# 1 INTRODUCTION TO THE REGISTRY

- 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

## 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**.


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

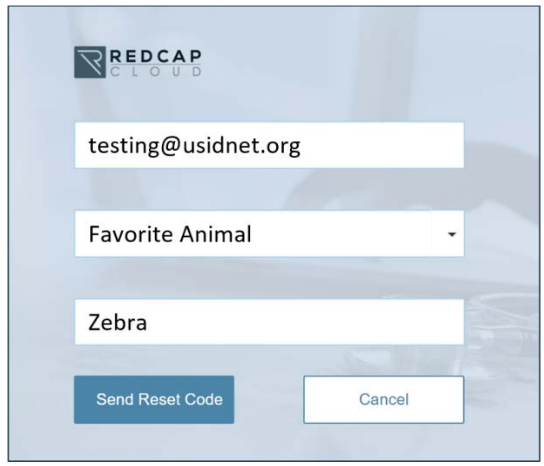
## 2.2 Forgot Password

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

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

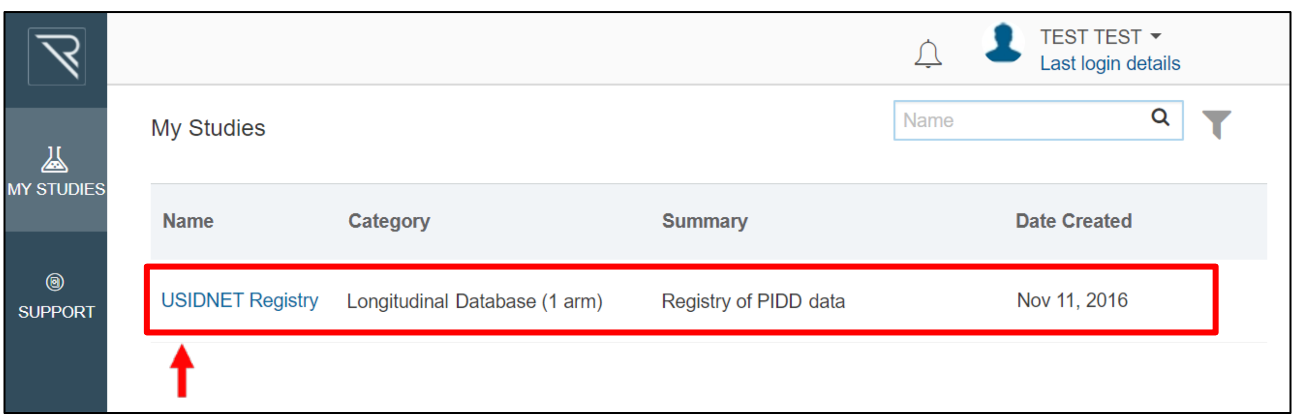

2) Answer the following
    - Username
    - Security Question
    - Security Answer

