ANZTCT
Cell Therapy REDCap User Guide

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ANZTCT Form Submission Workflow

Patient | Cell Therapy

Pre-Infusion

Patient Information Form
- ABMTRR ID
- Hospital
- Consent
- Demographics
- Survival
  - *Cause of Death*

Must be completed before proceeding to the Cell Therapy forms

Is all patient information completed?

Disease Classification Form – required for malignant haematologic disorders, non-malignant disorders or solid tumours

- Primary Disease for Cell Therapy

Disease Specific Form
- *ALL Pre-Infusion*
- *Lymphoma Pre-infusion*
- *Myeloma and CLL available soon*

Cell Therapy Pre-infusion Form
- Baseline recipient data
- Cell therapy indication

A course of cell therapy includes all infusions given per protocol, or when multiple infusions are given for the same indication using the same product/donor.

Multiple infusions of commercial products require a separate Form for each infusion.

Cell Therapy Product Form
- Product source
- Manipulation
- Cell product analysis

A separate form is required for each product – see definitions of single and multiple products

Infusion

Infusion # 2

Cell Therapy Infusion Form
- Product identifiers
- Infusion date
- Cell dose
- If product not infused no follow up forms required

A separate form is required for each infusion, as defined by the infusion date

Quality of Life – Form EuroQol Research Foundation

Measurement of health-related quality of life (EQ-5D-5L)

Cell Therapy – Follow up

30 day / 100 day / 6 months / annually

Post-Infusion

Cell Therapy Follow up Form
- Survival status
  - cause of death
- Subsequent infusions
- Disease response
- Persistence of cell product
- Toxicities
- Infections
- Second malignancies
- Pregnancies

Disease Specific follow up Form
- *ALL Post-Infusion*
- *Lymphoma Post-Infusion*
- *Myeloma and CLL Post-Infusion available soon*

New Malignancy Form
Report new malignancies that are different to the cell therapy indication

Quality of Life – Form EuroQol Research Foundation

Measurement of health-related quality of life (EQ-5D-5L)

Accessing the ANZTCT REDCap Database

Research Electronic Data Capture - REDCap was created in 2004 at Vanderbilt University and was offered to institutions as a user-friendly web-based interface. REDCap offers an easy-to-use, and secure method of flexible yet robust data collection.

REDCap is the ABMTRR web-based application that allows centres to electronically submit the required forms for the collection of cell therapy and transplant data.

Access to REDCap

The ANZTCT Data Manager will create a REDCap account for required users. Once the account is setup, an automatic message will be sent to the user advising the username and asking to setup a password:

[This message was automatically generated by REDCap]

A REDCap account has been created for you in which your REDCap username is "**username**". Click the link below to set your new password and log in.

After logging in, please make sure to set up your password recovery question, which will allow you to use the 'Forgot your password?' link on the login page without the need to contact the REDCap Administrator. You will be prompted to set your recovery question on the My Projects page, but you can also set it on your 'My Profile' page under 'Login-related options'.

[*Set your new REDCap password*]

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1. Click the [**Set your new REDCap password**] link in the email you receive to set your password.

2. Set up a Password recovery question, when promoted. Confirm your email address is correct before saving.

Access to REDCap Projects

The ABMTRR Data Manager will allocate the relevant REDCap project once your username has been verified. An automatic message will be sent to you advising confirmation of project access:

[This message was automatically generated by REDCap]

You have been given access to the REDCap project named "PROJECT NAME". Using your user name "username", you may log in to the project using the link below.

https://abmtrr.svha.org.au/

Logging into REDCap

1. Copy the link provided in the automatically generated email and paste into Chrome (preferred browser). Save the page to your favourites bookmark.

