UKITP Registry
Data Entry Database

Terms and Conditions

&

Self-Help Visual Guide

Welcome to the ITP Registry

Thank you for joining the UK ITP registry. The registry will help us investigate pathogenesis, clinical phenotype, treatment effectiveness and co-morbid conditions in patients with ITP.

We know that everyone that helps us collect data is incredibly busy, so thank you for taking the time to use this guide and enter your data onto the database.

If you are having trouble with the database and this guide has not answered your question, please contact us:

      email: uk-itp.registryteam@nhs.net

      Phone: 020 7377 7000 ext 61114

Our office hours are 9am -5pm, Monday to Friday

Terms and conditions

Before proceeding with the study, you will have been asked to confirm to the ITP Registry team, by email, that you have read, understood and accepted the full terms and conditions of using REDCap, the application which supports the ITP Registry database. Please let us know if you don't have a record of this.

Data Collection

- Only data belonging to participants who have consented to participate in the Registry should be entered on the database (i.e. a signed consent form has been obtained)

- Please ensure that participants meet the eligibility criteria for the study before entering their data

Data Entry Database

- For issues related to data collection and data entry on the database please contact the Registry team uk-itp.registryteam@nhs.net

Data Sharing

- Centres are able to use their own data for research purposes in line with the Registry's protocol

*please note that all documents, databases and designs that the UKITP Registry uses are copyrighted

Terms and conditions

In order to meet Data Protection regulations, local centres using the ITP registry database need to ensure the following:

- Only staff who are on a delegation log signed by the local Principle Investigator can have access to the database. In order to enter data, the 'data entry' role must be assigned to them on the delegation log.

- The login details, including username and password, should not be shared with anyone who is not the assigned user.

- The database should only be accessed within the trust site where staff are employed

- It is expected that the staff responsible for data entry have undertaken adequate GCP training before entering data on the database

Database data collection forms visual guide

Logging into REDCap

Step 1: Log into REDCap with the log in details provided to you by its-research-support@qmul.ac.uk

Entering the ITP Registry DATABASE

Queen Mary
University of London

Welcome to the REDCap service provided by Queen Mary University of London

Published research should cite REDCap as follows:

Study data were collected and managed using REDCap electronic data capture tools hosted at Queen Mary University of London [1]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

[1]Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. 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.

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

My Projects	📁 Organize			Filter projects by title		
Project Title		Records	Fields	Instrument	Type	Status
Multinational Immune Thrombocytopenia Registry_MITP1		743	3,108	20 forms		☑
Research Management System_MITP1		13	301	4 forms		☑

The projects listed below are public and are accessible by anyone. No authentication (i.e. username/password) is required to access them directly.
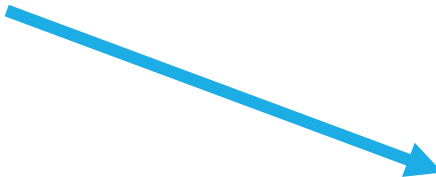
Public Projects
Basic Demography
Classic Database
Human Cancer Tissue Biobank
Longitudinal Database (1 arm)
Longitudinal Database (2 arms)
Multiple Surveys (classic)

You should have two projects under My Projects:

1. Multinational Immune Thrombocytopenia Registry_MITP . This is where to enter **patient data**.
   (It will have a number next to MITP which is for registry team use only)

2. Research Management System_MITP. This is the **staff details** database for your site. Please keep this up-to-date so we can easily contact you.

