. Access from anywhere, at any time.

Fast and flexible - Go from project creation to starting data collection in less than one day. Customizations and changes are possible any time, even after data collection has begun.

Advanced instrument design features - Auto-validation, calculated fields, file uploading, branching/skip logic, and survey stop actions.

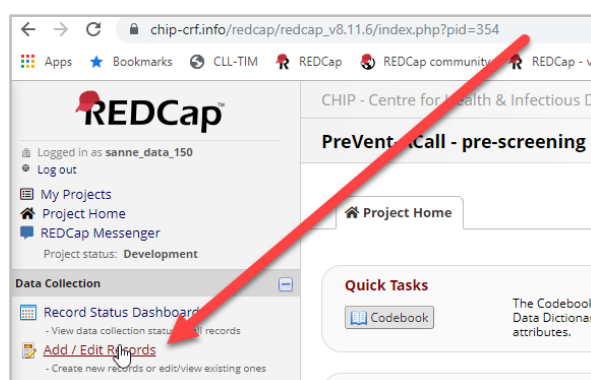
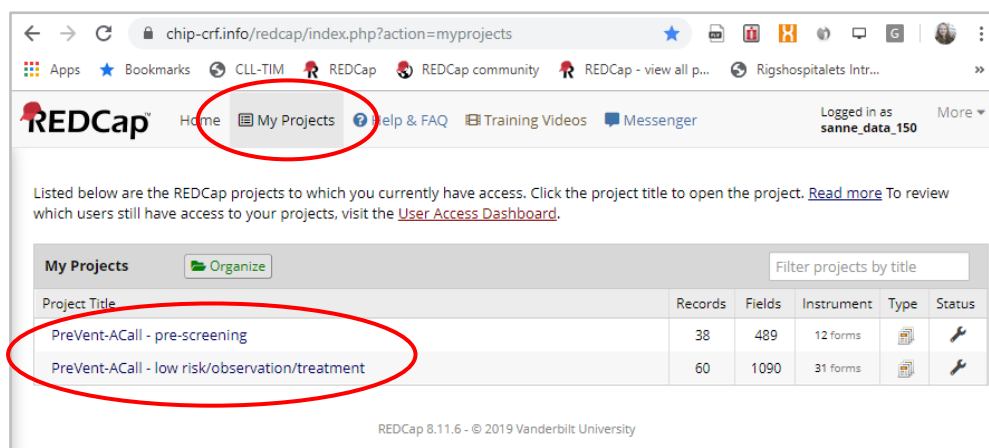
Diverse and flexible survey distribution options - Use a list of email addresses or phone numbers for your survey respondents and automatically contact them with personalized messages, and track who has responded. Or create a simple link for an anonymous survey for mass email mailings, to post on a website, or print on a flyer.

Data quality - Use field validation, branching/skip logic, and Missing Data Codes to improve and protect data quality during data entry. Open data queries to automatically identify and resolve discrepancies and other issues real-time.

Custom reporting - Create custom searches for generating reports to view aggregate data. Identify trends with built-in basic statistics and charts.

3 How to create a new participant/retrieve PID number

When logged in, the two PreVent-ACaLL projects can be found under *My projects*. All participants must be created in the “PreVent-ACaLL – pre-screening” project. NEVER create a new participant in the “PreVent-ACaLL – low risk/observation/treatment” project.



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, click the button below.

Total records: 25

Choose an existing Record ID

+ Add new record







1. Click on the “PreVent-ACaLL – pre-screening” project
2. Click *Add / Edit Records* in the left-hand menu
3. Click on the green button *+ Add new record*

A new record will automatically be assigned to the patient with a unique record identification (ID) number. This record ID is the patient’s participant ID (PID) during the entire trial.

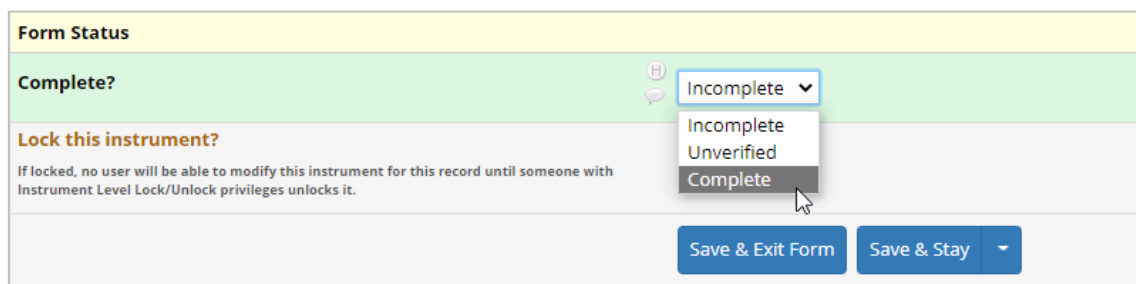
4 Data reporting in general

Each record ID/PID will have a data collection instrument that consists of different electronic case report forms (eCRFs). To open one of these forms, click on the status icon. The status icon is grey if no data is saved yet and turns red if some data is saved in the form.

Legend for status icons:

 Incomplete	 Incomplete (no data saved) ?
 Unverified	 Many statuses (all same)
 Complete	 Many statuses (mixed)

Data does not have to be reported into the forms chronologically. Once all data have been entered, the form status must be changed to *Complete* and the form must be saved. The status icon will now change to green.



4.1 Estimated date and time

Specific dates and timepoints should always be written if REDCap requires, however sometimes these can be unknown and in these cases, following estimates must be done:

Unknown date for medical history

In case date is unknown when reporting medical history for the participant (in the eCRF named medical history), an estimated date of 01 January the year before enrollment should be entered as the date.

Unknown time point

In case a time point is unknown 00:00 must be written.

4.2 How to use barcode scanner in REDCap

Barcode scanner model: GryphonTM GD4500

1. Plug in the barcode scanner in your computer (via USB).
The scanner will hereafter make a “bip” sound and a red scanning light will appear.
2. Open REDCap and log in to your account.
It does not matter if you plug in the barcode scanner before or after you have logged into REDCap.
3. Open the eCRF you want to scan the barcode data into.
4. Place the computer marker in the barcode field.
5. Scan the barcode by pointing the red lighted scanning arena at the barcode and press on the scanner’s button. The scanner will make another “bip” sound.
6. The barcode/sample ID should now be registered into the field.
7. Remember to save the eCRF when done with entering/scanning the data.

