

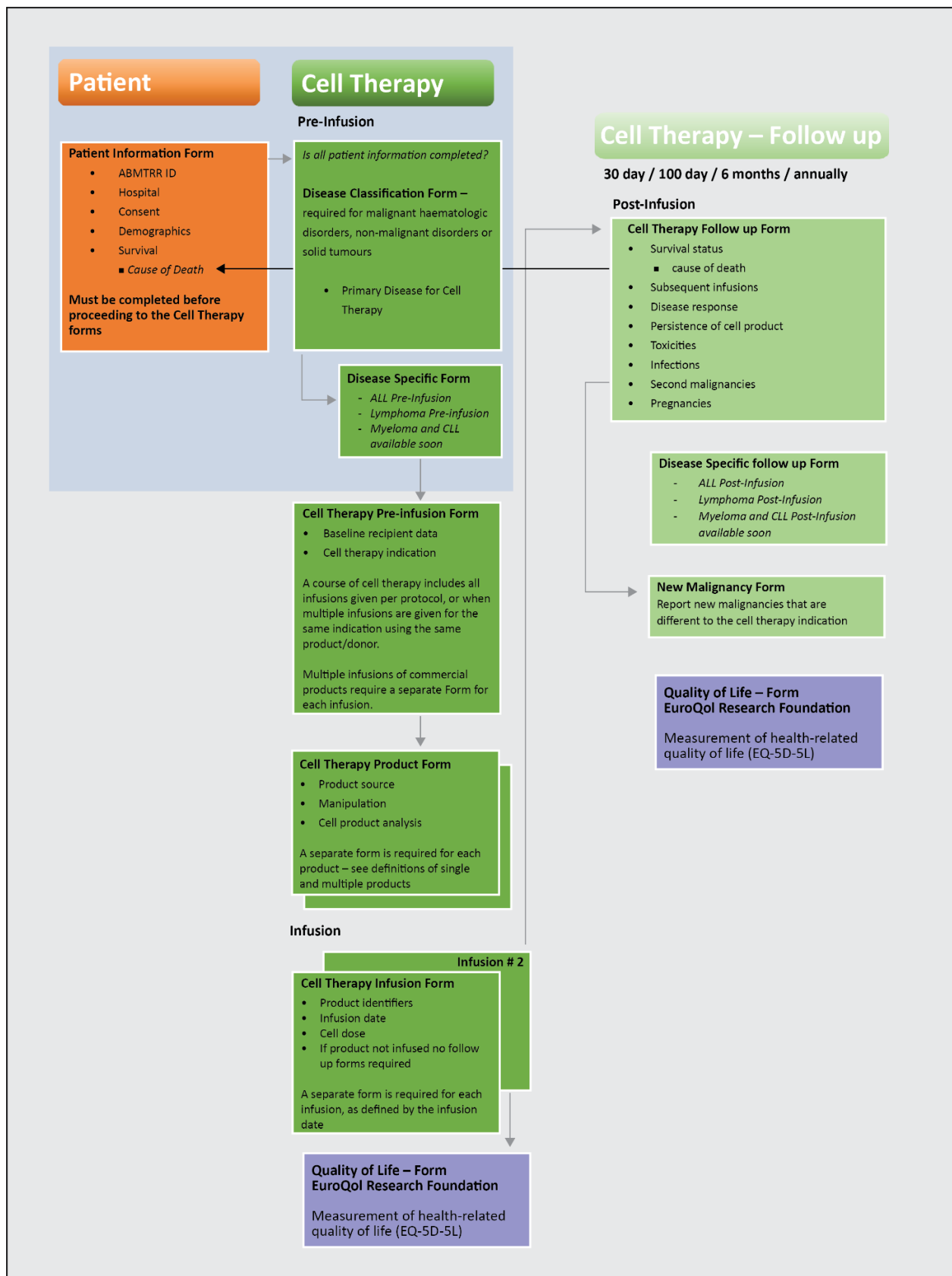


ANZTCT Cell Therapy REDCap User Guide

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ANZTCT Form Submission Workflow



