

# 1 INTRODUCTION TO THE REGISTRY

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- The **United States Immunodeficiency Network (USIDNET)** is an NIH -funded research program of the Immune Deficiency Foundation (IDF)
- **Registry was established to:**
  - Advance scientific research in PIDD
  - Maintain validated data from patients with PI
  - Provide a comprehensive picture of each disorder
  - Act as a clinical and lab-based resource

## 2 REGISTRY SOFTWARE

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### 2.1 ACCESSING THE DATABASE

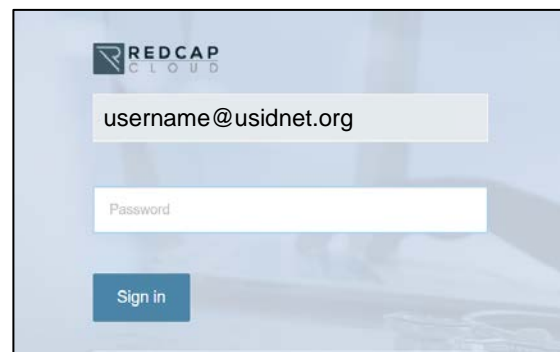
- The registry website is found at <https://login.redcapcloud.com>
  - **Registry is compatible with the latest version of most common browsers**

- 1) Enter your username. Your username will always end in **@usidnet.org**.



The screenshot shows the REDCAP Cloud login interface. At the top left is the REDCAP CLOUD logo. Below it is a text input field containing the placeholder text 'username@usidnet.org'. To the right of this field is a blue 'Sign in' button. Below the input field is a horizontal line, followed by a blue link that says 'Forgot password?'. At the bottom of the page, there is small text: 'Copyright © 2015-2017, nPhase, Inc. All rights reserved. Privacy | Terms'.

- 2) After the system validates your username, you will be prompted to enter your password.



The screenshot shows the next step in the login process. The username field now contains 'username@usidnet.org'. Below it is a password input field with the placeholder text 'Password'. At the bottom left of the form is a blue 'Sign in' button. The REDCAP CLOUD logo is visible at the top left.

## 2.2 FORGOT PASSWORD

- USIDNET users are now able to reset their passwords on their own.

- 1) Click on the **Forgot Password** link, below the Sign In button



REDCAP CLOUD

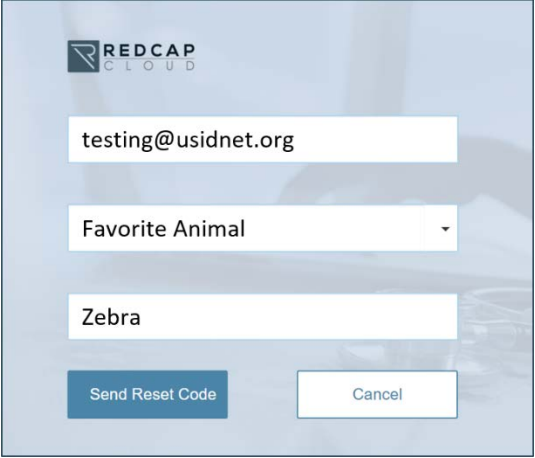
Username  Sign in

**Forgot Password?**

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Privacy | Terms

- 2) Answer the following
  - Username
  - Security Question
  - Security Answer

- 3) Password reset link will be sent to your inbox.



REDCAP CLOUD

testing@usidnet.org

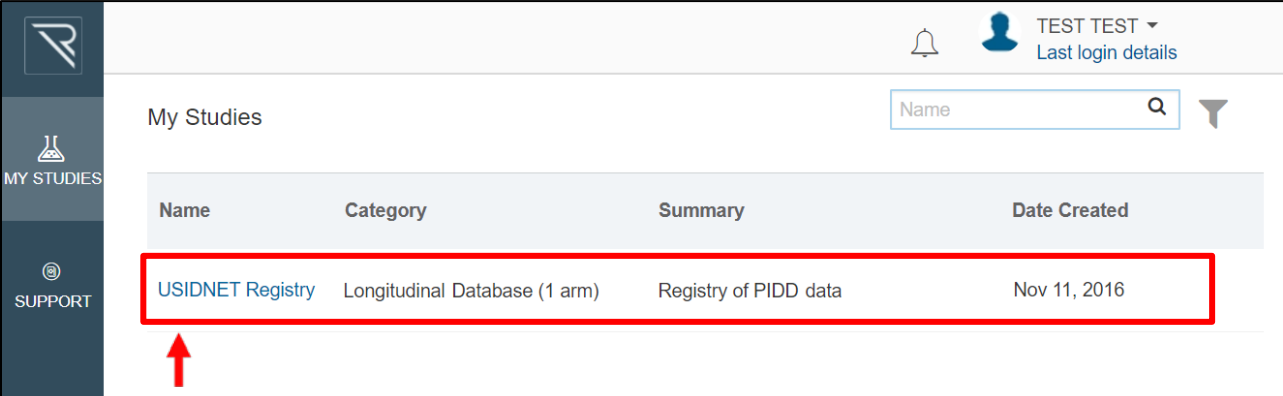
Favorite Animal

Zebra

Send Reset Code Cancel

## 2.3 MY STUDIES

- After logging in, you will be directed to the **My Studies** screen.
- Select **USIDNET Registry** (it should be the only option displayed).