If the barcode/sample ID is not registered correctly in REDCap (exactly as written on the barcode), please inform sponsor via email: chip-prevent.rigshospitalet@regionh.dk

5 Queries

Queries will be created in REDCap in case data resolution is needed. This can be done by sponsor or by monitor. Queries will be assigned to a specific person in REDCap when the query is created. This person will be notified about the query through a REDCap message or by email. Make sure to check spam/unwanted email folder.

To avoid unnecessary queries, please delete incorrectly entered data in branched fields before changing the response to the data field.

6 The Pre-screening project










In the pre-screening project, all the pre-screening data needed to run the CLL-TIM algorithm must be entered. In the picture below, you can see all the eCRFs for the pre-screening project. The eCRFs within the red square below are the eCRFs containing pre-screening data (data that are used in the CLL-TIM algorithm). When all pre-screening data has been entered, the CLL-TIM algorithm can be run in the eCRF "CLL-TIM assessment". Rest of the eCRFs are used after the participant has been pre-screened and only if the result from the pre-screening is high risk/high confidence.

Record Home Page














 **Record "25" is a new Record ID.** 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. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

-  Incomplete
-  Incomplete (no data saved) 
-  Unverified
-    Many statuses (all same)
-  Complete
-  Many statuses (mixed)

NEW Record ID 25

Data Collection Instrument	Pre-screening	Repeating forms - DO NOT USE
Pre-screening informed consent, age and sex		
Diagnose confirmation		
IGHV, FISH, TP53 and Coombs/DAT		
Binet stage and familial CLL		
Infection (blood culture) and inflammation		
Vaccine usage and ECOG Performance Status		
Hematology and blood chemistry		
CLL-TIM assessment		
Booking of screening/baseline visit (notification to sponsor)		
Informed consent		
Inclusion and exclusion criteria		
Randomize		
Infections (blood culture)		

6.1 CLL-TIM assessment eCRF

The CLL-TIM algorithm is built into the form “CLL-TIM assessment”. For all patients, please answer the field asking if the algorithm will be run.

The screenshot shows the 'CLL-TIM algorithm' section of a form. It contains two main fields. The first field is 'Will the algorithm be run for this patient?' with a red box around it. Below this field is a red asterisk and the text '* must provide value'. To the right of the field are two radio buttons: 'Yes' (selected) and 'No'. The second field is 'Date CLL-TIM algorithm is run:' with a red asterisk and the text '* must provide value'. To the right of this field is a date input field showing '2021-12-01', a calendar icon, a 'Today' button, and a 'Y-M-D' label. A 'reset' link is visible in the bottom right corner of the section.

To run the algorithm, you must tick off the marked box (see picture below) and click “Save & stay”. When clicking “Save & stay” the algorithm will be run. It might take a few minutes to run the algorithm - please make sure to stay on the page until the algorithm has been run. When finished, the result will be shown and indicate whether the patient’s risk is low or high risk and if the confidence is low or high.

The screenshot shows the 'Running of CLL-TIM algorithm' section of a form. It contains several text blocks and form fields. The first text block is 'Before you run the algorithm: Please make sure that all blood results since informed consent has been entered.' followed by 'Patients will be categorised as either high or low risk.' and 'Please check this box AND click "Save and stay" to run the algorithm that calculates the risk.' Below this is a checkbox labeled 'Please be patient - it might take a few minutes.' which is checked. To the right of this checkbox is a red circle. Below this is a text block: 'Sponsor will be notified once the algorithm has run and sponsor should contact you within 24 hours to let you know whether you can continue to create low risk patient or randomize.' Below this are two rows of radio buttons: 'Confidence:' with 'Low' and 'High' options, and 'Risk category:' with 'Low' and 'High' options. Below these is a yellow bar labeled 'Form Status'. Below the yellow bar is a 'Complete?' field with a dropdown menu showing 'Incomplete'. Below this is a 'Lock this instrument?' field with a checkbox and a 'Lock' button. Below this is a green bar containing three buttons: 'Save & Exit Form', 'Save & Stay' (with a hand cursor over it), and '-- Cancel --'.

The entered data must be verified by sponsor after the algorithm has been run. The data verification will be done within 24 hours. When data has been verified, sponsor will let you know whether you can continue to create the patient in the low risk category or randomize in case patient is in high risk. You can also see if data has been verified by the tick off as the box below.

The screenshot shows a single form field labeled 'Data verified by sponsor:'. To the right of the label is a checkbox which is checked, and it is circled in red.

6.1.1 CLL-TIM result: High risk/high confidence

If the patient's CLL-TIM result is high risk/high confidence, the patient is eligible for study participation and must be contacted to sign the informed consent for the main part of the study (see the instruction

The screenshot shows a REDCap form interface. At the top, a blue box contains the text: "Data has now been checked and verified. This patient is in the HIGH RISK category. Will the patient be enrolled in the study?". To the right of this box are radio buttons for "Yes" (selected) and "No", and a "reset" link. Below this is another blue box with the instruction: "Please complete the informed consent, inclusion and exclusion criteria forms and then **randomize the patient**." A yellow bar labeled "Form Status" follows. Below it, a section titled "Complete?" has a dropdown menu set to "Complete". Another section titled "Lock this instrument?" has a checkbox and a "Lock" button. At the bottom, there are buttons for "Save & Exit Form", "Save & Stay", and a dropdown menu. The dropdown menu is open, showing options: "Save & Go To Next Form" (circled in red), "Save & Exit Record", and "Save & Go To Next Record". A mouse cursor is pointing at the "Save & Go To Next Form" option.

"Enrollment procedure"). Hereafter, the instructions in the eCRF in REDCap must be followed. If the patient is not being enrolled, the patient must be created in the low risk category. If the patient is being enrolled, the eCRFs "informed consent", "inclusion and exclusion criteria" and "randomize" must be completed.

6.1.2 CLL-TIM result: Low risk category

If the patient's CLL-TIM result is either:

- low risk/low confidence
- low risk/high confidence
- high risk/low confidence

the patient must be created in the low risk category, which is done through the eCRF in REDCap.

The screenshot shows a REDCap form interface. A blue box contains the text: "Data has now been checked and verified. This patient is in the LOW RISK category and should NOT be randomized. However we do collect survival status, CLL treatment and infection data on low risk patient every 6 months." Below this text, the link "Create patient in low risk category" is circled in red.