Entering the ITP Registry DATABASE

Click on the project titled
Multinational Immune
Thrombocytopenia Registry_MITP

Adding a new patient

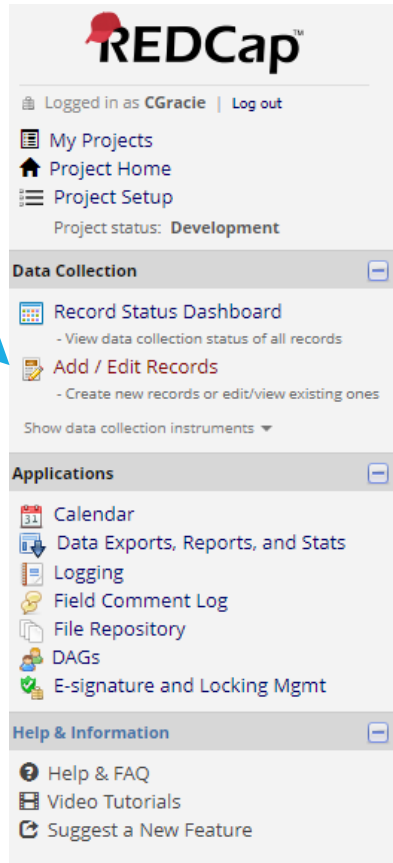1. Add the new patient to your Participant's Log.

This will automatically assign them the next available Registry Identification Code (RIC).

If you do not have access to a copy of your site Participant Log please email us at uk-itp.registryteam@nhs.net

	Row number	Registry Identification Code (pre-assigned)	ITP Reference Number	Patient Identifiation Number (PIN)	NHS Number	Participant's Surname	Participant's First name	Participant's Middle Name (if any)
		A	B	C	D	E	F	G	H
2	1	ABC33216				Bloogs	Joe	
3	3	ABC78447				Doe	Jane	
4	4	ABC99727						
5	7	ABC39450						
6	9	ABC43496						
7	10	ABC97832						
8	11	ABC84824						
9	13	ABC22795						
10	14	ABC60506						
11	15	ABC78056						
12	17	ABC96509						
13	18	ABC58327						
14	19	ABC43643						
15	20	ABC58435						

Adding a new patient

Accessing an existing patient record

1. click add/edit records

REDCap™

🔒 Logged in as **CGracie** | Log out

📑 My Projects
🏠 Project Home
☰ Project Setup
   Project status: **Development**

Data Collection ⊟

🔲 Record Status Dashboard
   - View data collection status of all records
📝 Add / Edit Records
   - Create new records or edit/view existing ones
Show data collection instruments ▾

Applications ⊟

📅 Calendar
📊 Data Exports, Reports, and Stats
📋 Logging
🔖 Field Comment Log
🗒 File Repository
👥 DAGs
✅ E-signature and Locking Mgmt

Help & Information ⊟

❓ Help & FAQ
📖 Video Tutorials
🔄 Suggest a New Feature

Multinational Immune Thrombocytopenia Registry_test 4

📝 Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-down, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: **1**

Choose an existing Registry Identification Code (RIC)	-- select record -- ▼
Enter a new or existing Registry Identification Code (RIC)	RIC
	RIC61114

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.	

⚠ NOTICE:

2. Select the appropriate RIC from the drop down menu box

OR

2. Start to type in the appropriate RIC and click on it as it appears below your typing

1

2

NB. It is possible to search for records using other information. The field to be searched needs to be selected before entering the value to be searched.

Adding participant information

Multinational Immune Thrombocytopenia Registry_test 4

▦ **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.

Legend for status icons:
- 🔴 Incomplete   ⦿ Incomplete (no data saved) [?]
- 🟡 Unverified
- 🟢 Complete

☑ Choose action for record ▽

Registry Identification Code (RIC) **RIC61114**

Data Collection Instrument	Status
Participant Details	🟢
Follow Up Data Collection Status Update	⦿
Clinician Information	⦿
Anthropometric And Lifestyle Data	⦿
Bleeding Events	⦿
Itp Treatments	⦿
Blood Product Transfusion	⦿
Other Itp Treatments	⦿
Trial	⦿
Cotherapies	⦿
Comorbidities	⦿
Family History	⦿
Biochemical Fields At Itp Diagnosis	⦿
Haematological Fields At Itp Diagnosis	⦿
Platelet Counts Manual Entry	⦿
Platelet Counts File Upload Function	⦿
Immunological Fields At Itp Diagnosis	⦿
Coagulation Fields At Itp Diagnosis	⦿
Bm Aspirate Trephine Biopsy Dat	⦿
Comments	⦿

REDCap sidebar:

Logged in as CGracie | Log out

📋 My Projects
🏠 Project Home
≣ Project Setup
  Project status: **Development**

Data Collection ⊟

▦ Record Status Dashboard
  - View data collection status of all records
📝 Add / Edit Records
  - Create new records or edit/view existing ones

▦ Registry Identification Code (RIC) **RIC61114**
  Select other record

Applications ⊟

📅 Calendar
📊 Data Exports, Reports, and Stats
📄 Logging
💬 Field Comment Log
🗀 File Repository
👤 DAGs
✅ E-signature and Locking Mgmt

Help & Information ⊟

❓ Help & FAQ
🎞 Video Tutorials
↪ Suggest a New Feature

✉ Contact REDCap administrator

You should now be on the "Record Home Page". Click on the status circle next to the section that you'd like to fill out first.