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




## 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).



## 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

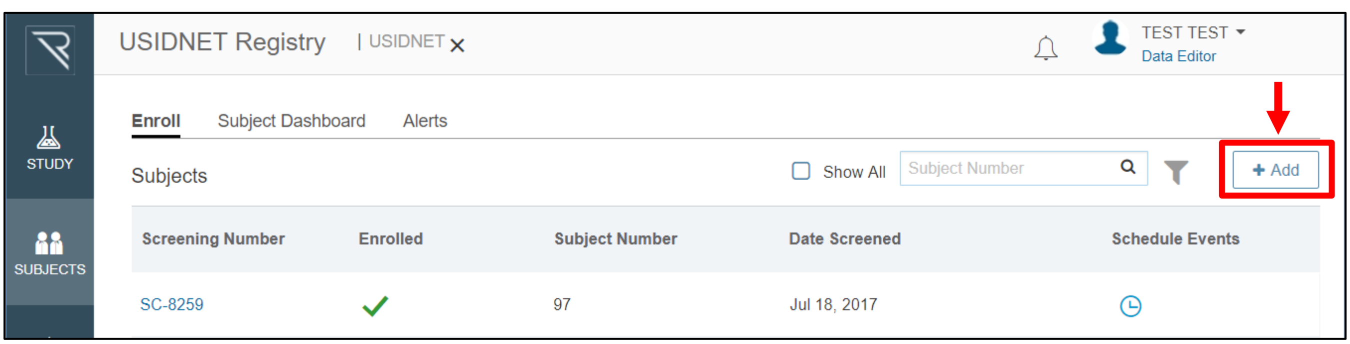
# 3 Registry Enrollment

- 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

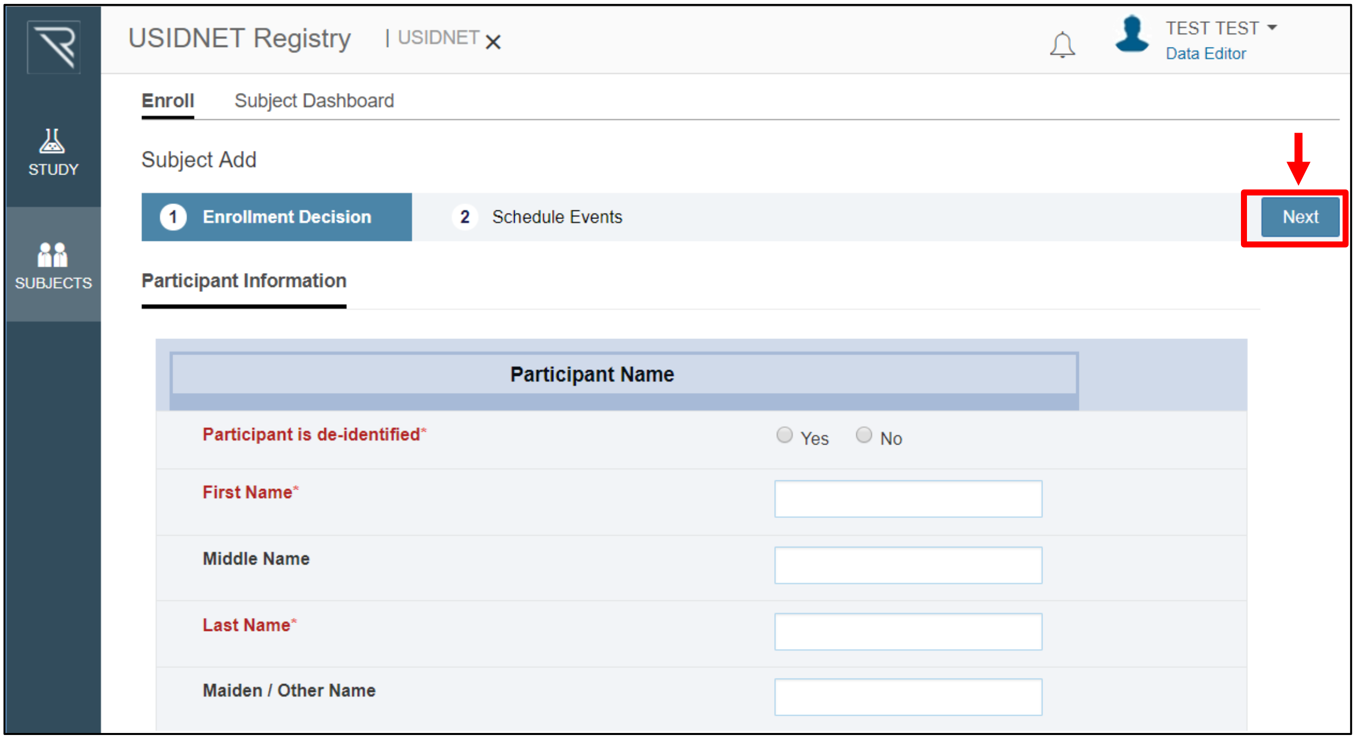
All new patient records will be added from the **Enroll** screen, in the **Subjects** module.