My Studies

TEST TEST Last login details

Name

Name	Category	Summary	Date Created
<b>USIDNET Registry</b>	Longitudinal Database (1 arm)	Registry of PIDD data	Nov 11, 2016

SUPPORT

## 2.4 MODULES



There are three modules within the USIDNET Registry, accessed on the sidebar.

- **Study Module:** first screen that you see when you enter the USIDNET registry
  - View enrollment progress for your enrolling site
  - View users assigned to your enrolling site
- **Subjects Module:** used for all data entry
  - **Enroll:** subjects can be added, updated, or marked for deletion.
  - **Subject Dashboard:** clinical data can be added to your subject.
  - **Queries:** if any values trigger a warning, will see a list of alerts.
- **Data Module:** used for data reading
  - Data Export
  - File Repository

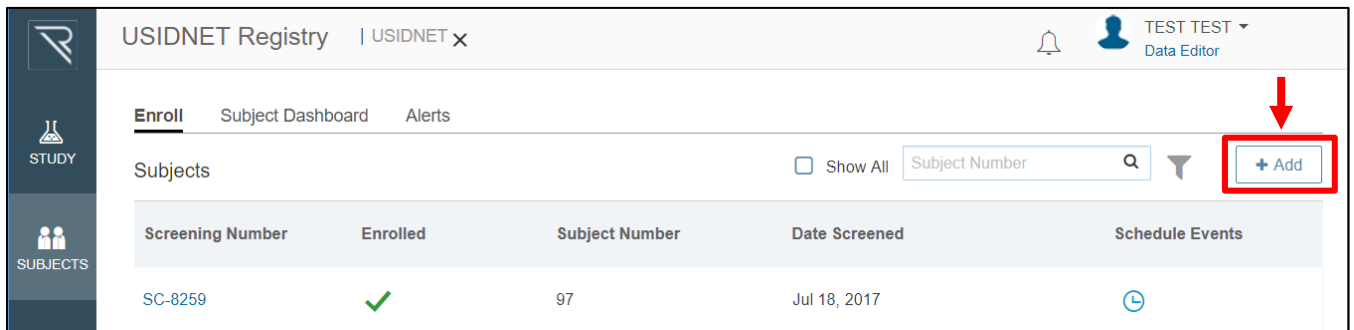
## 3 REGISTRY ENROLLMENT

- A **Patient Record** holds all data related to a participant.
  - Records are automatically assigned a record ID.
- Patient Records are referred to as **Subjects** in this software.
  - Before any clinical data can be entered, you must create a subject.

### 3.1 ENROLLING A NEW SUBJECT

All new patient records will be added from the **Enroll** screen, in the **Subjects** module.

- 1) Click the **+Add** button at the top of the Enroll screen.



You will be asked to complete some basic subject information. **All red fields are required.**

2) When you have completed this section, click **Next**.

USIDNET Registry | USIDNET x

Enroll Subject Dashboard

Subject Add

1 Enrollment Decision 2 Schedule Events

**Next**

Participant Information

Participant Name

Participant is de-identified\*  Yes  No

First Name\*

Middle Name

Last Name\*

Maiden / Other Name

3) On this screen, simply press **Save and Exit**.  
*YOU DO NOT NEED TO CHANGE ANY OF THE DATES OR TIMES.*

USIDNET Registry | USIDNET x

Enroll Subject Dashboard

Subject Add

1 Enrollment Decision 2 Schedule Events

Generate Schedule\* Yes

Start Date\* Jul 19, 2017

Schedule Events

Event Name	Date / Day of Week	Time
Consent	Jul 19, 2017	0 0
Family History	Jul 19, 2017	0 1

**Save and Exit** Cancel

Back

Congratulations, you have created a subject!

You can now view that subject in the **Subject Dashboard**.

## 4 ENTERING CLINICAL DATA

### 4.1 DEFINITIONS

- **Case Report Form (CRF):** any form in the registry where clinical data is entered.
- **Event:** infrastructure which holds the case report forms
  - Events may be repeating (such as the Registry Visit) or only collected at one time point (such as Patient Consent)

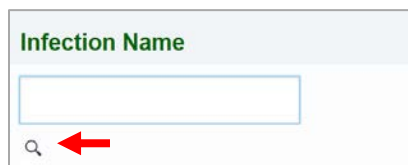
### 4.2 SPECIAL CASE FIELDS

#### 4.2.1 Red and Green Fields

- **Red Fields:** these fields are required.
  - You **MUST** enter this data in order to complete the visit.
- **Green Fields:** these fields contribute to the visit score
  - Visit scores will be discussed later

#### 4.2.2 Medical Coding

A magnifying glass denotes the presence of a **Medical Coding Dictionary**.