7 Notification of study visit date to sponsor

Electronic CRF: Booking of study visit (notification to sponsor)

For those study visits where study specific samples are collected from the participant, sponsor must be notified about date and time for when the specific study visit takes place. Study visits where study specific samples are collected are:

- Screening/baseline
- C1D8 (treatment arm only)
- C1D15 (treatment arm only)
- C2D1
- C3D1
- 12 weeks after C1D1 /
End of treatment
- 24 weeks after C1D1
- 1 year after C1D1
- 2 years after C1D1
- Progressive Disease

C2D1							
Booking of study visit (notification to sponsor)	Adverse Events	Dose modifications	Medications, procedures and immunoglobulins (concomitant and AE)	Physical examination, clinical response and lab values	Quality of Life	Study samples shipped to central labs	Biobank CLL Lab (Rigshospitalet)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

When date and time has been entered into the form and the form status is changed to *Complete* and saved, sponsor will automatically be notified about the study visit date and time. Sponsor will hereafter book courier to pick-up the study samples at site for the same date as the study visit.

Form Version 2.0

Form Description

The purpose of this form is to notify sponsor about the participant's study visit date.

The form must be filled out when date and time of the participants study visit is known.

Sponsor is automatically informed when form status is changed to **Complete** and the form is saved.

When sponsor has been notified, sponsor will book courier to pick up the study samples at site.

Form details

Completed by:

jvol0009

Date:

2022-12-09

Y-M-D

Study visit information

Date and time of C2D1 study visit:

2022-12-09 14:27

Now

Y-M-D H:M

* must provide value

Comments to data in this form:

Expand

Please remember to change form status to **Complete** and **save form** in order to send notification to sponsor.

Form Status

Complete?

Complete

8 The Low risk/observation/treatment project

Important: Patients must NEVER be created in the “PreVent-ACaLL – low risk/observation/treatment” project using the *Add new record* button. The auto-number functionality is enabled, and the patient will therefore not get the same participant/record ID as in pre-screening project. Patients should therefore always be added via links in the CLL-TIM assessment eCRF or randomization eCRF in the pre-screening REDCap project.

Low risk: To create a patient in the low-risk category, you should open the form “CLL-TIM assessment” and create the patient in the low-risk category after data has been verified by sponsor (see previous page).

Observation/treatment: To create a patient in the high-risk category, you should fill out the forms “Informed consent” and “Inclusion and exclusion criteria”. In case patient is eligible for enrollment and have signed the informed consent to the main study, the patient should be randomized in the form “Randomize”. After randomization, you can create the patient in the arm the patient has been randomized to: observation or treatment.


















































































This patient has been randomized to the OBSERVATION arm.

[Create patient in observation arm](#)

This patient has been randomized to the TREATMENT arm.

[Create patient in treatment arm](#)

After clicking on one of the two links, a screen as the picture below will appear. Click on the eCRF’s status icon to report data in the form. **Important:** Even though you are not ready to enter data, you should always access one of the forms and click save – otherwise the data collection instrument will not be created in the project.

NEW Record ID 45 Arm 3: Observation														
Data Collection Instrument	(Serious-/) Adverse event	Protocol deviations	Screening	C1D1	C2D1	C3D1	End of treatment	24 weeks after C1D1	9 months after C1D1	1 year after C1D1	1 year and 3 months after C1D1	1 year and 6 months after C1D1	1 year and 9 months after C1D1	2 years after C1D1
Patient information														
Vaccine usage and binet stage														
ECOG Performance Status														
CCI, CIRS, ECG and TLS risk category														
Medical history														
Adverse Events														
Medications, procedures and immunoglobulins (concomitant and AE)														
Physical examination, clinical response and lab values														
Quality of Life														
Biobank														
Patient samples shipped to central lab														
Biobank - Rigshospitalet														
Hepatitis B and C														
Bone marrow														
Serious adverse event														

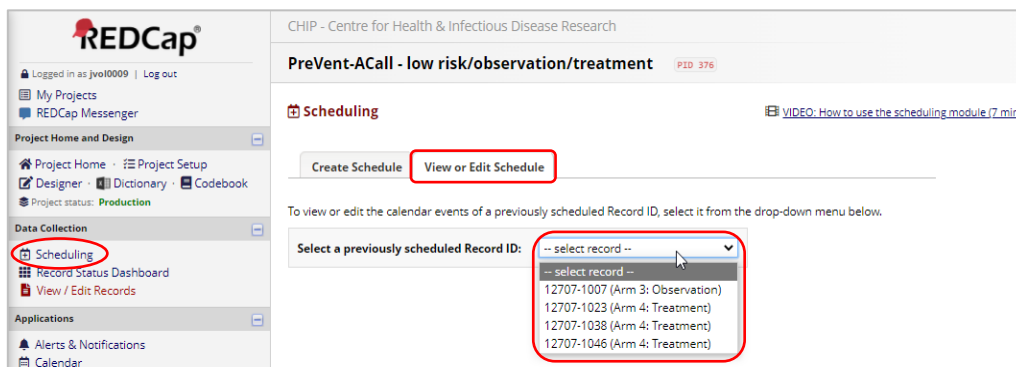
8.1 How to automatically create visit schedule

In the “PreVent-ACaLL – low risk/observation/treatment” project, study visits can automatically be scheduled for each participant once the C1D1 date has been entered in the “Physical examination and clinical response” form. **Important: Do NOT use the create schedule function since the schedule will be automatically created as soon as you have entered the C1D1 date.**

8.1.1 How to view or edit visit schedule for a participant

To get an overview of all scheduled study visits for one participant:

1. Click **Scheduling** in the left-hand menu
2. Click on **View or Edit Schedule** and select the participants record ID



Study visit schedule

The scheduled study visit can be changed by clicking on the small pen icon to the left.

By clicking on the small loop, a new window will pop-up, which shows more details on the visit, e.g. data entry forms to be reported and notes to the study can be written if necessary.