Redcap uses a traffic light system to record whether each data collection category is complete. You control this system and can choose which colour to mark each section (this will be demonstrated in the next section). This system is for you to track your own records.

Participant Details

Retype the RIC here

The 'PIN' will appear here if this patient was on the 'old' database.

Please fill out the participants details.

The First Data Collection Date is usually around when the patient was consented.

The "last ITP-related clinic date" will need updating as the patient attends clinic. It should be the date of the most recent clinic the patient has attended.

Age at Consent | 100 | view equation
(years)

Date of this First Data Collection | 04-12-2017 | Today | D-M-Y

When was the last ITP-related clinic visit for this participant? | 04-12-2017 | Today | D-M-Y
this date can be updated after each visit

> If this is not the first data collection and all the information required on this page is complete, please proceeed to the section 'Follow Up Data Collection Status Update' to state if this is a data update.

Please fill out the remaining information regarding the patients consent to take part in the registry

Has the participant consented to provide biological sample?
* must provide value

⦿ Yes
◯ No

reset

Please do not take or send any samples without a signed consent form from the participant

Biological Samples

The Registry will add the "Sample Received Date"

Type of sample | [▼]
Please refer to the Registry Sample collection/transfer protocol

Was a biological sample sent ?
⦿ Yes
◯ No

reset

Sample Sent Date | [ ] | Today | D-M-Y

Sample Received Date | [ ] | Today | D-M-Y
to be updated by the Registry

Form Status

Complete? | Complete ▼

State whether data entry for this page is complete, incomplete or unverified. What you choose here controls the traffic light system on the record home page, complete=green, unverified=yellow, incomplete=red.

Lock this record for this form?
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

☐ 🔒 Lock

Save & Exit Form | Save & Go To Next Form ▼

-- Cancel --

Delete data for THIS FORM only

Exiting a section of the database

Option 2: Click "Save & Exit Form". This will take you back to the Record Home Page. From here, you can see which sections you have completed and can choose which section to fill out next

Option 1: Click "Save and go to Next Form". This will take you to the next form to be filled out for this patient.

NB. the first time you do this the box will say "save &..". You will have to click on the arrow on the right hand side of the box and set your option as "Save & Go To Next Form". This will then set the preference as "Save & Go To Next Form".

Option 3: Click "Save and Stay". This will save your changes but not change the form. This allows you to review your changes

Follow Up Data Collection Status Update

Multinational Immune Thrombocytopenia Registry_test 4

Save & Exit Form
Save & Go To Next Form
-- Cancel --

Actions: 📄 Download PDF of instrument(s) ▽   🎬 VIDEO: Basic data entry

📋 Follow Up Data Collection Status Update

Data Access Group: [No Assignment] ?

✏️ Editing existing Registry Identification Code (RIC) **RIC61114**

Registry Identification Code (RIC)   RIC61114

ITP Diagnosis date: 04-12-2017   **Consent Date: 04-12-2017**

Is this a follow up data collection (i.e. not the initial data collection at registration but the 1st update after)?   ⊙ Yes   ○ No

reset

Follow up date 1   [   ] 📅 [Today] D-M-Y

What is the current status of the participant?   [▼]

Active
Discharged
Moved to a different hospital
Lost to follow-up
Primary ITP diagnosis revised/changed
Deceased

Add Next Follow-up Data Collection Details (follow up #2)

reset

Form Status

Complete?

Lock this record for this form?
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

☐ 🔒 **Lock**

Save & Exit Form   Save & Go To Next Form

-- Cancel --

Delete data for THIS FORM only

NOTE: To delete the entire record (all forms/events), see the record action drop-down at top of the Record Home Page.

