eCRF COMPLETION GUIDELINES

Portal vein Obstruction Revascularisation Therapy After Liver transplantation registry

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CRF on paper version 3.0 and date 12-01-2021
Table of Contents

REDcap terminology ........................................................................................................ 3

General eCRF Completion Guidelines ............................................................................. 4
  Login Instructions ............................................................................................................. 4
  Data Entry ....................................................................................................................... 5
  Record status dashboard (general flowchart) ................................................................. 6
  Record Home Page/Subject specific flowchart .............................................................. 6
  Form Status .................................................................................................................... 7
  Data Completion ............................................................................................................. 7
  Dates ............................................................................................................................... 7
  Numbers ......................................................................................................................... 8
  Free Text ....................................................................................................................... 8
  Radio Buttons ............................................................................................................... 8
  Check box ........................................................................................................................ 9
  Go to Next Form (page) / Return to Previous Form (page) ............................................ 9
  Repeating Instruments .................................................................................................. 10
  Repeating Events .......................................................................................................... 11
  Missing data in a single field .......................................................................................... 11
  Missing data for a complete Instrument ....................................................................... 12
  Missing data for a complete Event ............................................................................... 12
  Saving data .................................................................................................................... 12
  Correcting data .............................................................................................................. 12
  Additional Clarifying Data ............................................................................................. 13
  Contact information for questions regarding CRF completion .................................... 13
  Discrepancy Management (Data Resolution Workflow) ............................................... 14
  Resolve issues ............................................................................................................... 14

Panel specific (e)CRF Completion Guidelines ............................................................... 17
  Patient numbers and sites ............................................................................................. 17
  Repeating Instruments .................................................................................................. 17
  Repeating Events ......................................................................................................... 17
<table>
<thead>
<tr>
<th><strong>REDCAP TERMINOLOGY</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm(s)</td>
<td>Groups of Events. Multiple arms can be created when using different treatment groups (control, experimental etc.)</td>
</tr>
<tr>
<td>Branching logic</td>
<td>Fields/questions that are hidden for data entry under certain conditions. For instance, one may want to hide the question “What is the date of written informed consent”? until a YES answer is checked for the previous question: “Was written informed consent obtained?”</td>
</tr>
<tr>
<td>DAG</td>
<td>Data Access Group/site/centre. One can only view the records within the DAG one is assigned to. If not assigned to a DAG one can view all records</td>
</tr>
<tr>
<td>Data Resolution Workflow</td>
<td>The Data Resolution Workflow provides a process for managing and documenting the resolution of issues through so called queries in the REDCap data of a study</td>
</tr>
<tr>
<td>eCRF</td>
<td>Electronic Case Report Form – designed to enter all the data collected during a study</td>
</tr>
<tr>
<td>Event</td>
<td>Visit</td>
</tr>
<tr>
<td>Instrument</td>
<td>CRF page/panel/form</td>
</tr>
<tr>
<td>Form</td>
<td>CRF Page/panel/instrument</td>
</tr>
<tr>
<td>Form Status</td>
<td>Status of the record’s data form completeness, denoted with a color; red – incomplete; yellow- unverified; green – complete; blue – multiple statuses (Survey* responses are denoted with a color and a checkmark; orange – partial survey response; green – complete survey response)</td>
</tr>
<tr>
<td>REDCap</td>
<td>Real time Electromagnetic Digitally Controlled Analyzer and Processor = REsearchDataCapture</td>
</tr>
<tr>
<td>Record</td>
<td>Subject/patient</td>
</tr>
<tr>
<td>Record Status Dashboard</td>
<td>Overview of all Events, Instruments per Record (subject)</td>
</tr>
</tbody>
</table>
GENERAL ECRF COMPLETION GUIDELINES

Login Instructions

To be able to log in into REDCap you should have a REDCap account (accounts can be requested by the study coordinator). REDCap account has been created you will automatically receive an e-mail with the login instructions.