	Time	Date / Day of Week Y-M-D	Event Name	Status	Notes
		1994-05-31 Tuesday	Serious Adverse event	☆ Due Date	
		1994-06-02 Thursday	Screening	☆ Due Date	
		2021-10-14 Thursday Range: 2021-10-10 - 2021-10-18	C1D1	☆ Due Date	
		2021-10-22 Friday Range: 2021-10-18 - 2021-10-26	C1D8	☆ Due Date	
		2021-10-29 Friday Range: 2021-10-25 - 2021-11-02	C1D15	☆ Due Date	
		2021-11-05 Friday Range: 2021-11-01 - 2021-11-09	C1D22	☆ Due Date	
		2021-11-11 Thursday Range: 2021-11-07 - 2021-11-15			
		2021-12-09 Thursday Range: 2021-12-05 - 2021-12-13			
		2022-01-06 Thursday Range: 2022-01-02 - 2022-01-10			
		2022-03-31 Thursday Range: 2022-03-27 - 2022-04-04			
		2022-07-15 Friday Range: 2022-07-08 - 2022-07-22			
		2022-10-14 Friday Range: 2022-10-07 - 2022-10-21			
		2023-01-12 Thursday Range: 2023-01-05 - 2023-01-19			
		2023-04-13 Thursday Range: 2023-04-06 - 2023-04-20	1 year and 6 months after C1D1	☆ Due Date	
		2023-07-13 Thursday Range: 2023-07-06 - 2023-07-20	1 year and 9 months after C1D1	☆ Due Date	
		2023-10-14 Saturday Range: 2023-10-07 - 2023-10-21	2 years after C1D1	☆ Due Date	
		2024-04-14 Sunday Range: 2024-03-31 - 2024-04-28	Long-term follow-up 1	☆ Due Date	

View/Edit Calendar Event
Record ID: 12707-1046 [view schedule](#)
Data Access Group: 12707 (Rigshospitalet)
Event Name: 1 year and 3 months after C1D1 (Arm 4: Treatment)
Status: ☆ Due Date [change status](#)
Date: 2023-01-12 (Thursday)
Time: HH:MM [Save Time](#)
Notes: [Save Notes](#)
[Delete from Calendar](#)

Data Entry Forms

- Adverse Events
- Medications, procedures and immunoglobulins (concomitant and AE)
- Physical examination, clinical response and lab values
- Long-term / discontinuation follow up

8.1.2 How to view scheduled study visits for all participants

To get an overview of all scheduled study visits for all participants:

1. Click **Calendar** in the left-hand menu
2. As needed, browse the Day, Week, Month or Agenda tabs

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Calendar [VIDEO: How to use the calendar \(7 min\)](#)

The Calendar application can be used as a project calendar within this project to help organize your schedule and keep track of any upcoming events. It will allow you to add or modify calendar events and then view them either in a daily, weekly, or monthly format below. To add a new note or calendar event to any day, click **+New** at the top of that day's box to begin entering the information. Since you have already defined multiple events for this project, you may additionally [generate a schedule](#) using your pre-defined Events, which will then be added to the calendar.

Day Week **Month** Agenda

January 2022 [Print Calendar](#)

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						+ New 1
+ New 2	+ New 3	+ New 4 12707-1038 (24 w	+ New 5	+ New 6 12707-1046 (E	+ New 7	+ New 8
+ New 9	+ New 10	+ New 11	+ New 12	+ New 13	+ New 14	+ New 15
+ New 16	+ New 17	+ New 18	+ New 19	+ New 20 12707-1023 (1 yea	+ New 21	+ New 22
+ New 23	+ New 24	+ New 25	+ New 26	+ New 27	+ New 28	+ New 29
+ New 30	+ New 31					

8.2 Data reporting in the low risk/observation/treatment project

When you need to report data in an existing record, go to either the *Record Status Dashboard* or click on *Add / Edit Records* in the left-hand menu. In the *Record Status Dashboard*, all transferred pre-screening participants can be seen for all three arms: low risk, observation and treatment. The participants will be listed in rows, while the forms will be listed in columns under each associated study visit.

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 (red circle with exclamation mark)
- Incomplete (no data saved) (grey circle with exclamation mark)
- Unverified (yellow circle with exclamation mark)
- Complete (green circle with checkmark)
- Many statuses (all same) (red circle with exclamation mark)
- Many statuses (mixed) (blue circle with exclamation mark)

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

Displaying Data Access Group: -- ALL --

Displaying record: Page 1 of 1: "14" through "43" of 12 records ALL (12) records per page

[+ Add new record for this arm](#)

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)

Arm 2: Low risk | Arm 3: Observation | Arm 4: Treatment

Record ID	(Serious-/) Adverse event	Protocol deviations	Screening	Physical examination, clinical response and lab values	Quality of Life	Biobank	Patient samples shipped to central lab	Biobank - Rigshospitalet	Hepatitis B and C	Bone marrow	Central Lab - TruCulture incubation
14	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗
15	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗
16	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗
24	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗
25	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗

When clicking *Add / Edit Records*, record ID must be chosen. When done, the Data Collection Instrument for this chosen participant will be shown as picture below. Here the study visits are listed in columns and the eCRFs are listed in rows.

Record ID 14
Arm 3: Observation

Data Collection Instrument	(Serious-/) Adverse event Update at every visit	Protocol deviations Update at every visit	Screening	C1D1	C2D1	C3D1	End of treatment	24 weeks after C1D1	9 months after C1D1	1 year after C1D1	1 year and 3 months after C1D1	1 year and 6 months after C1D1	1 year and 9 months after C1D1	2 years after C1D1
Patient information			⊗											
Vaccine usage and binet stage			⊗											
ECOG Performance Status			⊗				⊗			⊗				⊗
CCI, CIRS, ECG and TLS risk category			⊗											
Medical history			⊗											
Adverse Events				⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗
Medications, procedures and immunoglobulins (concomitant and AE)			⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗

Make sure to change the form status to *Complete* when all data has been reported in the form.

Form Status

Complete?

Incomplete

Incomplete

Unverified

Complete

-- Cancel --

8.3 Specific data reporting: Adverse Events

The eCRF “Adverse Events” must be filled out at every study visit. In the instruction “How to handle AE and SAEs”, the AE definition is stated and it is described when an AE must be reported. The “Adverse Events” eCRF is listed for all study visits.