Step 1: If this is <u>not</u> the first time you are adding data to the registry for this patient, click yes and more boxes will appear below.

Step 2: Select the current status of the participant

Select the completion status, then click "Save & Go To The Next Form"

Haematologist's and GP's details

Step 1: Enter the participant's Haematologist's details

Step 2: Select the relevant options. Note that some will require further information

Step 3: Assign completion status and click on "Save & Go To The Next Form"

Anthropometric and lifestyle data

Step 1: Input the appropriate values using the units specified underneath the white box

Step 2: Select whether the date is available. There are different options according to how specific the date available is. We'd always prefer a full date, but if you only have part of the date then please provide us with what you have. This may be a month and year or just a year.

Step 3: Input the date of the measurement.

Step 4: Assign completion status and click on "Save & Go To The Next Form"

Bleeding Events

Bleeding Events

Data Access Group: **[No Assignment]** ?

Editing existing Registry Identification Code (RIC) **RIC61114**

Registry Identification Code (RIC)	RIC61114
ITP Diagnosis date: 04-12-2017	**Consent Date: 04-12-2017**

Bleed Event Type Purpura ▼

Bleeding Event Date Status complete date available ▼

Full bleeding event Date 08-12-2017 📅 Today D-M-Y
* must provide value

Bleeding Event Severity
Description of severity of bleed

Bleed Site Finger - Left Hand (Joint) ▼

Bleed Event Type

Form Status

Complete?

Lock this record for this form?
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

Petechiae
Purpura
Bruise (traumatic)
Bruise (spontaneous) [ecchymosis]
Haematoma
Cutaneous Bleed - Unspecified
Vitreous haemorrhage
Conjunctival haemorrhage
Retinal hemorrhage
Choroidal haemorrhage and rupture
Sub conjunctival bleed
Haemorrhage in Eye - Unspecified
Oral cavity bleed
Gastrointestinal bleed
Haematemesis
Melaena
Mucocutaneous Bleed Site Unspecified
Epistaxis (nosebleed)
Haemoptysis

Step 1: Select the appropriate bleed type from the drop down box.

Step 2: Select whether the date is available

Step 3: Enter the date

Step 4: Enter a description of the severity of bleed if available

Step 5: Choose a bleed site from drop down box

Please enter all bleeding events available in the patient's notes

Step 6: Select the completion status, then click "Save & Go To The Next Form"

Can't find the appropriate bleed event or site?

There is an "other option" if you scroll to the bottom of the drop down list. This will allow you to manually enter your own option. We ask you to please check all options before using this. We have tried to include as any possibilities as possible to avoid users choosing this option.

ITP Treatments- Part I: Splenectomy

Itp Treatments

Data Access Group: **[No Assignment]** ?

Editing existing Registry Identification Code (RIC) **RIC61114**

Registry Identification Code (RIC) — RIC61114

ITP Diagnosis date: 04-12-2017 — **Consent Date: 04-12-2017**

Has this participant had a splenectomy? — ⦿ Yes / ○ No — reset

Splenectomy Type — Laparoscopic ▼

Is the treatment date available? — complete date available ▼

Full Treatment date — [ ] 📅 Today D-M-Y
* must provide value

ITP Treatment — [▼]

Form Status

Complete? — Incomplete ▼

Lock this record for this form?
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.
☐ 🔒 **Lock**

[Save & Exit Form] [Save & Go To Next Form ▾]

[-- Cancel --]

[Delete data for THIS FORM only]

NOTE: To delete the entire record (all forms/events), see the record action drop-down at top of the Record Home Page.

Has the patient had a splenectomy?

Step 1: Click yes or no to specifcy whether the patient has had a splenectomy

Step 2: If you choose yes, the splenectomy type box will appear. Choose an option from the drop down menu

Step 3: Choose whether the date is available

Step 4: Enter the date

Step 5: Select the completion status, then click "Save & Go To The Next Form"

ITP Treatments- Part II: Other treatments

ITP Treatments

Step 1: Choose drug from drop down menu

Step 2: Note the unit written below the box and enter the correct dose. The unit will differ for each drug.