You can log in via [https://redcap.umcg.nl](https://redcap.umcg.nl) (users within the UMCG).

For users outside the UMCG the login procedure is equal, with the addition that a second authorization has to take place as well (two-step verification). This authorization means that, after entering your username and password into REDCap, an e-mail will be automatically sent to you with a temporary code. This code has to be entered as well to be able to log in.

**REDCap login screen**

Another way to generate a temporary code (instead of via e-mail) is the Google Authenticator app, available for both Android and Iphone. Contact the REDCap administrator for further instructions on how to enable this option for obtaining the secondary code.
As soon as you are logged in, you will see the table “My Projects”. All REDCap projects for which you have access to are listed in this table under “Project Title”. Click on the project title Portal vein Obstruction Revascularisation Therapy After Liver transplantation registry (PORTAL registry).

Newflash!

There is an updated version available of the COVID-19 CORE and RAPID Case Report Form, released on February 2, 2021. We have created a project template for both CRFs and they are now available in the Project Template List which can be used when a New Project is created/requested. For any further information or material like the CRF in pdf format with highlighted changes, please get in touch with us at imo-servicedesk@umcg.nl

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project.

Dashboard pages:
- User Access Dashboard
- Sponsor Dashboard (R Users)

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Records</th>
<th>Fields</th>
<th>Instruments</th>
<th>Type</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CURSST48</td>
<td>0</td>
<td>63</td>
<td>2 forms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portal vein Obstruction Revascularisation Therapy After Liver transplantation registry (PORTAL registry)</td>
<td>10</td>
<td>325</td>
<td>4 forms</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data Entry

To add or edit a subject/patient, select “Add/Edit Records” in the “Data Collection” table on the left side of the screen.

Note: study specific information on how to create subject/patient numbers can be found below in chapter “Panel specific eCRF Completion Guidelines” – section: patient numbers

To adjust a subject/patient number, select the record it concerns (via Add/Edit Records - Choose an existing Patient number – select your subject/patient). The Record Home Page will appear. Go to “Choose action for record” and select “Rename record” from the dropdown menu. Change the subject/patient number and click on the “Rename record” button.
Record status dashboard (general flowchart)
To view all subjects/patients of the study and all Events and Instruments, select “Record Status Dashboard” in the “Data Collection” table on the left side of the screen.

![Record Status Dashboard](image)

**Legend for status icons:**
- Incomplete
- Incomplete (no data saved)
- Unverified
- Complete
- Many statuses (same)
- Many statuses (mixed)

**Record Home Page/Subject specific flowchart**
As soon as you have created or selected a record/subject/patient, you will see a record/subject/patient specific flowchart.

![Record Home Page](image)

**Legend for status icons:**
- Incomplete
- Incomplete (no data saved)
- Unverified
- Complete
- Many statuses (same)
- Many statuses (mixed)
Form Status
At the end of every instrument you will find the Form Status. A dropdown field is present with the options: Incomplete (default status), Unverified and Complete. Please make sure that you will manually set the Form Status to “Complete” for every instrument that has been filled in. If not all data is present yet for the applicable instrument the status can remain “Incomplete”.

Data Completion
Dates
It is not possible to enter partial dates in REDCap. Also, it is not possible to leave an empty date section. If date is not (completely) known, if the complete date is missing / unknown then please fill in a comment for this in the Field Comment Log ( ). You can enter your comment on the left side of every field that is present in an instrument.

As soon as you click on an icon as shown above, the Data Resolution Workflow screen will appear. The default selected option: “Verified data value” can remain ticked. Fill in your comment and press the “Verified data value” button after that.
Numbers
Numerical values are checked against the field definition when being entered. If the entered value does not comply with the definition, a pop-up will appear (e.g. where a number is expected and text is entered).

Free Text
Please use precise medical terminology. Common medical abbreviations are acceptable. Answers should be provided in English.