Record ID 26
Arm 4: Treatment — 12707 (Rigshospitalet)

Table not displaying properly

Data Collection Instrument	(Serious-/) Adverse event Update at every visit	Protocol deviation Update at every visit	Screening	C1D1 2022-11-25	C1D8	C1D15	C1D22	C2D1	C3D1	End of treatment	24 weeks after C1D1	9 months after C1D1	1 year after C1D1	1 year and 3 months after C1D1	1 year and 6 months after C1D1	1 year and 9 months after C1D1	2 years after C1D1
Patient information																	
Booking of study visit (notification to sponsor)																	
Vaccine usage and binet stage																	
ECOG Performance Status																	
CCI, CIRS, ECG and TLS risk category																	
Medical history																	
Adverse Events																	
Dose modifications																	

In the form, all AEs reported so far for this participant will be listed. When reporting a new AE, you must answer “Yes” to the question Any new adverse events since last visit? and click on + Add new.

Adverse events

Any new adverse events since last visit? ☐ No ☒ Yes reset

Show 10 entries Search:

#	Disease/symptom:	If applicable, please specify:	Infection:	Infection, specify:	Blood culture drawn:	Date:	Result:	Bl
1	Kidney infection (Kidney infection)		Yes (1)		No (0)			No (

Showing 1 to 1 of 1 entries Previous 1 Next

[+ Add new](#)

Comments to data in this form

Hereafter a pop-up window will open, which must be completed with data regarding the AE:

COPY for testing***PreVent-ACaLL - low risk/observation/treatment | REDCap - Arbejde - Microsoft...

https://www.chip-crf.info/redcap/redcap_v10.6.8/DataEntry/index.php?pid=390&id=26&ev...

Adverse Events (arm 4)

Editing existing Record ID 26 (Instance #2)

Event Name: **Repeating forms - DO NOT USE (Arm 4: Treatment)**

Record ID 26

Specification

Disease/symptom: * must provide value

You can search for the disease in the field. However the list shown is a limited number of results, so if you do not find the disease you are looking for, you can also browse [CTCAE ontology](#) to find the disease and then enter the term.

IMPORTANT: If you cannot find a suitable term, then please select "General disorders and administration site conditions - Other, specify" and specify in the text field below.

If applicable, please specify: Add additional term for disease, if the selected does not match 100%

AE considered:

Date of onset: * must provide value Today Y-M-D

Serious event: ☐ No ☐ Yes * must provide value [reset](#)

Related to Venetoclax: * must provide value

Related to Acalabrutinib: * must provide value

Outcome: * must provide value

Adjustment of study drug: ☐ No ☐ Yes * must provide value [reset](#)

Any treatment for adverse event necessary: ☐ No ☐ Yes * must provide value [reset](#)

Any treatment / supportive therapy / care (including administration of growth factors, transfusions etc.)

Comments to data in this form

Comments to data in this form: Note: This field should only be used to explain estimated dates or other important information.

Form Status

Complete? Incomplete

Lock this instrument?

If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it. ☐ [Lock](#)

[Save & Exit Form](#) [Save & Stay](#)

8.4 Specific data reporting: Serious Adverse Events

When reporting an AE you will be asked if the event is serious. In case of a serious event you must ALSO fill out an Serious Adverse Event form.

Serious event:
* must provide value

☐ No ☒ Yes

reset

Please remember to ALSO fill in a "Serious adverse event" form.

The eCRF "Serious adverse event" must be filled out if a participant develops a serious adverse event (SAE). All SAEs should also have an AE eCRF. The SAE definition is stated in the instruction "How to handle AE and SAEs".

All SAEs must be reported in the eCRF within 24 hours from awareness.

The "Serious adverse event" eCRF can be found in the beginning of the data collection instrument.

For each new SAE, a new eCRF must be created. When one SAE has been reported, a new eCRF can be created by clicking *+ Add new* in the participants Data Collection Instrument.

Record ID **26**
Arm 4: Treatment — 12707 (Rigshospitalet)

Data Collection Instrument	+ Add new (Serious-/) Adverse event Update at every visit	Protocol deviation Update at every visit	Screening	C1D1 2022-11-25
MRD-Flow result			<input type="radio"/>	
Hepatitis B and C			<input type="radio"/>	
Bone marrow (biopsy and aspirate local)			<input type="radio"/>	
Serious adverse event	<input checked="" type="radio"/>			

In this form, data on the SAE must be reported and linked to the related AE (indicated below).

Initial SAE report

Date of initial report:
* must provide value

Specification

Serious adverse event:
* must provide value

SAE considered:

Infection:
* must provide value

☐ No ☒ Yes

Bleeding:
* must provide value

☒ No ☐ Yes

Cardiac:
* must provide value

☒ No ☐ Yes

Malignancy:
* must provide value

☒ No ☐ Yes

Tumor lysis syndrome (TLS):
* must provide value

☒ No ☐ Yes

8.5 Specific data reporting: Protocol Deviation

The eCRF “Protocol Deviation” must be filled out if a protocol deviation occurs. The eCRF and the instruction ‘Reporting of protocol deviations’ lists which protocol deviations that must be reported for this trial, however these are also listed in the CRF as shown below.

Record ID **26**
Arm 4: Treatment — 12707 (Rigshospitalet)

Data Collection Instrument	+ Add new (Serious-/) Adverse event Update at every visit	Protocol deviation Update at every visit	Screening	C1D1 2022-11-25
officer				
Protocol Deviation		<input type="radio"/>		

Example on Protocol Deviation form (version 1.0) can be seen below.

Reporting

Protocol deviation to report

In all clinical trials, there can be deviations from the protocol. Some deviations are important for the patient's safety or the quality of the trial data. It is your responsibility as a study nurse/PI to report protocol deviations to sponsor. Below you can see which protocol deviations that should be reported to sponsor.

IMPORTANT: Only one protocol deviation per form!
If more than one protocol deviation occurs per participant a new Protocol Deviation form must be created.

Date protocol deviation occurred:
 date Y-M-D

Please tick off which protocol deviation has occurred

- ☐ Patient enrolled into the study even though its been more than 1 year from CLL diagnosis to randomization
- ☐ Patient enrolled into the study even though its been more than 42 days from signed informed consent (main study) to randomization
- ☐ Patient enrolled into the study even though its been more than 14 days from randomization to start of study treatment
- ☐ No pregnancy test result were collected before start of study treatment
- ☐ Collected pregnancy test were older than 7 days before start of study treatment
- ☐ Incorrect dose of study treatment prescribed or dispensed to the participant
- ☐ Participant did not ingest the fully assigned study treatment
- ☐ Participant wants to end study treatment before planned
- ☒ Visit window was not kept within timeframe
- ☐ Study data were collected from the patient before informed consent were signed

reset

Please elaborate:

If deviation revolves around study treatment, then please also note exact dose prescribed/dispensed to participant.