The image shows a text input field labeled "Infection Name". Below the field is a magnifying glass icon. A red arrow points to the magnifying glass icon.

Medical coding standardizes responses, making data easier to query.

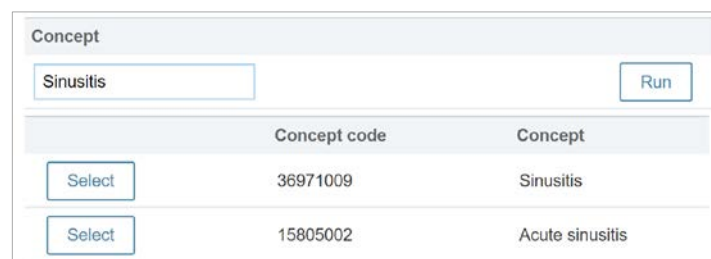
To use a medical coding field, follow these steps

- 1) Enter a term in the text box and press **enter**



The image shows the "Infection Name" field with the text "Sinusitis" entered. A magnifying glass icon is visible below the field.

- 2) When a dialog box appears, review and select the best-fitting term.



The image shows a dialog box titled "Concept". It contains a search input field with "Sinusitis" and a "Run" button. Below the input field is a table with two rows of results.

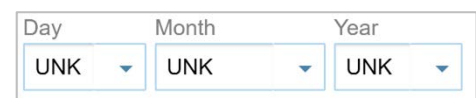
	Concept code	Concept
Select	36971009	Sinusitis
Select	15805002	Acute sinusitis

#### 4.2.3 Partial Date Fields

In many areas of the registry, you may enter **partial dates**.

When using partial dates, follow these guidelines:

- Provide at least YEAR if entering data.
- An entry of *March* is not helpful, but *March 2006*, or *2006* is.







The image shows three dropdown menus labeled "Day", "Month", and "Year". Each menu has "UNK" selected.

### 4.3 THE SUBJECT DASHBOARD

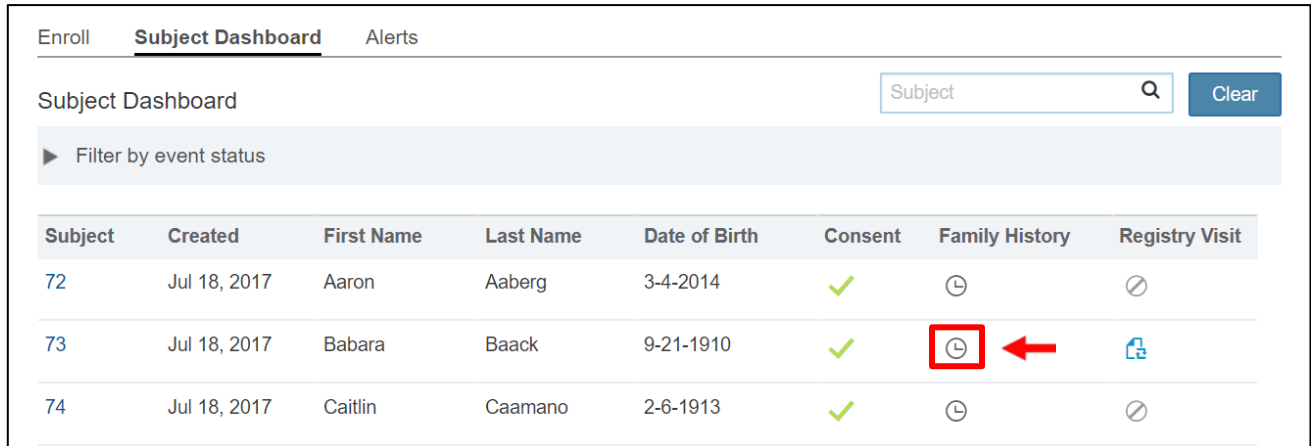
On the [Subject Dashboard](#), you will see all of your enrolling site's participants.

These icons will tell you the status of an event:

	No event created
	Event created, Data entry not started
	Data entry started
	Complete

### 4.4 ENTERING DATA IN AN EXISTING EVENT

To enter data in an event that *has already been created*, click the event icon or select the subject row.