Step 3: Enter whether the date is available

Step 4: Add the date

Step 5: Note the unit of the course length which is written the box and enter how long the patient received the drug for. The unit will differ for each drug

Please enter all ITP treatments that are available in the patient's notes

Step 6: Select the completion status, then click "Save & Go To The Next Form"

Blood product transfusions

Step 1: Use the drop down box to select the type of blood product received

Step 2: Enter number of units

Step 3: Enter whether the date is available

Step 4: Enter for how many consecutive days they received the transfusion.

Step 5: Select the completion status, then click "Save & Go To The Next Form"

Other ITP Treatments- i.e. Protein A Immunoadsorption, H.pylori treatment, Vitamin C Supplements, Plasmapheresis and other

Step 1: Select the appropriate treatment from the drop down box

Step 2: Enter the dose of the treatment

Step 3: Enter whether the date is available

Step 4: Enter for how long the patient received the treatment

Step 5: Select the completion status, then click "Save & Go To The Next Form"

Trial ITP Treatments

Step 1: Select the trial the patient is part of

Step 2: Enter the dose of the trial treatment

Step 3: Enter whether the date is available

Step 4: Enter for how many days the patient received the trial treatment.

Step 5: Select the completion status, then click "Save & Go To The Next Form"

Co-therapies - anti-lipids, anti-hypertensives, anti-coagulants, thrombolysis and anti-fibrinolytics

Step 1: Select the type of co-therapy the patient received

Step 2: Select the name of the specific co-therapy the patient received
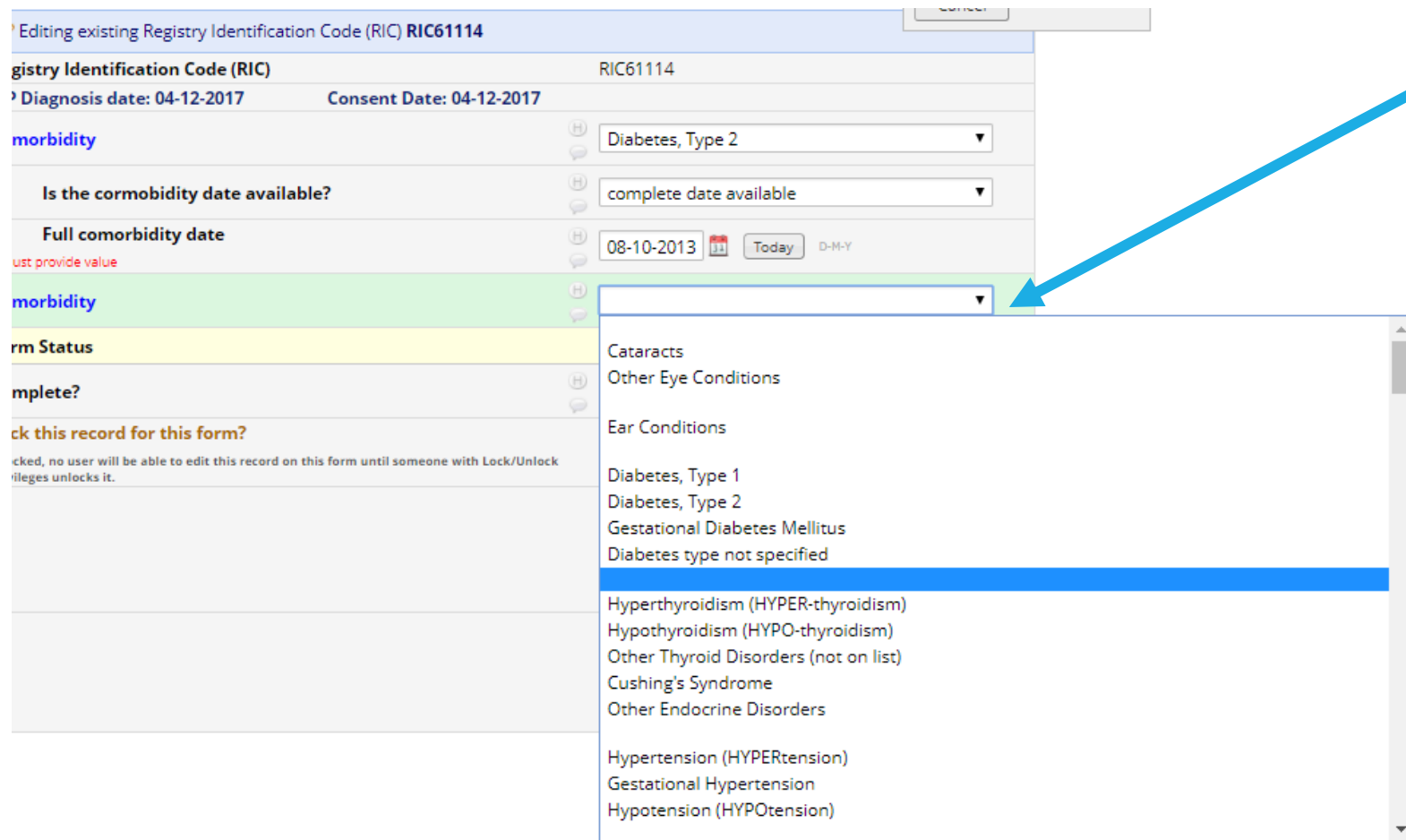
Step 3: Enter whether the course was continuous, a one-off or whether it is unknown which of these it was.