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]

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



Set Your Password

Your password has not been set yet or has been reset. You will need to set your password here to whatever value you wish. Please enter your desired password below and click the 'Submit' button. Once your password has been set, you may use it with your username whenever you log in to REDCap. Please make sure that you write down or remember your new password for future use. **The new password entered must be AT LEAST 9 CHARACTERS IN LENGTH and must consist of AT LEAST one lower-case letter, one upper-case letter, and one number.**

Username:	sharks
Password:	<input type="password"/>
Re-type password:	<input type="password"/>

REDCap 10.1.2 - © 2020 Vanderbilt University

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

Set Up Password Recovery Question

To help you easily and quickly recover your REDCap password (in case you forget it in the future), we need you to select a security question of your choice below and then provide an answer for it. Once you have filled out this information, if you forget your password, you can click the "Forgot Your Password?" link on the REDCap login screen, and it will ask you to provide a correct answer to your security question (the one you will select below). In such a case, it will send a new temporary password to the email address associated with your REDCap account. Setting up your password recovery question below will prevent you from having to wait on a REDCap administrator to reset it manually if you ever forgot your password.

NOTICE: It is highly recommended that you set your password recovery question now, or else you might get accidentally locked out of your REDCap account.

Select a question: - select a security question -


Provide answer to question: (not case sensitive)

Please confirm your email address: (If you attempt to recover your password, your new password will be sent to this email address.)

Save

[Not now. Remind me again in 2 days.](#)

Set Up Password Recovery Question

 SUCCESS! You have now set up your password recovery question. You will be able to easily recover your password in the future.

Close

REDCap®

Home

My Projects

New Project

Help & FAQ

Training Videos

Send-It

Messenger

Login via your SVHA Username / Password. Once you have access, please contact the ABMTRR Data Manager (+61 2 9355 5694) to get your projects approved, or be granted access to an existing project.

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 [ABMTRR Data Manager \(+61 2 9355 5694\)](#).

REDCap Features

Build online surveys and databases quickly and securely - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.

Fast and flexible - Conception to production-level survey/database in less than one day.

Export data to common data analysis packages - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis.

Ad Hoc Reporting - Create custom queries for generating reports to view or download.

e-Consent - Perform informed consent electronically for participants via survey

Easily manage a contact list of survey respondents or create a simple survey link - Build a list of email contacts, create custom email invitations, and track who responds, or you may also create a single survey link to email out or post on a website.

Scheduling - Utilize a built-in project calendar and scheduling module for organizing your events and appointments.

REDCap Mobile App - Collect data offline using an app on a mobile device when there is no WiFi or cellular connection, and then later sync data back to the server.

Send files to others securely - Using "Send-It", upload and send files to multiple recipients, including existing project documents, that are too large for email attachments or that contain sensitive data.

Save your data collection instruments as a PDF to print - Generate a PDF version of your forms and surveys for printing to collect data offline.

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



Log In

Login via your SVHA Username / Password. Once you have access, please contact the ABMTRR Data Manager +61 2 9355 5694 to get your projects approved, or be granted access to an existing project.

Please log in with your user name and password. If you are having trouble logging in, please contact [ABMTRR Data Manager \(+61 2 9355 5694\)](#).

Username:

Password:

[Forgot your password?](#)

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

REDCap® Home **My Projects** + New Project Help & FAQ Training Videos Send-It Messenger Logged in as rcaldwell My Profile Log out

Login via your SVHA Username / Password. Once you have access, please contact the ABMTRR Data Manager +61 2 9355 5694 to get your projects approved, or be granted access to an existing project.