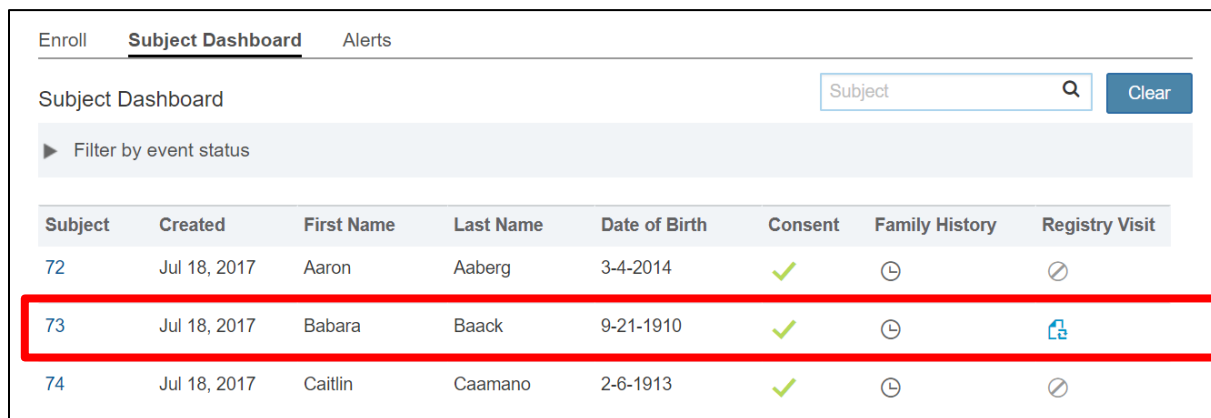
The screenshot shows the 'Subject Dashboard' interface. At the top, there are tabs for 'Enroll', 'Subject Dashboard', and 'Alerts'. Below the tabs is a search bar labeled 'Subject' with a 'Clear' button. A 'Filter by event status' dropdown is visible. The main content is a table with the following columns: Subject, Created, First Name, Last Name, Date of Birth, Consent, Family History, and Registry Visit. The table contains three rows of data. The row for subject 73 is highlighted, and the clock icon in the 'Family History' column is circled in red with a red arrow pointing to it.

Subject	Created	First Name	Last Name	Date of Birth	Consent	Family History	Registry Visit
72	Jul 18, 2017	Aaron	Aaberg	3-4-2014	✓	🕒	🚫
73	Jul 18, 2017	Babara	Baack	9-21-1910	✓	🕒	📄
74	Jul 18, 2017	Caitlin	Caamano	2-6-1913	✓	🕒	🚫

### 4.5 CREATING A REGISTRY VISIT EVENT

To add a new registry visit, click anywhere in the subject's row.

You will be directed to the [Subject Detail Page](#).



This screenshot is identical to the one in section 4.4, showing the 'Subject Dashboard' interface. However, the entire row for subject 73 is highlighted with a red rectangular box, indicating that clicking anywhere in the row will lead to the subject's detail page.

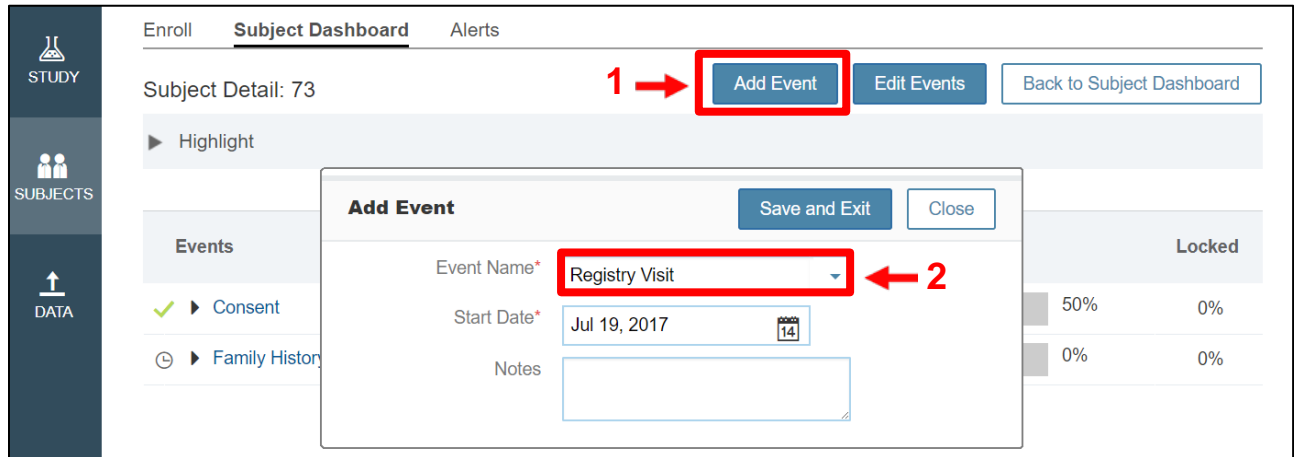
Subject	Created	First Name	Last Name	Date of Birth	Consent	Family History	Registry Visit
72	Jul 18, 2017	Aaron	Aaberg	3-4-2014	✓	🕒	🚫
73	Jul 18, 2017	Babara	Baack	9-21-1910	✓	🕒	📄
74	Jul 18, 2017	Caitlin	Caamano	2-6-1913	✓	🕒	🚫

### 4.5.1 The Subject Detail Page

On this page, you will see all events currently scheduled for the selected patient.