Step 4: Enter how much of the start date is available and then enter the start date

Step 5: Enter how much of the end date is available and then enter the end date

Step 6: Select the completion status, then click "Save & Go To The Next Form"

Co-morbidities

Step 1: Select the co-morbidity from the drop down box

Step 2: Select whether the diagnosis date is available

Step 3: Enter as much of the date as is available

Please enter all co-morbidities available in both hospital and GP notes.

Step 4: Select the completion status, then click "Save & Go To The Next Form"

Family History- cancer, ischaemic heart disease, stroke, ITP, autoimmune disease and other

There are six questions to complete

If you answer 'yes' to any question additional drop down boxes appear

Step 1: Answer have they had a family history of this type of condition

Step 2: Add specific form of disease e.g. acute myeloid leukaemia for cancer

Step 3: Specify which relation had the disease

Step 4: Repeat for all incidences in the family

Step 5: Select the completion status, then click "Save & Go To The Next Form"

Biochemical Fields at ITP Diagnosis

Please enter ALT, AST, ALP and Bilirubin levels. These values should be obtained as close to the diagnosis date as possible. If you do not have results for these fields close to diagnosis please use what you have, but be sure to specify the date.

Step 1: Enter the blood result making sure it is in the same unit as that stated

Step 2: Select whether the date is available

Step 3: Enter the date

Step 4: Select the completion status, then click "Save & Go To The Next Form"

Haematological Fields at ITP Diagnosis

As with "Biochemical Fields at ITP Diagnosis", please use the results which are closest to the time of ITP diagnosis and remember to specify the date the results were obtained.

Step 1: Enter the blood result making sure it is in the same unit as that stated

Step 2: Select whether the date is available

Step 3: Enter the date

Step 4: Select the completion status, then click "Save & Go To The Next Form"

Platelet Counts Manual Entry

Step 1: Enter the platelet count (unit= x10^9/l)

Step 2: Select whether the date is available

Step 3: Enter the date

If there are too many platelet counts to enter manually, please use the excel spreadsheet which you can upload (shown on the next page).

Step 4: Select the completion status, then click "Save & Go To The Next Form"