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	Instruments	Type	Status
Cell Therapy	2	2828	15 forms		

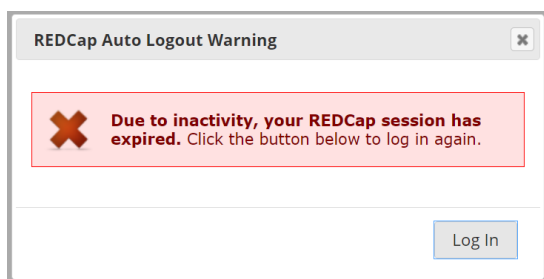
5. Select the project you wish to start entering data into, this will take you to the **Project Home and Design Page**

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

Callouts:

- Login details / Log out option:** Points to the 'Logged in as sharks | Log out' link.
- Project you are working in:** Points to the 'Cell Therapy Test' header.
- Takes you back to your project list:** Points to the 'My Projects' link in the sidebar.
- Your associated Data Access Group (DAG) (Centre):** Points to the 'Data Collection' link in the sidebar.
- View all records and status:** Points to the 'Record Status Dashboard' link in the sidebar.
- Create and edit records:** Points to the 'Add / Edit Records' link in the sidebar.
- Data Export and reports / Field comment log(s):** Points to the 'Data Exports, Reports, and Stats' link in the sidebar.

Project Home Content:

Project Home and Design

- Project Home
- Codebook
- Project status: Development

Data Collection — WH

- Survey Distribution Tools
- Scheduling
- Record Status Dashboard
- Add / Edit Records

Applications

- Calendar
- Data Exports, Reports, and Stats
- Field Comment Log
- File Repository

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature
- Contact REDCap administrator

Project Statistics

Records in project	Total: 6 / In group: 3
Most recent activity	14/09/2020 10:55pm
Space usage for docs	0.00 MB

Upcoming Calendar Events (next 7 days)

Time	Date	Description
		No upcoming events

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.

Cell Therapy PID 14

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
- Unverified
- Complete
- Many statuses (mixed)
- Incomplete (no data saved)
- Partial Survey Response
- Completed Survey Response
- Many statuses (all same)

Dashboard displayed: [Default dashboard] Create custom dashboard

Displaying Data Access Group: --ALL--


Displaying record: Page 1 of 2: "9" through "1179" of 1004 records 1000 records per page

+ Add new record

Displaying: Instrument status only | Lock status only | All status types

AID (ABMTRR ID)	Patient Information	Cell Therapy						Cell Therapy Follow Up					
		Disease Classification	ALL	Lymphoma Preinfusion	CELL THERAPY Preinfusion	CELL THERAPY Product	CELL THERAPY Infusion	Quality Of Life Eq 5d SI	CELL THERAPY Follow Up	ALL Post Infusion	Lymphoma Post Infusion	Quality Of Life Eq 5d SI	New Malignancy
9 UPN: 116	●	●	●	●	●	●	●	●	●	●	●	●	
101 UPN: 118	●	●	●	●	●	●	●	●	●	●	●	●	
102 UPN: 533702	●	●	●	●	●	●	●	●	●	●	●	●	

* 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

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. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

 Choose action for record 




Legend for status icons:

-  Incomplete
-  Unverified
-  Complete
-  Many statuses (mixed)
-  Incomplete (no data saved) 
-  Partial Survey Response
-  Completed Survey Response
-  Many statuses (all same)

AID (ABMTRR ID) **9** UPN: 118

Data Collection Instrument	Patient	Cell Therapy Infusion:	Cell Therapy Follow Up Infusion:	Transplant	Transplant FU
Patient Information					
Disease Classification					
ALL Preinfusion					
Lymphoma Pre Infusion					
CELL THERAPY Preinfusion					
CELL THERAPY Product					
CELL THERAPY Infusion					
CELL THERAPY Follow Up					
ALL Post Infusion					
Lymphoma Post Infusion					
Quality Of Life Eq 5d 5l					
TRANSPLANT					
HLA typing					
TRANSPLANT Follow Up					
New Malignancy					
Delete all data on event:					

Cell Therapy PID 14

Actions:  Modify instrument  Download PDF of instrument(s)  VIDEO: Basic data entry

Disease Classification

Data Access Group: [No Assignment] 

 Editing existing AID (ABMTRR ID) **9** UPN:

Event Name: **Cell Therapy**


AID (ABMTRR ID) **9**


Patient identification

UPN : 118


DOB : 01-05-1962

DIAGNOSIS

Date of diagnosis  Today D-M-Y

Primary Disease for HCT / Cell Therapy 

DISEASE STATUS ASSESSMENT DATE
Applies to diagnoses with Disease Status at Infusion assessments

Date disease status assessed  Today D-M-Y

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 & ... 