To add a registry visit follow these steps

- 1) Click the **Add Event** button at the top of the screen.
- 2) Select **Registry Visit** from the drop-down box
- 3) Click **Save and Exit**.

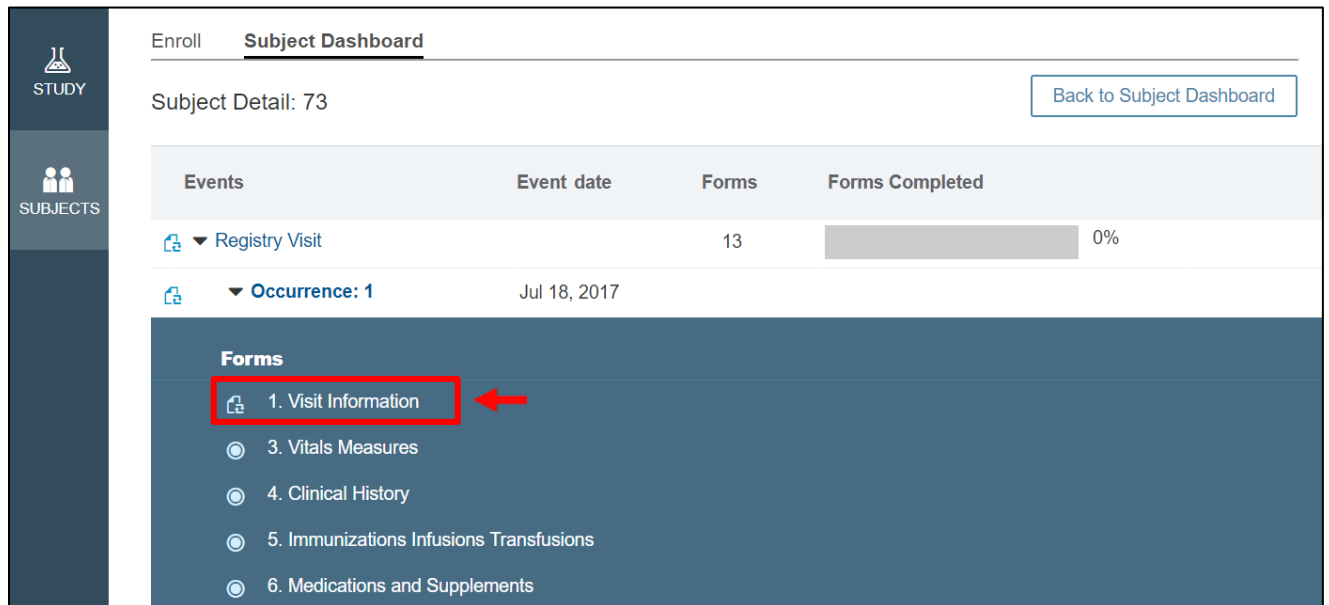


### 4.6 ENTERING DATA IN AN EVENT

On the Subject Detail page, each scheduled event will expand to display all its forms.

Click on a CRF to enter a form.

Click **Save and Exit** at any time to return to this screen.