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

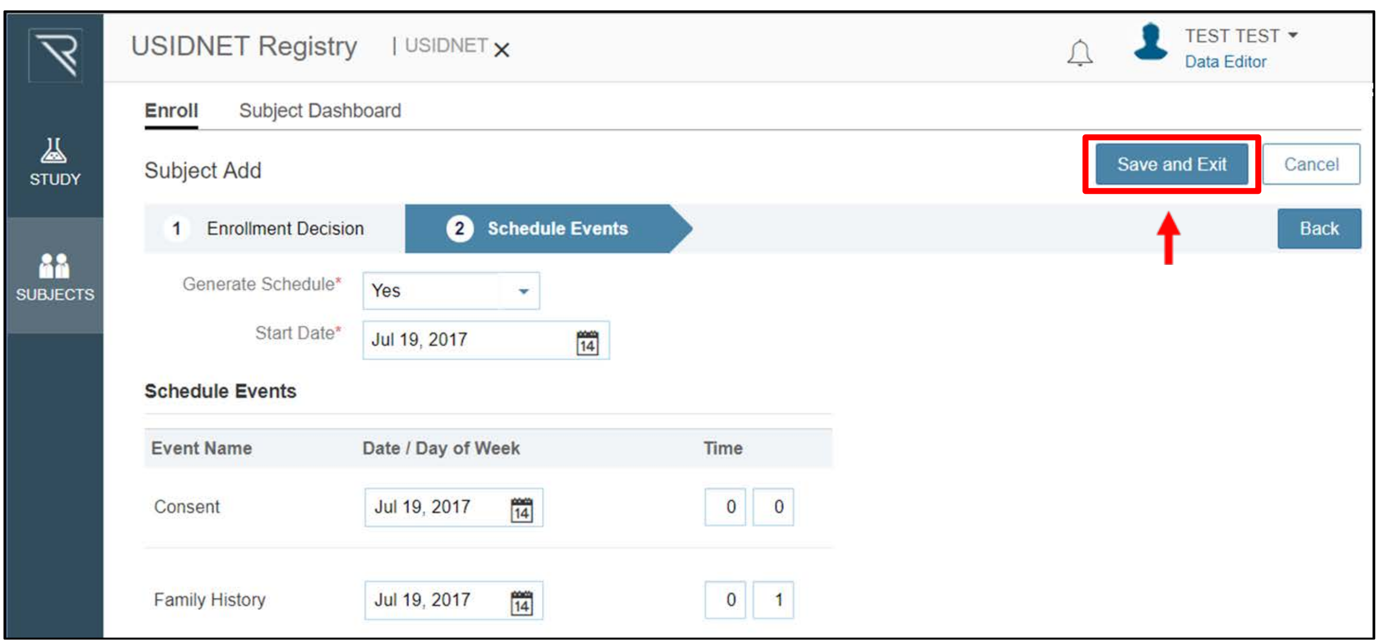



You will be asked to complete some basic subject information. **All red fields are required.**

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




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




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

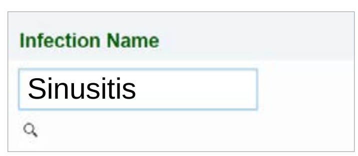
### 4.2.2 Medical Coding

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

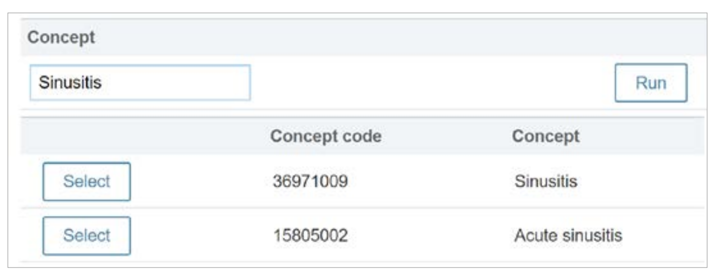

Medical coding standardizes  responses, making data easier to query.