 Cancel 

Add / Edit Records

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

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: 1004	
Choose an existing AID (ABMTRR ID)	-- select record --
+ Add new record	

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.	

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

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.

NOTICE: This project is currently in Development status. **Real data should NOT be entered** until the project has been moved to Production status.

Total records: 1004	
Choose an existing AID (ABMTRR ID)	-- select record --
+ Add new record	

Data Search	
Choose a field to search (excludes multiple choice fields)	record_id1 (AID (ABMTRR ID))
Search query Begin typing to search the project data, then click an item in the list to navigate to that record.	<div>11</div> <div>"1011" in AID (ABMTRR ID) 1011 UPN: 422 for event Patient "110" in AID (ABMTRR ID) 110 UPN: 192 for event Patient "1100" in AID (ABMTRR ID) 1100 UPN: 171 for event Patient "1101" in AID (ABMTRR ID) 1101 UPN: 172 for event Patient "1102" in AID (ABMTRR ID) 1102 UPN: 173 for event Patient "1103" in AID (ABMTRR ID) 1103 UPN: 174 for event Patient "1104" in AID (ABMTRR ID) 1104 UPN: 175 for event Patient "1106" in AID (ABMTRR ID) 1106 UPN: 404310 for event Patient "1107" in AID (ABMTRR ID) 1107 UPN: A102 for event Patient "1108" in AID (ABMTRR ID) 1108 UPN: 81 for event Patient "1109" in AID (ABMTRR ID) 1109 UPN: 83 for event Patient "111" in AID (ABMTRR ID) 111 UPN: 815 for event Patient</div>

Data Exports, Reports, and Stats

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

Data Exports, Reports, and Stats

 VIDEO: [How to use Data Exports, Reports, and Stats](#)

[+ Create New Report](#)

[My Reports & Exports](#)

[Other Export Options](#)

This module allows you to easily view reports of your data, inspect plots and descriptive statistics of your data, as well as export your data to Microsoft Excel, SAS, Stata, R, or SPSS for analysis (if you have such privileges). If you wish to export your **entire** data set or view it as a report, then Report A is the best and quickest way. However, if you want to view or export data from only specific instruments (or events) on the fly, then Report B is the best choice. You may also create your own custom reports below (if you have such privileges) in which you can filter the report to specific fields, records, or events using a vast array of filtering tools to make sure you get the exact data you want. Once you have created a report, you may view it as a webpage, export it out of REDCap in a specified format (Excel, SAS, Stata, SPSS, R), or view the plots and descriptive statistics for that report.

My Reports & Exports			
	Report name	View/Export Options	Management Options
A	All data (all records and fields)	View Report Export Data Stats & Charts	
B	Selected instruments and/or events (all records)	Make custom selections	

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.

Data Collection Instrument	Patient	Cell Therapy	Infusion:	Infusion:	Cell Therapy Follow Up	Infusion/fu	Infusion/fu	Infusion/fu	Infusion/fu	Infusion/fu	Infusion/fu	Infusion/fu
		Infusion: 30-09-2020 (#1)	30-06-2020 (#2)	05-11-2020 (#3)	Infusion/fu Period: 30-09-2020, 30 day (#1)	30-06-2020, 30 day (#2)	30-06-2020, 1 year (#3)	05-11-2020, 100 day (#4)	30-06-2020, 6 month (#5)	05-11-2020, 30 day (#6)	30-06-2020, 100 day (#7)	
Patient Information												
Disease Classification												
ALL Preinfusion												
Lymphoma Pre Infusion												
CELL THERAPY Preinfusion												
CELL THERAPY Product												
CELL THERAPY Infusion												
CELL THERAPY Follow Up												
ALL Post Infusion												
Lymphoma Post Infusion												
Quality Of Life Eq 5d SI												
New Malignancy												
Delete all data on event:												

Collapse / un-collapse
repeating event columns

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	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown reset

Disease assessments at diagnosis	
Were cytogenetic testing performed	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown reset
Tested by FISH	<input type="radio"/> Yes <input type="radio"/> No reset
Tested by karyotyping	<input type="radio"/> Yes <input type="radio"/> No reset
Molecular tests were performed (eg. PCR, NGS)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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.