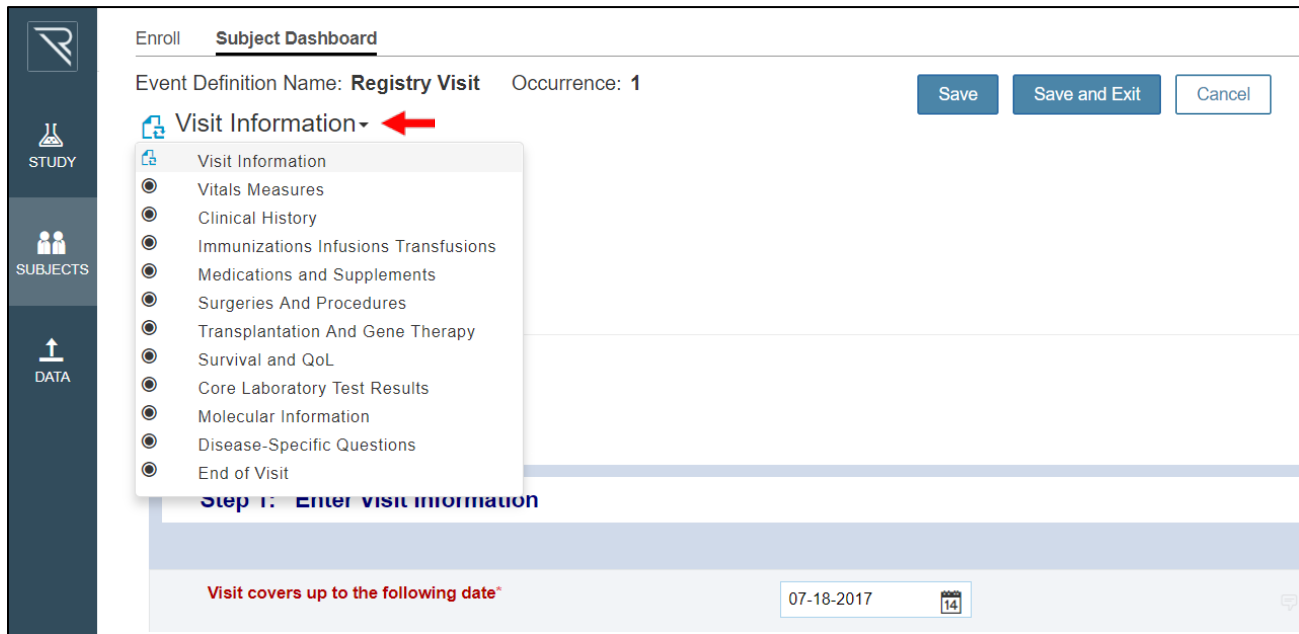


## 4.6.1 Navigating an Event with Multiple Forms

In a *Registry Visit*, you can navigate between forms without having to return to the subject detail screen.

- 1) Click on the carrot beside the CRF title.
- 2) You will then see a drop-down of available CRFs.
- 3) **Save your work before moving from one CRF to another!**

**NOTE:** In a Registry Visit event, the Visit Information CRF must be completed first.

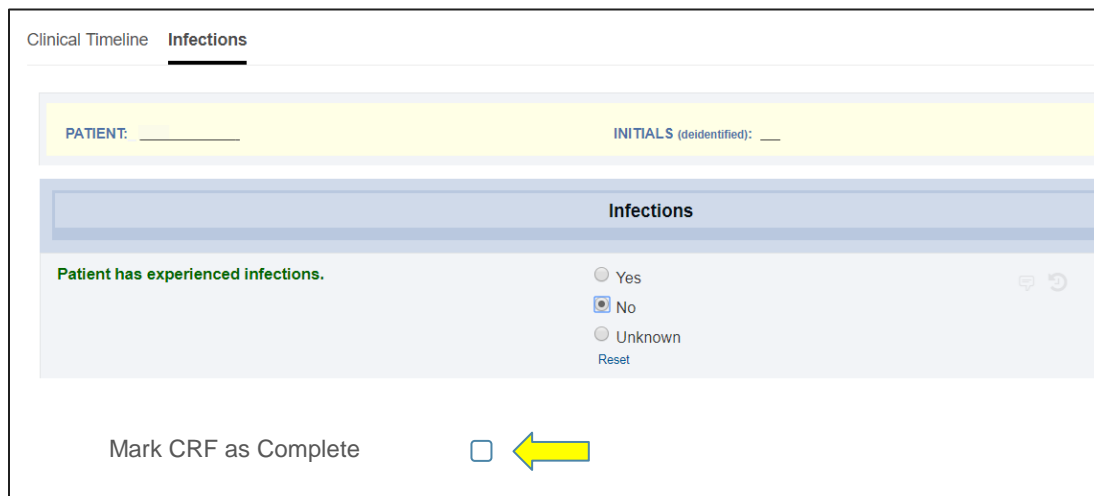


The screenshot shows the 'Subject Dashboard' interface. At the top, it displays 'Enroll Subject Dashboard' and 'Event Definition Name: Registry Visit Occurrence: 1'. There are three buttons: 'Save', 'Save and Exit', and 'Cancel'. A dropdown menu is open under 'Visit Information', with a red arrow pointing to the dropdown arrow. The dropdown menu lists several CRFs: Visit Information, Vitals Measures, Clinical History, Immunizations Infusions Transfusions, Medications and Supplements, Surgeries And Procedures, Transplantation And Gene Therapy, Survival and QoL, Core Laboratory Test Results, Molecular Information, Disease-Specific Questions, and End of Visit. Below the dropdown, the text 'Step 1: Enter visit information' is visible. At the bottom, there is a field for 'Visit covers up to the following date\*' with the value '07-18-2017' and a calendar icon.

## 4.6.2 Completing a Form

When you are completely finished entering data on a form, click the checkbox at the bottom of the screen labeled **Mark CRF as complete**

- The software will make sure that all required fields have been filled out
- **Please note: only click the checkbox after all sections in a form have been completed.**  
The box applies to the ENTIRE FORM, not just an individual section.