To use a medical coding field, follow these steps

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




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




### 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.

## 4.3 The Subject Dashboard

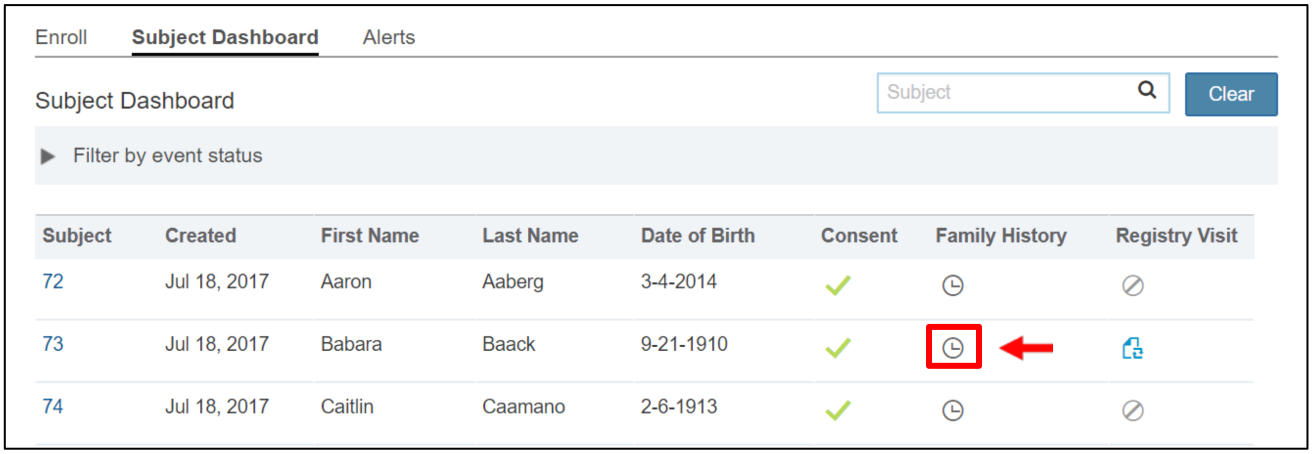
On the **Subject Dashboard**, you will see all of your enrolling site's participants.

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

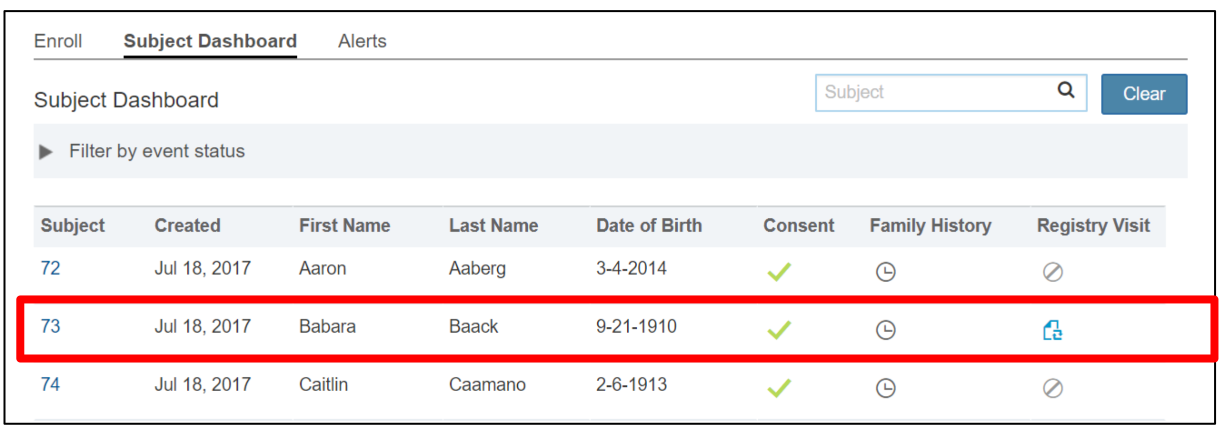
To enter data in an event that *has already been created*, click the event icon or select the subject row.