Platelet Counts File Upload Function: downloading template

Step 1: Click on "File Repository" under the "Applications" bar on the left hand side
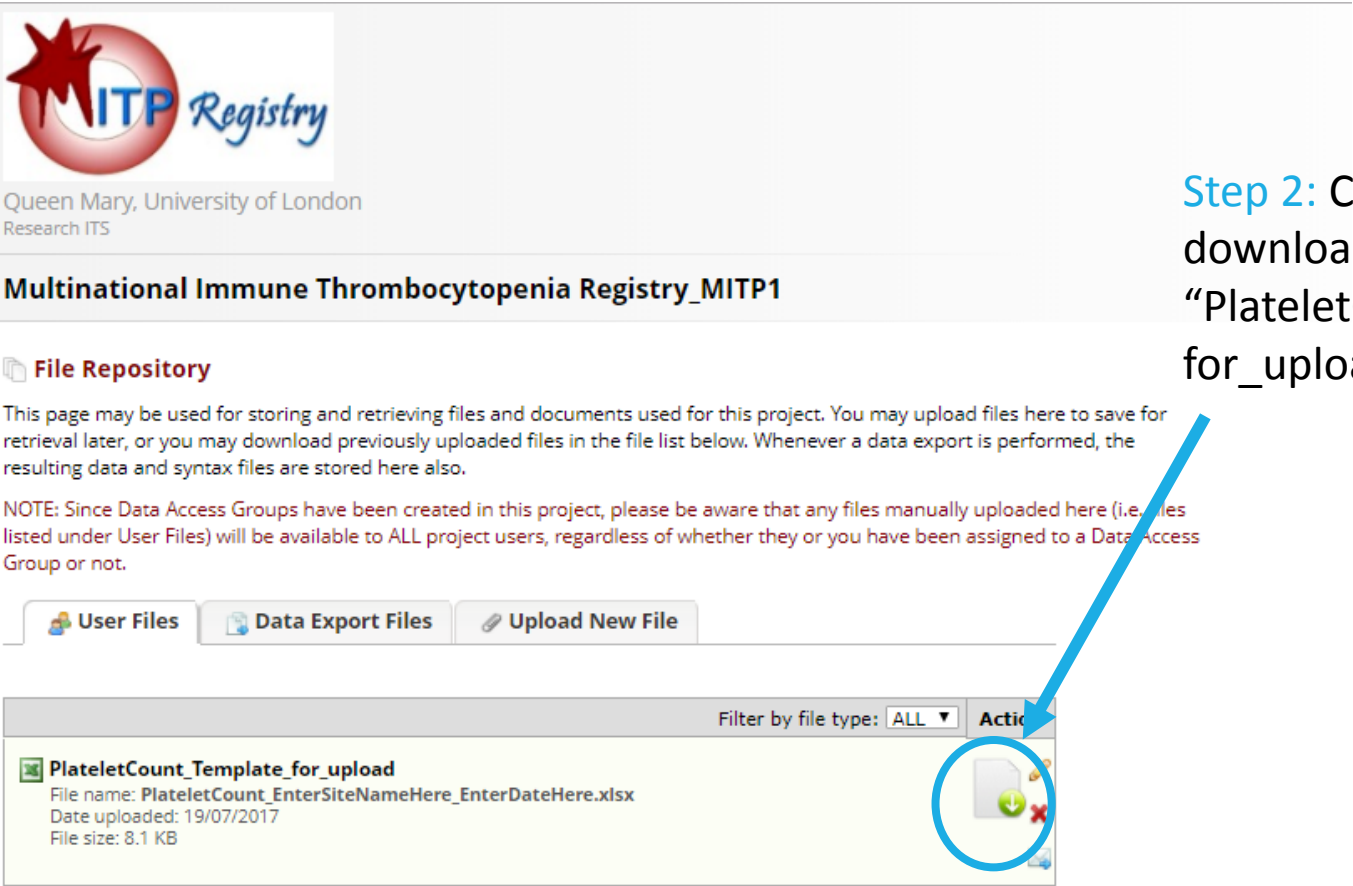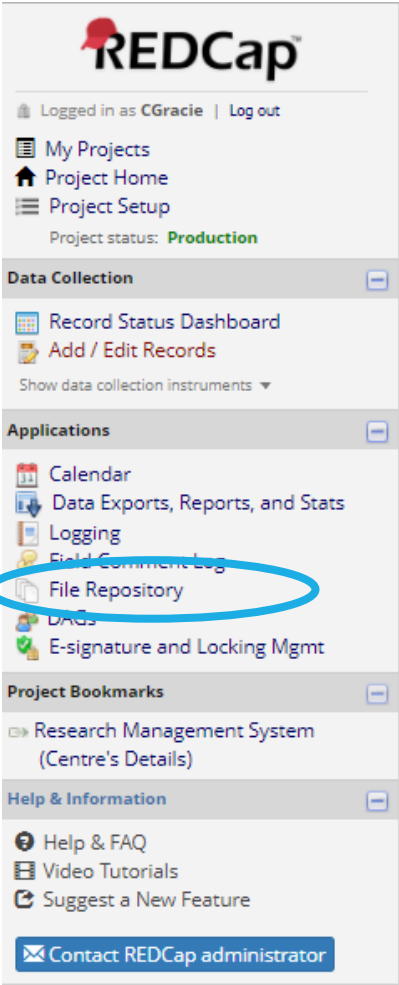
Step 2: Click on the download symbol next to "PlateletCount_Template_for_upload"