The screenshot shows the 'Clinical Timeline Infections' form. At the top, there are fields for 'PATIENT:' and 'INITIALS (deidentified):'. Below this is a section titled 'Infections' with the text 'Patient has experienced infections.' and three radio buttons: 'Yes', 'No' (which is selected), and 'Unknown'. There is a 'Reset' button below the radio buttons. At the bottom of the form, there is a checkbox labeled 'Mark CRF as Complete' with a yellow arrow pointing to it.



A completed form will look like the form displayed below.

The screenshot shows a web interface with a tabbed menu at the top containing 'Clinical Timeline' and 'Infections'. The 'Infections' tab is active. Below the tabs is a yellow header bar with 'PATIENT: \_\_\_\_\_' and 'INITIALS (deidentified): \_\_\_\_'. Underneath is a blue header bar with the title 'Infections'. The main content area has a light blue background and contains the text 'Patient has experienced infections.' in green, followed by 'No' in black. To the right of 'No' are three small icons: a pencil, a speech bubble, and a refresh symbol. At the bottom of the form, there is a 'Mark CRF as complete' button with a checkmark icon and a refresh icon.

## 4.7 END OF VISIT FORM

The final form in a **Registry Visit Event** is entitled **End of Visit**. This form serves two functions:

- Check the current **Visit Score** to see if the visit is eligible for reimbursement (80% score or higher)
- Confirm that data entry is complete and ready for review.

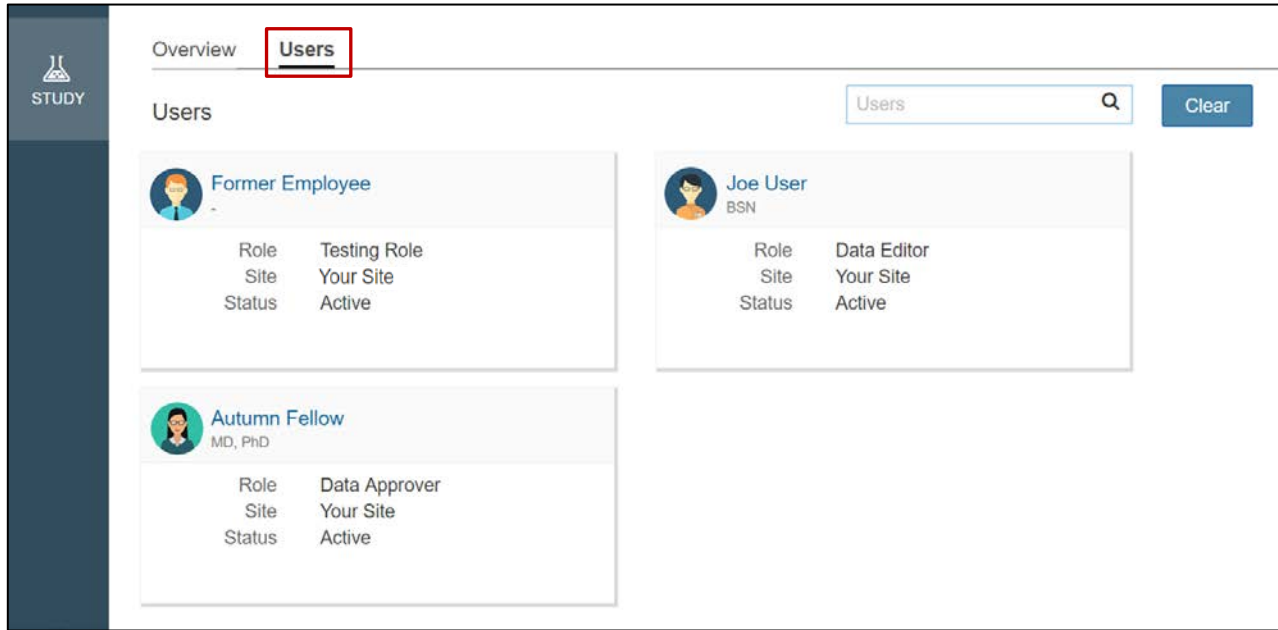
The screenshot displays the 'End of Visit' form. At the top left, there is a radio button selected next to 'End of Visit'. Below this, the 'Subject ID: 73' and 'Event Date: 07-18-2017' are shown. A navigation bar includes 'Summary Page' and 'Visit Score Breakdown' links, along with 'Save', 'Save and Exit', and 'Cancel' buttons. The main content area features the USIDNET logo (a program of IDF) and the heading 'Data Entry Complete'. Below the heading is the instruction: 'When you are completely finished entering data, please answer the question which follows.' A 'Data Entry Finished\*' label is followed by a red arrow pointing to an unchecked checkbox with the text 'I have finished entering data for this participant.' and a 'Reset' link. Below this is a section titled 'USIDNET Registry Visit Score' which contains a table with a 'Total Score' row showing '100' in a text input field followed by a '%' sign, with a red arrow pointing to the percentage symbol. At the bottom of the form, a green message reads 'Congratulations! Visit score meets criteria for compensation.'