Radio Buttons
Radio buttons are used to make a selection from a predefined number of options. You select the correct answer with a mouse click. To reselect a different answer, click on the new button you wish to choose. To clear the selection, click on “reset” (in blue at the right side of the page).

Note
The average time to finish the database for one patient is about 30-45 minutes.
Check box
Ticking a check box means YES. When you leave the Check box blank the answer will be interpreted as NO.
A mouse click will activate the box, to clear the selection, please repeat the mouse click.

Go to Next Form (page) / Return to Previous Form (page)

Go to Next Form (page)
As soon as you have selected a record (subject/patient) and an instrument you will always be able to go to the next form (=page) by clicking on the blue button at the bottom of each instrument; “Save & Go to Next Form”.
Note: if you click on “Save & Go to Next Record”, you will go the next subject/patient and NOT the next form/page.

Return to Previous Form (page)
There is no button present in REDCap to return to previous form (page). However, you will be able to go back to the previous form (page) by clicking on the Instrument you would like to return to, on the left side of the screen, below “Data Collection Instruments”.
Repeating Instruments

For some instruments (panels) it cannot be defined in advance how much data will have to be collected, e.g. repeating interventions. In order to allow unlimited entry of data, it is possible to add additional pages. These instruments are indicated as “Repeating instruments”.

The procedure for repeating instruments can be done as follows:

- Go to the applicable subject/patient and the applicable Instrument. Click on the subject and enter data. After all data has been filled in, click on “Save & Add New Instance”. OR;
- Click on (+) next to the instrument under Record Home Page.

The second instance will be ready to be filled in.

**Record Home Page**

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.

![Record Home Page Grid]

**Legend for status icons:**
- Incomplete (no data saved)
- Unverified
- Many statuses (all same)
- Complete
- Many statuses (mixed)

**Record ID 1**

<table>
<thead>
<tr>
<th>Data Collection Instrument</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASELINE</td>
<td></td>
</tr>
<tr>
<td>CLINICAL CHARACTERISTICS AT DIAGNOSIS</td>
<td></td>
</tr>
<tr>
<td>TREATMENT INFORMATION</td>
<td></td>
</tr>
<tr>
<td>FOLLOW-UP</td>
<td></td>
</tr>
</tbody>
</table>

**Repeating Instruments**

<table>
<thead>
<tr>
<th>CLINICAL CHARACTERISTICS AT DIAGNOSIS (1)</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Add new</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TREATMENT INFORMATION (1)</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Add new</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FOLLOW-UP (1)</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Add new</td>
<td></td>
</tr>
</tbody>
</table>
Missing data in a single field
Complete all questions on every instrument unless otherwise instructed.

A field that is left open but should have been filled in (required) will result in a query (a pop-up will appear with a note that indicates that required field(s) has/have not yet been filled in) which has to be answered by the site and forwarded to the data manager.
If the field was erroneously left open, you can still fill in this field. (Click on “Okay” in the query/pop-up and complete the field).
If the field was left open because the data is indeed missing, please fill in a comment for this in the Field Comment Log ( ). You can enter your comment on the left side of every field that is present in an instrument. You can fill in this comment on the left side of every field in an instrument. The query (pop-up) that still appears indicating that data is missing can be ignored after that. (Click on “Ignore and leave record” or “Ignore and go to next form”). Don’t forget to set Form Status to “Complete”.
**Missing data for a complete Instrument**

If a whole instrument was not performed, please follow these instructions:

Open the applicable instrument and fill in a comment in the Data Resolution Workflow for the very first field of the instrument. Indicate reason there for the instrument not being performed.

All other fields of the instrument can be left open/blank. Query (pop-up) that will appear, indicating that required fields are not filled in, can be ignored. (Click on “Ignore and leave record” or “Ignore and go to next form”). Don’t forget to set Form Status to “Complete”.

**Missing data for a complete Event**

If a whole Event was not performed, please follow these instructions:

Open the Visit instrument of the applicable Event and tick the box “Not Done” and fill in reason for this in the field “Specify reason for not performing visit” that will appear as soon as Not Done has been ticked.