Platelet Counts File Upload Function: filling out template

Step 3: Fill out the template as this example has been

RIC in every row →

Step 4: Save the template. Make sure the name includes the RIC of the patient

	A	B	C	D	E	F
1	Registry Identification Code (RIC)	Platelet Count (platelet_ct)	Date (platelet_dt)			
2	ABC12345	100	01/01/2001			
3	ABC12345	35	02/01/2001			
4	ABC12345	10	03/01/2001			
5	ABC12345	9	04/01/2001			
6	ABC12345	15	05/01/2001			
7	ABC12345	25	06/01/2001			
8	ABC12345	60	07/01/2001			
9	ABC12345	65	08/01/2001			
10	ABC12345	67	09/01/2001			
11	ABC12345	59	10/01/2001			
12	ABC12345	60	11/01/2001			
13	ABC12345	30	12/01/2001			
14	ABC12345	27	13/01/2001			
15	ABC12345	23	14/01/2001			
16	ABC12345	25	15/01/2001			
17	ABC12345	21	16/01/2001			
18	ABC12345	86	17/01/2001			
19	ABC12345	90	18/01/2001			
20	ABC12345	100	19/01/2001			
21	ABC12345	98	20/01/2001			
22						

Date the platelet count was measured as short date format ←

Platelet Counts File Upload Function: uploading template

Step 5: Click on "Platelet Counts File Upload Function"

Step 6: Click on "Upload Document"

Step 7: This box will appear. Click choose file, find the file and click open

Step 8: Click on "Upload Document"

Platelet Counts File Upload Function: uploading template

Step 9: Make sure you can see the uploaded document here

Step 10: Select the completion status, then click "Save & Go To The Next Form"

Immunological Fields at ITP Diagnosis

Please give whichever set of results you have available that are closest in time to the ITP diagnosis date

Step 1: Enter the result making sure it is in the same unit as those stated

Step 2: Select whether the date is available

Step 3: Enter the date

Step 4: Select the completion status, then click "Save & Go To The Next Form"

Coagulation Field at ITP Diagnosis

Please give whichever set of results you have available that are closest in time to the ITP diagnosis date

Step 1: Enter the result making sure it is in the same unit as those stated

Step 2: Enter other values specified if available to you

Step 3: Select whether the date is available

Step 4: Enter the date

Step 5: Select the completion status, then click "Save & Go To The Next Form"

BM Aspirate, Trephine Biopsy & DAT

Step 1: Click Yes/NO/ Uncertain to show whether they have had the procedure. More options will appear if you click yes.

Step 2: Select whether the date is available

Step 3: Enter the date

Step 4: Choose the conclusion from the drop down box

Step 5: Select the completion status, then click "Save & Go To The Next Form"

Comments

This final page is for you to add anything extra that you think we should know about the patient.

Select the completion status, then click "Save & Go To The Next Form"

Finished record

At the end of adding patient data you should end up with "Record home page" which looks like this. This patient record is now complete.

We ask that every patient is followed up at least annually, but it is up to you if you wish to do it more frequently. Clinic visits offer convenient times to add more data for the patient. With each subsequent addition of data, you only need to add the new information. Do not delete the data that is already there, simply add the extra events at the end of the form.

Thank you for taking the time to add your patient data to our database.

For any queries with regards to data entry not addressed in this set of slides please contact the registry team at uk-itp.registryteam@nhs.net or call 02073 777 000 ext 61114 9am-5pm, Mon-Fri