# 5 ADDITIONAL TOOLS

## 5.1 VIEW USERS

In the **Study Module**, you can see all users that belong to your enrolling site.

If you see someone who should not have access, or if someone needs access, please **contact the Registry Manager**




## 5.2 SYSTEM-GENERATED QUERIES

- **Queries** are alerts that notify a user if a certain value falls out of an expected range.
  - If your data entry triggers a **query**, the system will alert you to check the value.
- You can view all open queries in the **Queries** section of the **Subjects** module.

To review and correct queries, follow these steps

- 1) Click on the **magnifying glass** to enter the CRF and view the field.

The screenshot shows the 'Queries List' table. The table has a search bar at the top with 'Subject ID' and 'Event Name' search fields, and a dropdown menu for 'Open query'. The table has the following columns: Note ID, Subject ID, Status, Event Name, CRF, and Field. A red arrow points to a magnifying glass icon in the first row, indicating where to click to view the query details.

Note ID	Subject ID	Status	Event Name	CRF	Field
 13380	00008000	Open query	Registry Visit	Core Laboratory Test Results	Absolute Lymph Count

- 2) A field with an open query will be marked with a **red message icon**. Review the data input.
  - a. If it is incorrect, update the value.
  - b. If it is correct, click the icon.
- 3) A new box will appear. Mark the **Close Query** box and write “**value is correct**”

Note ID	Query	Close Query / Comment
13380	Comment	<div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> Close Query           <div style="margin-left: 20px;">             Comment* <input style="border: 1px solid blue; padding: 2px 10px;" type="text" value="Value is correct"/> </div> </div>

- 4) Click **Save and Exit** to close the query.

### 5.3 DATA EXPORT TOOL

The **Data Export** tool allows you to export data from **your site**. This tool is located in the **Data Module**.

- 1) Click the **+Add** button to start a new export.

Data Export		File Repository		
Data Export		Name	Q	+ Add
Name	Description	Creation Date	Status	Download
071817	071817	07/18/2017	Ready	

- 2) **Select the following**
  - a. Instrument (Subject, CRF, etc.)
  - b. CRF Status
  - c. Dataset Format

**Dataset Properties**

Name\*

Description\*

Export Data From\*

Instruments\*

Instrument Name	Delete
Patient Information	

CRF Status

Dataset Format

- 3) Click **Save and Exit**

4) To download your saved export, click on the **Download** icon.

The screenshot shows the 'Data Export' section of a 'File Repository'. At the top, there is a search bar labeled 'Name' and a '+ Add' button. Below this is a table with the following columns: Name, Description, Creation Date, Status, and Download. A single row is visible with the following data: Name: 071817, Description: 071817, Creation Date: 07/18/2017, Status: Ready. The 'Download' column for this row contains a green download icon, which is highlighted by a red arrow pointing to it from the right.

5) Select the desired file underneath **Extracted Files**.

The screenshot shows the 'Data Export' section. At the top right, there are three buttons: 'Generate' (highlighted in blue), 'Clear', and 'Cancel'. Below these buttons is a list of export parameters: Name: Subjects Imported, Description: Subjects Imported, Export Data From: Your Site, Instruments: All, CRF Status: All, and Dataset Format: Excel. A red arrow points down from the 'Generate' button area to the 'Extracted Files' section. The 'Extracted Files' section contains a table with the following columns: File Name, Run Time (s), File Size (Bytes), Created Date, and Action. A single row is visible with the following data: File Name: EXCEL\_071817.xlsx, Run Time (s): 0, File Size (Bytes): 7242, Created Date: Jul 18, 2017. The 'Action' column for this row contains a trash icon.

6) If you would like to re-run the report at a later date, click on the **Generate** button.

The screenshot shows the 'Data Export' section. At the top right, there are three buttons: 'Generate' (highlighted in blue), 'Clear', and 'Cancel'. A red arrow points up to the 'Generate' button. Below these buttons is a list of export parameters: Name: Subjects Imported, Description: Subjects Imported, Export Data From: Your Site, Instruments: All, CRF Status: All, and Dataset Format: Excel. The 'Extracted Files' section contains a table with the following columns: File Name, Run Time (s), File Size (Bytes), Created Date, and Action. A single row is visible with the following data: File Name: EXCEL\_071817.xlsx, Run Time (s): 0, File Size (Bytes): 7242, Created Date: Jul 18, 2017. The 'Action' column for this row contains a trash icon.