The participant had the 24 weeks study visit within a five day visit window instead of a four day visit window.

Expand

For every new protocol deviation that occurs, a new eCRF must be created. When first deviation has been completed, a new eCRF can be created by clicking on the + button as shown below.

Data Collection Instrument	+ Add new (Serious-/) Adverse event Update at every visit	Protocol deviation Update at every visit	Screening	C1D1 2022-11-25
officer				
Protocol Deviation				

8.6 Specific data reporting: Progressive Disease

If a participant's disease progresses, the eCRFs listed under "Progressive disease" (see below) must be filled out. These can be found after all the long-term follow-up visit forms in the Data Collection Instrument.

Progressive disease									
Booking of study visit (notification to sponsor)	Adverse Events	Medications, procedures and immunoglobulins (concomitant and AE)	Physical examination, clinical response and lab values	Study samples shipped to central labs	MRD-Flow results	Hepatitis B and C	Bone marrow	IGHV, FISH and TP53	New CLL treatment

8.7 Specific data reporting: Long term / Discontinuation follow-up

When the participant has had the last physical study visit (2 years after C1D1), the participant must still be followed with long term study visit every 6 months for additional five years (the participants will be followed for a total of 7 years). These eCRFs are listed in REDCap as shown here:

Long-term follow-up 1	Long-term follow-up 2	Long-term follow-up 3	Long-term follow-up 4	Long-term follow-up 5	Long-term follow-up 6	Long-term follow-up 7	Long-term follow-up 8	Long-term follow-up 9	Long-term follow-up 10
Long term / Discontinuation Follow-up	Long term / Discontinuation Follow-up	Long term / Discontinuation Follow-up	Long term / Discontinuation Follow-up	Long term / Discontinuation Follow-up	Long term / Discontinuation Follow-up	Long term / Discontinuation Follow-up	Long term / Discontinuation Follow-up	Long term / Discontinuation Follow-up	Long term / Discontinuation Follow-up

The data that must be collected at these study visits are survival status, use of alternative CLL therapy and infections (see screenshot below).

Event Name: Long-term follow-up 1 (Arm 4: Treatment)	
Record ID	26
Form details	
Completed by:	<input type="text" value="jvol0009"/>
Date:	<input type="text" value="2023-03-13"/> Y-M-D
Status	
Date of assessment:	<input type="text"/> <input type="button" value="Today"/> Y-M-D
* must provide value	
Survival status:	<input type="radio"/> Alive <input type="radio"/> Dead
* must provide value	
reset	
Infections	
Has the patient had any new infections since last follow-up?	<input type="radio"/> No <input type="radio"/> Yes
* must provide value	
reset	
CLL treatment	
Has the patient had any new CLL treatment since last follow-up?	<input type="radio"/> No <input type="radio"/> Yes
reset	
Comments	
Comments to data in this form:	<input type="text"/> <small>Note: This field should only be used to explain estimated dates or other important information.</small>

If the participant's disease progresses before the last physical study visit: 2 years after C1D1, the participant must still be followed with all remaining study visits – however, only “Long-term / discontinuation follow-up” form should be filled out. These eCRFs can be found in REDCap as the last form underneath all study visit post study visit 12 weeks after C1D1/End of treatment:

1 year and 9 months after C1D1			
Adverse Events	Medications, procedures and immunoglobulins (concomitant and AE)	Physical examination, clinical response and lab values	Long term / Discontinuation Follow-up
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Following message will be shown in all other forms:

You have entered a date for progression before 2 years after C1D1. Please follow the normal visits, but only fill in the Long-term/discontinuation follow-up form.

For all the other eCRFs listed underneath the study visit, please go into the form and change form status to *Complete* and save the form. Hereafter fill out the “Long term / Discontinuation follow-up” eCRF.

8.8 Specific data reporting: Discontinuation / Death

The eCRF "Discontinuation / Death" must be filled out if:

- participant dies
- participant has withdrawn informed consent for the trial verbally or in writing
- PI no longer finds the participant eligible for study participation

It must also be listed in this form whether or not the participant terminated treatment before planned (only relevant for the treatment arm).

Example on a Discontinuation / Death form (version 2.0) can be seen below.

Discontinuation	
This discontinuation / death form has to be submitted: <ul style="list-style-type: none">- in case participant dies- in case participant has verbally or in writing withdrawn consent from the study- in case PI has no longer finds participant eligible for study participation <p>Disease progression should not be registered in this "Study Discontinuation / Death" form. If participant's disease has progressed, please fill out the eCRFs listed under "Progressive Disease".</p>	
Date of discontinuation: <small>* must provide value</small>	<div><div><div>2023-03-13</div><div>31</div><div>Today</div></div><div>Y-M-D</div></div> <p>Please fill in date of first day without treatment.</p>
Date of decision to discontinue:	<div><div><div>2023-03-13</div><div>31</div><div>Today</div></div><div>Y-M-D</div></div> <p>Please fill in if this date is more than 7 days before/after date of discontinuation.</p>
Reason(s) for discontinuation	
Adverse event or intercurrent illness:	<div><div><div>2023-03-13</div><div>31</div><div>Today</div></div><div>Y-M-D</div></div> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>reset</p>
Participant has withdrawn consent:	<div><div><div>2023-03-13</div><div>31</div><div>Today</div></div><div>Y-M-D</div></div> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>reset</p>
Participant has agreed to have data collected via local medical record reviews and/or registries for future infectious events, treatment initiation and survival?	<div><div><div>2023-03-13</div><div>31</div><div>Today</div></div><div>Y-M-D</div></div> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>reset</p>
PI has concluded that participant is no longer eligible for study participation:	<div><div><div>2023-03-13</div><div>31</div><div>Today</div></div><div>Y-M-D</div></div> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>reset</p>
Participant is dead:	<div><div><div>2023-03-13</div><div>31</div><div>Today</div></div><div>Y-M-D</div></div> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>reset</p>
Other:	<div><div><div>2023-03-13</div><div>31</div><div>Today</div></div><div>Y-M-D</div></div> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>reset</p>
Treatment termination	
Participant terminates treatment before planned: <small>* must provide value</small>	<div><div><div>2023-03-13</div><div>31</div><div>Today</div></div><div>Y-M-D</div></div> <p><input type="radio"/> No <input type="radio"/> Yes</p> <p>reset</p>

8.9 Specific data reporting: Low risk participants (arm 2)

All participants pre-screened with a low-risk result will be listed in the Low risk arm (arm 2) when created in the low-risk category. Each participant's Data Collection Instrument will appear as the picture below.