2. Log into RedCap using your username and password, set in previous steps

3. Successful login will take you to the REDCap Home page, upon your first login

4. Access your projects by selecting the **My Projects** icon at the top of the REDCap screen

5. Select the project you wish to start entering data into, this will take you to the **Project Home and Design Page**

Logging out of REDCap

1. Select the **Log out** option at the top left of the Project Home screen **OR** if you are on the REDCap Home Page, select the logout option at the top right of the screen

Note: REDCap will timeout after 30 minutes if there has been no activity. Logging back in will return you to the most recent page from your previous session, using the Log In button on the REDCap Auto Logout Warning screen. If you go back to the URL (favourite link) and log into REDCap from there, it will take you back to the Projects page. Please save regularly to avoid losing your data.
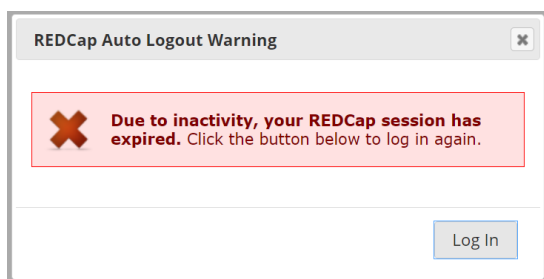
Navigating REDCap

Project Home

Login details / **Log out** option

Project you are working in

Takes you back to your **project list**

Your associated Data Access Group (DAG) (Centre)

View all records and status

Create and edit records

Data Export and reports / Field comment log(s)

Record Status Dashboard

Users will be assigned a Data Access Group (DAG), which will allow users / centres to create and view only their centre records.

* Each record (row) represents an individual patient record

1. To add a new record, select the **+Add New record** button

2. To update a record, click the **AID (ANZTCT ID) number** which will open the record you have selected **AND/OR** to update a specific form, click the grey or coloured ⬤ radio button

Add / Edit Records

1. To add a new record, select the **+Add New record** button

2. To search records, type in the search query, you can search all fields or search specific fields.

Data Exports, Reports, and Stats

You will have access to the proforma report(s) to export data from.

How to use the repeat event / form function

In some circumstances a form or event may be repeated, for a patient / record. The Cell Therapy Form Guidelines will advise when and where to use these options. If an event or form offers this function, you will see a **+Add new** above the event.

Update and editing forms

Required fields

If required fields are missing values, and you save the form, you will receive the following message:

NOTE: Some fields are required! ✖

Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.

Provide a value for...
- **Date of contact**

[Okay] [Ignore and leave record]

Please ensure that all required fields are completed before continuing to the next form.

Question Subsets

In some questions, the forms are designed to show a subset of questions based on an answer in the previous question. For example, if you select yes – *were cytogenetic testing performed*, a subset of questions will appear.

Disease assessments at diagnosis

| **Were cytogenetic testing performed** | ⬡ ○ Yes ○ No ○ Unknown | reset |

Disease assessments at diagnosis

Were cytogenetic testing performed	⬡ ⦿ Yes ○ No ○ Unknown	reset
Tested by FISH	⬡ ○ Yes ○ No	reset
Tested by karotyping	⬡ ○ Yes ○ No	reset
Molecular tests were performed (eg. PCR, NGS)	⬡ ○ Yes ○ No ○ Unknown	reset

If you reset the question – *were cytogenetic testing performed* to remove your answer you will receive a message if you have data entered in the subset of questions:

abmtrr-uat.svhanational.org.au says

ERASE CURRENT VALUE OF THE FIELD "amlfish" ?

The current field for which you just entered data requires that the field named "amlfish" be hidden from view. However, that field already has a value, so its value might need to be reset back to a blank value.