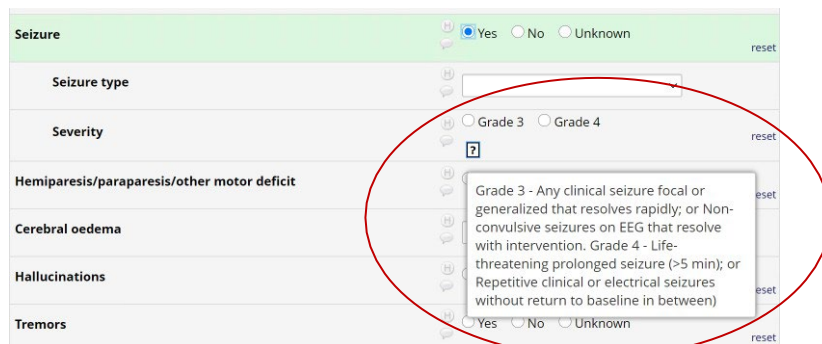
OK

Cancel

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

Help Text

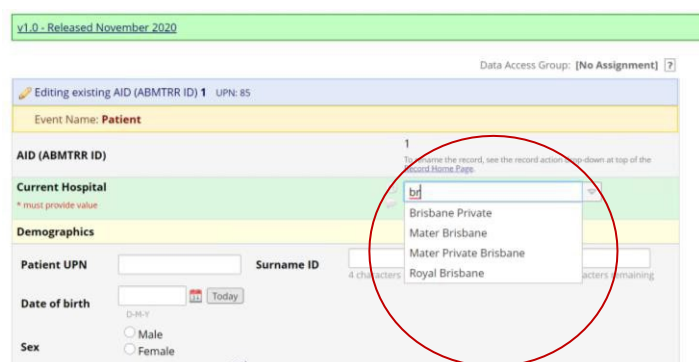
Questions that require further explanation will have help text associated with it. Hover over the  to reveal the text.



The screenshot shows a form with several fields: 'Seizure', 'Seizure type', 'Severity', 'Hemiparesis/paraparesis/other motor deficit', 'Cerebral oedema', 'Hallucinations', and 'Tremors'. The 'Severity' field has a help icon (a question mark in a square) next to it. A red circle highlights the 'Severity' field and its help tooltip. The tooltip text reads: 'Grade 3 - Any clinical seizure focal or generalized that resolves rapidly; or Non-convulsive seizures on EEG that resolve with intervention. Grade 4 - Life-threatening prolonged seizure (>5 min); or Repetitive clinical or electrical seizures without return to baseline in between'.

Auto Fill in dropdown lists

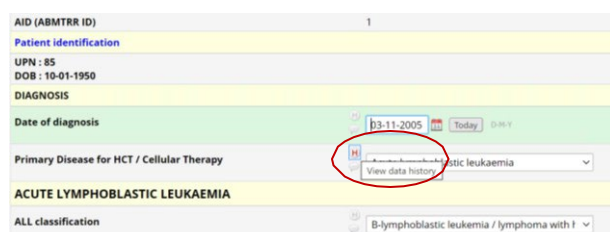
For large dropdown list questions, these fields have an auto fill function as you start typing key words. Start typing in the word and it will display options from the dropdown list that you can choose from.