Record ID 12709-1019 Arm 2: Low risk — 12707 (Rigshospitalet)							
Data Collection Instrument	Patient information	Follow-up 1 6 months after screening 2021-12-09	Follow-up 2 12 months after screening	Follow-up 3 18 months after screening	Follow-up 4 24 months after screening	Discontinuation/Death	Repeating forms - DO NOT USE
Patient information	<input checked="" type="radio"/>						
Discontinuation / Treatment termination / Death						<input type="radio"/>	
Low risk follow-up		<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Infections							<input type="radio"/>
CLL treatment							<input type="radio"/>

Low risk data must be reported every 6 months from the participant's pre-screening date. An automatic email notification will be forwarded to the data collector(s) approximately two weeks before data must be entered. The email notification will look like the one below. The link can be used to enter the participant's Data Collection Instrument in REDCap.

>>THIS IS AN AUTOMATED MESSAGE<<

It is time to fill in low risk follow-up data for participant below:

PID: 12709-1019

Date the CLL-TIM algorithm was run: 2021-08-02

https://www.chip-crf.info/redcap/redcap_v9.4.0/DataEntry/record_home.php?pid=376&arm=2&id=12709-1019

Thank you for your help!

Data that must be collected as low-risk data is survival status, infections and use of alternative CLL therapy.

Survival status	
Date of assessment:	<input type="text"/>
* must provide value	
Infections	
Has the patient had any new infections since last follow-up?	<input type="radio"/> No <input type="radio"/> Yes
* must provide value	
CLL treatment	
Has the patient had any new CLL treatment since last follow-up?	<input type="radio"/> No <input type="radio"/> Yes
* must provide value	
Comments to data in this form	
Comments to data in this form:	<input type="text"/>
Note: This field should only be used to explain estimated dates or other important information.	
Form Status	
Complete?	<input type="text" value="Incomplete"/>

8.10 Specific data reporting: TruCulture (local central labs)

TruCulture data reporting in REDCap is only relevant for those sites that are incubating, harvesting and freezing the TruCulture blood sample themselves. For site 12707 and 12708, this is done by Kvalitetskontrolllab at Rigshospitalet, hence this section is not relevant for these sites.

All the TruCulture sample data must be reported in REDCap. Following eCRFs must be completed for each TruCulture blood sample tube received:

TruCulture Blood Sample	TruCulture Stimuli Tubes	Matrix Tubes (Luminex)	Matrix Tubes (Biobank)	Shipment to Rigshospitalet (DK)
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

For all eCRFs: Once all data have been entered, the form status must be changed to *Complete* and the form must be saved. The status icon will then change to green.

It is described in sections below how and what to report for all five TruCulture eCRFs. The data that must be reported is the same data as on the Specimen & Shipping Log for local central lab. It is recommended to enter the data into REDCap a long the way as stated in the TruCulture instruction since barcodes must be scanned into REDCap.

8.10.1 eCRF: TruCulture Blood Sample

In the eCRF “TruCulture Blood Sample”, information about the TruCulture blood sample received from site must be reported.

Form Version 1.0

Form details

Completed by:

Date: Y-M-D

TruCulture (TC) blood sample

Have you received TruCulture blood sample from site? ☒ Yes ☐ No
* must provide value [reset](#)

Date and time TruCulture blood sample was received: Y-M-D H:M
* must provide value

Barcode:
TruCulture blood sample
* must provide value
0 characters remaining
Barcode structure: PAC-TC-XX-XXX

Form Status

Complete?

Lock this instrument?
If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.

8.10.2 eCRF: TruCulture Stimuli Tubes

In the eCRF “TruCulture Stimuli Tubes”, information about the five TruCulture stimuli tubes that are incubated with whole blood must be entered – including storage information about the cell pellets that remains in the TruCulture stimuli tubes after harvest of the supernatant. On the screenshot below you can see how this eCRF looks like.

One form must be completed per stimuli. When first form has been saved, a new form is created by clicking + Add new in the ‘Current instance’ drop down on top of the page or by clicking on the plus button in the Record Status Dashboard or the participant’s Data Collection Instrument.

Form Version 1.0	
Form details	
Completed by:	<input type="text" value="jvoI0009"/>
Date:	<input type="text" value="2022-04-25"/> Y-M-D
TruCulture stimuli tubes	
Please fill out fields below The information you fill out is per TC stimuli tube. Create a new instrument for each TC stimuli tube.	
Choose stimuli of TC tube: * must provide value	<input checked="" type="radio"/> CD3/CD28 <input type="radio"/> LPS <input type="radio"/> R848 <input type="radio"/> POLY I:C <input type="radio"/> NULL reset
Has TruCulture stimuli tube CD3/CD28 been incubated? * must provide value	<input type="radio"/> Yes <input type="radio"/> No reset
Date and time for incubation: * must provide value	<input type="text"/> <input type="button" value="Now"/> Y-M-D H:M
Barcode ID: <i>TC stimuli tube: CD3/CD28</i> * must provide value	<input type="text"/> <small>NB: The barcode should be scanned and not entered manually!</small>
Mark this box if TC stimuli tube CD3/CD28 was hemolyzed after incubation	<input type="checkbox"/>
Storage of TruCulture stimuli tubes	
Please fill out fields below when you are ready to store the tubes in the freezer. The tubes must be placed in a -20 degree C freezer first. When samples are frozen, relocate tubes to a -80 degree C freezer.	
Will TC stimuli tube CD3/CD28 containing cell pellets be stored in freezer? * must provide value	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Date and time for storage of TC tube in freezer: * must provide value	<input type="text"/> <input type="button" value="Now"/> Y-M-D H:M
Box barcode ID: <i>From the box you place TC stimuli tube: CD3/CD28 in.</i> * must provide value	<input type="text"/> <small>15 characters remaining The barcode should be scanned and not entered manually!</small>
Placement in box: <i>TC stimuli tube: CD3/CD28</i> * must provide value	<input type="text"/> <small>3 characters remaining For example: A01</small>

8.10.3 eCRF: Matrix Tubes (Luminex)

In the eCRF “Matrix Tubes (Luminex)”, information about the five matrix tubes containing supernatant for Luminex analysis must be entered – including storage information about when the tubes are being stored in freezer. On the screenshot below you can see how this eCRF looks like.