Click OK to HIDE this field and ERASE its current value. Click CANCEL if you DO NOT wish to hide this field or erase its current value.
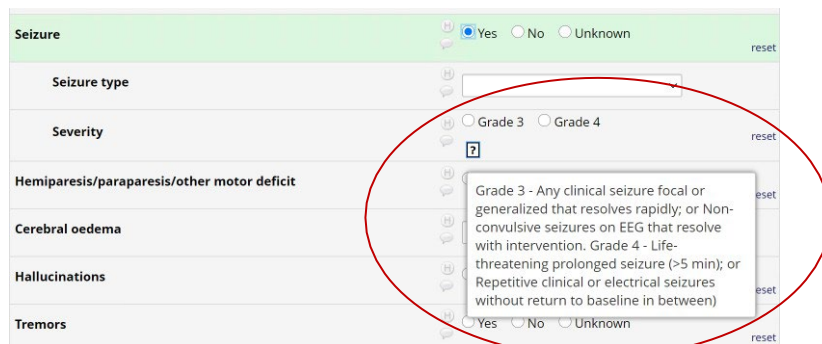
[OK] [Cancel]

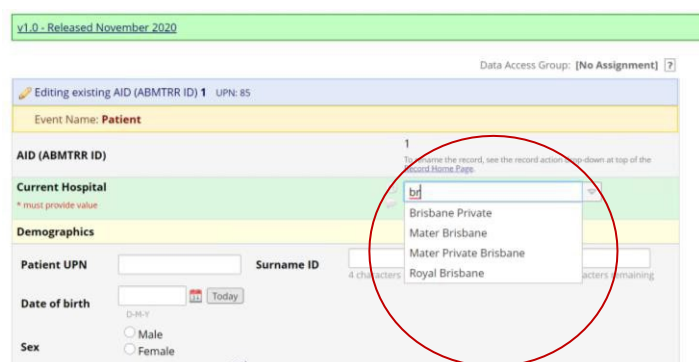By clicking OK, it will reset all the subset questions.

Help Text

Questions that require further explanation will have help text associated with it. Hover over the [?] to reveal the text.
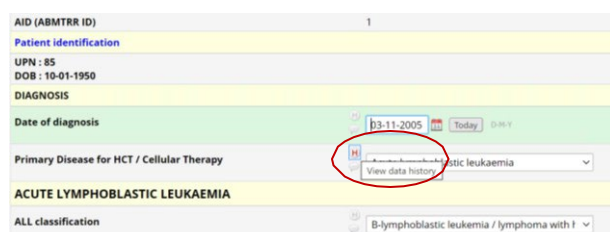

Auto Fill in dropdown lists

For large dropdown list questions, these fields have an auto fill function as you start typing key words. Start typing in the word and it will display options from the dropdown list that you can choose from.
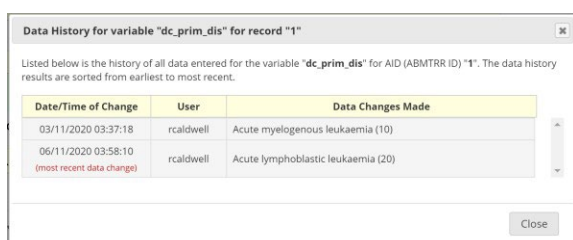

Field History / Field log comments

Each question / field has a history and comment log associated with it. Click on the H to view the data history of the field:

Click the comment logo [💬] to enter in comments:

The comment icon will now show as yellow, to signify that comments are added to the field.

You can view all field comments in a project by accessing the **Field Comment Log**

ANZTCT Cell Therapy Form Guidelines

For assistance in completing the cell therapy forms, follow the *ANZTCT Cell Therapy Form Guidelines*

For Further Help

Website: https://anztct.org.au/registry/data-management-resources/

Email: registry@anztct.org.au

References

PA Harris, R Taylor, R Thielke, J Payne, N Gonzalez, JG. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

PA Harris, R Taylor, BL Minor, V Elliott, M Fernandez, L O'Neal, L McLeod, G Delacqua, F Delacqua, J Kirby, SN Duda, REDCap Consortium, The REDCap consortium: Building an international community of software partners, J Biomed Inform. 2019 May 9 [doi: 10.1016/j.jbi.2019.103208]