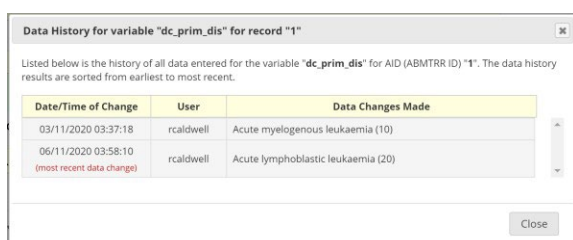
The screenshot shows a form with a header 'v1.0 - Released November 2020' and a 'Data Access Group: [No Assignment]' label. The form is for 'Editing existing AID (ABMTRR ID) 1 UPN: 85'. The 'Event Name' is 'Patient'. The 'Current Hospital' field has a dropdown list with the following options: 'Brisbane Private', 'Mater Brisbane', 'Mater Private Brisbane', and 'Royal Brisbane'. A red circle highlights the dropdown list.

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:



The screenshot shows a form with the following fields: 'AID (ABMTRR ID) 1', 'Patient identification', 'UPN : 85', 'DOB : 10-01-1950', 'DIAGNOSIS', 'Date of diagnosis' (with a date picker set to '03-11-2005'), 'Primary Disease for HCT / Cellular Therapy' (with a dropdown list showing 'Acute myelogenous leukaemia (10)' and a 'View data history' button), 'ACUTE LYMPHOBLASTIC LEUKAEMIA', and 'ALL classification' (with a dropdown list showing 'B-lymphoblastic leukemia / lymphoma with I'). A red circle highlights the 'View data history' button.





The screenshot shows a window titled 'Data History for variable "dc_prim_dis" for record "1"'. It contains a table with the following data:

Date/Time of Change	User	Data Changes Made
03/11/2020 03:37:18	rcaldwell	Acute myelogenous leukaemia (10)
06/11/2020 03:58:10 (most recent data change)	rcaldwell	Acute lymphoblastic leukaemia (20)



There is a 'Close' button at the bottom right of the window.

Click the comment logo  to enter in comments:

Primary Disease for HCT / Cellular Therapy  Acute lymphoblastic leukaemia 

ACUTE LYMPHOBLASTIC LEUKAEMIA

View comment log

ALL classification  B-lymphoblastic leukemia / lymphoma with t 

Field Comment Log

This pop-up displays all the field comments for the record and field specified below. Users with access to data entry forms may leave one or more comments on any field on a data collection instrument, after which the balloon icon will stay lit up to signify that comments exist for that field for this record. All field comments for all records/fields can also be viewed, keyword searched, and filtered on the [Field Comment Log](#) page in this project. NOTE: If you wish to prevent all users in this project from editing or deleting field comments below, see the Additional Customizations popup on the Project Setup page.

AID (ABMTRR ID): **1**

Event: **Cell Therapy**

Field: **dc_prim_dis** ("Primary Disease for HCT / Cellular Therapy")

	Date/Time	User	Comments
	11/11/2020 10:18pm	rcaldwell	Field updated as per new correspondence

Comment

Cancel



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

Primary Disease for HCT / Cellular Therapy  Acute lymphoblastic leukaemia 


You can view all field comments in a project by accessing the [Field Comment Log](#)


Field Comment Log


This page displays the Field Comment Log for all records/events/fields in this project. You may use the controls below to perform keyword searches in the comments as well as filter the comments by record, event, field, or data access group. Keep in mind that if you do not have user privileges to view some data collection instruments, then comments for any fields on those instruments will not be displayed in the table. Also, if you belong to a data access group, then you will only see results for records that belong to your group. The entire Field Comment Log is downloadable as a file in Excel/CSV format.

Field Comment Log Filters: All records  for All events 

Results returned: **1**

All fields 


All users 

All data access groups 

Keyword search [Search tips](#)

[Apply filters](#) [Reset](#)

[Export entire log](#)

Click button to view comment log	Record	Field	Comments
 1 comment	1 (#1) UPN: 85 Cell Therapy	dc_prim_dis (Primary Disease for HCT / Cellular Therapy)	rcaldwell (11/11/2020 10:19pm): "Field updated as per new correspondence"

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]