All other instruments of this Event can be left open/blank. Status: incomplete (no data saved) (color grey).

**Saving data**

Before you save an instrument please always manually set the Form Status to “Complete”.

Only in case data of a certain instrument is not yet present you can leave the status to “Incomplete”.

Please add the missing data as soon as possible and then set Form Status to “Complete”.

**Correcting data**

If you want to correct data on an instrument, you can. Just open the applicable subject and the applicable instrument/form and change the data. You will be asked to specify (a) reason(s) for change as soon as you press “Save”. Fill in reason(s) and click on “Save & Exit Form or Save & Go to Next Form”.

---

**Please supply reason for data changes**

You must now supply the reason for the data changes being made on this page in the text box below.

Reason for changes:

Save
**Note:** if you change data in fields that have “branching logic” then be aware that a pop-up screen will appear with the message that a field that already has a value needs to be reset back to a blank value due to the change(s) you have made in another field on the form.

You can either choose to accept this deletion (click OK) or cancel the deletion (click Cancel)/Annuleren for instance if you made a mistake. See an example below.

![Pop-up Screen Example](image)

**Additional Clarifying Data**

To avoid any unnecessary queries from the Monitor or Data Manager you can fill in (a) comment(s) in the Field Comment Log ( ). You can enter your comment on the left side of every field that is present in an instrument.

**Contact information for questions regarding CRF completion**

Your first line of contact is the PORTAL registry organization via (b.a.m.alfares@umcg.nl).

If not available or no solution can be provided, your queries will be forwarded to the Data Manager of IM-Onderzoek office.

Please always indicate study name, record/subject/patient number and instrument + Event and your question. Please copy you’re the study organization in your e-mails.
Discrepancy Management (Data Resolution Workflow)

Resolve issues

If there is any issue with a data value in your study, you will receive a query on which you can respond. You will find an overview of these issues (queries) on the left side of your screen under "Applications – Resolve Issues"; see example below

![Resolve Issues](image)

The Resolve Issues page displays all data queries that are currently unresolved or have already been resolved as in example below.

![Resolve Issues example](image)

You can set "Filters" to make a selection in the status of the issues/queries you want to see or you can make a selection in fields/rules/events/user assigned etc.

**Note:** The number of issues to be resolved in tab "Resolve issues" (in the red circle) will decrease as soon as you have indeed resolved one or more issues/queries. However this will only be visible after the page has been "refreshed" by clicking the F5 button.

- If you click on the field in the red circle (15001), as seen in the example below, the instrument/page on which the issue applies, will open. You can adjust data on that particular instrument/page if necessary and click on the icon with the exclamation mark to respond to the issue.
Note: unfortunately the applicable instrument/page on which the issue applies will only open if the issue concerns only one instrument. If an issue concerns more than one instrument, the Record home page will appear. You then have to select the applicable instruments yourself.

- If you click on the field in the red square, as seen in the example below, the data resolution workflow will appear. Here you can respond to the issue/query.

Example of how an issue/query looks like on an instrument/page itself:
If you click on the icon (inside the red circle), the Data Resolution Workflow screen will appear.

The responses you can choose from in replying to the issue/query are:

- Corrected – Data Missing
- Corrected – Typographical error
- Corrected – Wrong source use
- Verified – Confirmed correct (no error)
- Other

Choosing a response to the issue/query is required. The Comment field as seen in the example above is required to be filled in as well.

As soon as the issue/query has been resolved. The status of the icon will look like this:
### Patient numbers and sites
Please start the subject number with the number of your site, followed by 001, 002, 003, etc.

### Repeating Instruments
Repeating instruments in this study are:
- CLINICAL CHARACTERISTICS AT DIAGNOSIS/TREATMENT
- TREATMENT INFORMATION
- FOLLOW-UP

### Repeating Events
Repeating events in this study are:
N/A