One form must be completed per matrix tube. When first form has been saved, a new form is created by clicking + *Add new* in the ‘Current instance’ drop down on top of the page or by clicking on the plus button in the Record Status Dashboard or the participant’s Data Collection Instrument.

Form Version 1.0	
Form details	
Completed by:	<input type="text" value="jvol0009"/>
Date:	<input type="text" value="2022-04-25"/> Y-M-D
Matrix tube for biobank	
Please fill out fields below The information you fill out is per matrix tube. Create a new instrument for each matrix tube. <i>A total of 5 matrix tubes: one for each stimuli</i>	
Choose stimuli of supernatant in matrix tube: <small>* must provide value</small>	<input checked="" type="radio"/> CD3/CD28 <input type="radio"/> LPS <input type="radio"/> R848 <input type="radio"/> POLY I:C <input type="radio"/> NULL <small>reset</small>
Has supernatant from TC stimuli tube CD3/CD28 been harvested to a matrix tube? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
Date and time of harvest: <small>* must provide value</small>	<input type="text"/> <input type="button" value="Now"/> Y-M-D H:M
Barcode ID: Matrix tube: CD3/CD28 <small>* must provide value</small>	<input type="text"/> <small>10 characters remaining NB: The barcode should be scanned and not entered manually!</small>
Storage of matrix tubes for Luminex	
Please fill out fields below when you are ready to store the tubes in the freezer. <i>The tubes must be placed in a -20 degree C freezer first. When samples are frozen, relocate tubes to a -80 degree C freezer.</i>	
Will matrix tube CD3/CD28 containing supernatant for Luminex be stored in freezer? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
Date and time matrix tube has been stored in freezer: <small>* must provide value</small>	<input type="text"/> <input type="button" value="Now"/> Y-M-D H:M
Placement in box: Matrix tube: CD3/CD28 <small>* must provide value</small>	<input type="text"/> <small>3 characters remaining For example: A01</small>

8.10.4 eCRF: Matrix Tubes (Biobank)

In the eCRF “Matrix Tubes (Biobank)”, information about the 10 matrix tubes containing supernatant for biobank storage must be entered – including storage information about when the tubes are being stored in freezer. On the screenshot below you can see how this eCRF looks like.

One form must be completed per matrix tube. When first form has been saved, a new form is created by clicking + *Add new* in the ‘Current instance’ drop down on top of the page or by clicking on the plus button in the Record Status Dashboard or the participant’s Data Collection Instrument.

Form Version 1.0	
Form details	
Completed by:	<input type="text" value="jvol0009"/>
Date:	<input type="text" value="2022-04-25"/> Y-M-D
Matrix tube for biobank	
Please fill out fields below The information you fill out is per matrix tube. Create a new instrument for each matrix tube. A total of 10 matrix tubes: two for each stimuli	
Choose stimuli of the matrix tube * must provide value	<input checked="" type="radio"/> CD3/CD28 <input type="radio"/> LPS <input type="radio"/> R848 <input type="radio"/> POLY I:C <input type="radio"/> NULL reset
Has supernatant from TC stimuli tube CD3/CD28 been harvested to matrix tube? * must provide value	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Date and time of harvest: * must provide value	<input type="text"/> <input type="button" value="Now"/> Y-M-D H:M
Barcode ID: <i>Matrix tube: CD3/CD28</i> * must provide value	<input type="text"/> 10 characters remaining NB: The barcode should be scanned and not entered manually!
Storage of matrix tubes for Luminex	
Please fill out fields below when you are ready to store the tubes in the freezer. The tubes must be placed in a -20 degree C freezer first. When samples are frozen, relocate tubes to a -80 degree C freezer.	
Will matrix tube CD3/CD28 containing supernatant for biobank be stored in freezer? * must provide value	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
Date and time matrix tube has been stored in freezer: * must provide value	<input type="text"/> <input type="button" value="Now"/> Y-M-D H:M
Box barcode ID: <i>Matrix tube: CD3/CD28</i> * must provide value	<input type="text"/> 15 characters remaining Barcode from the box you place the matrix tube in. The barcode should be scanned and not entered manually!
Placement in box: <i>Matrix tube: CD3/CD28</i> * must provide value	<input type="text"/> 3 characters remaining For example: A01

8.10.5 eCRF: Shipment to Rigshospitalet (DK)

In the eCRF “Shipment to Rigshospitalet (DK)”, information about shipment of the tubes (TruCulture stimuli tubes and matrix tubes) must be entered. This eCRF must be completed prior to the shipment.

Form Version 1.0	
This form must be filled out when TruCulture tubes (TC stimuli and matrix tubes) are being shipped to Denmark	
Form details	
Completed by:	<input type="text" value="jvol0009"/>
Date:	<input type="text" value="2022-04-25"/> Y-M-D
Shipment to Rigshospitalet (Denmark) at end of study	
Will all the tubes* be shipped to Denmark (Rigshospitalet)?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Partly
* must provide value	reset <small>*TC stimuli tubes containing cell pellets (n = 5) and matrix tubes containing supernatant for Luminex (n = 5) and supernatant for biobank (n = 10).</small>

In case not all tubes are being shipped, it must be reported whether or not the specific tube is being shipped or not (example shown below):

If partly, please choose which samples that are 'Shipped' and which samples that are 'Not shipped'		
	Shipped	Not shipped
TC stimuli tube (CD3/CD28)	<input type="radio"/>	<input type="radio"/>
TC stimuli tube (LPS)	<input type="radio"/>	<input type="radio"/>
TC stimuli tube (R848)	<input type="radio"/>	<input type="radio"/>
TC stimuli tube (POLY I:C)	<input type="radio"/>	<input type="radio"/>
TC stimuli tube (NULL)	<input type="radio"/>	<input type="radio"/>

9 Resolve issues

The resolve issues function can be accessed from the left-hand menu and provides an easy way for e.g. the monitor or sponsor to communicate regarding problems with specific values/data for a specific patient. Here it is also possible to view all queries created in the project.

You are also more than welcome to write to the project email: chip-prevent.rigshospitalet@regionh.dk