## 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**.

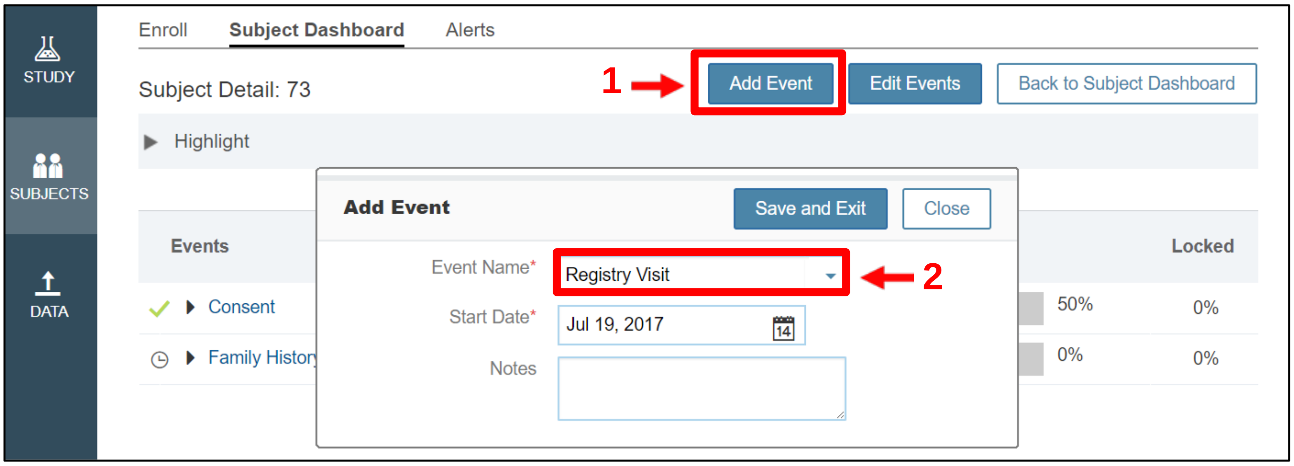


### 4.5.1 The Subject Detail Page

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**.

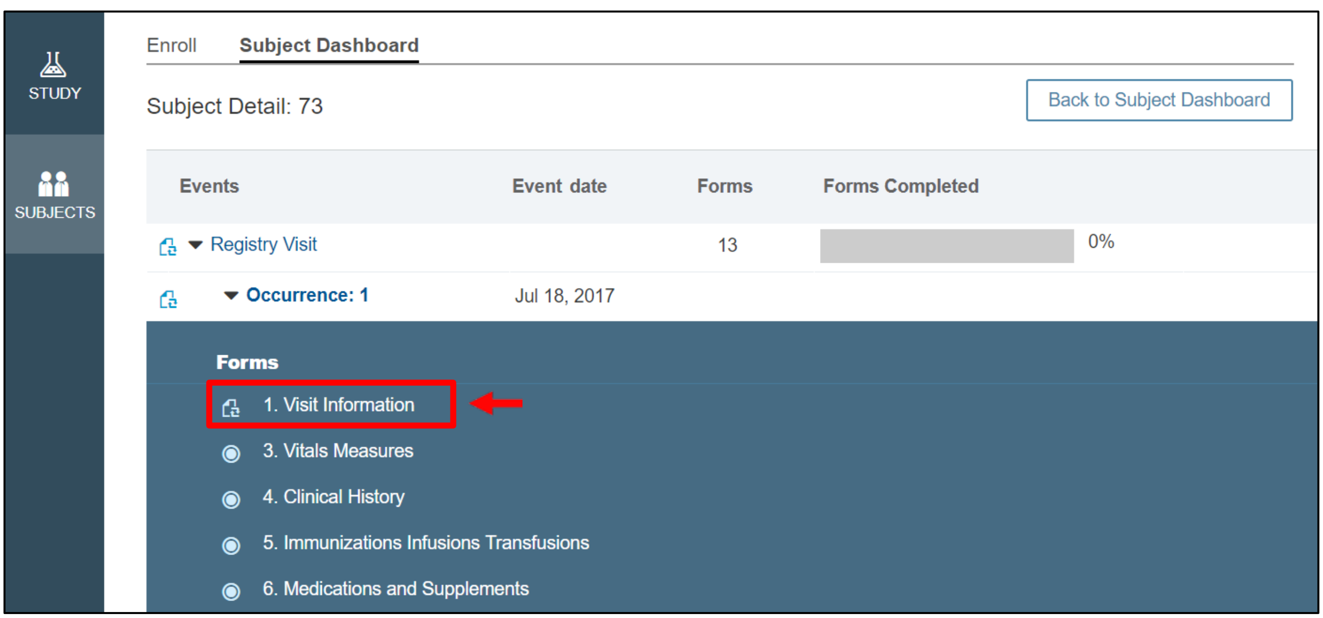



## 4.6 ENTERING DATA IN AN EVENT

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

Click on a CRF to enter a form.

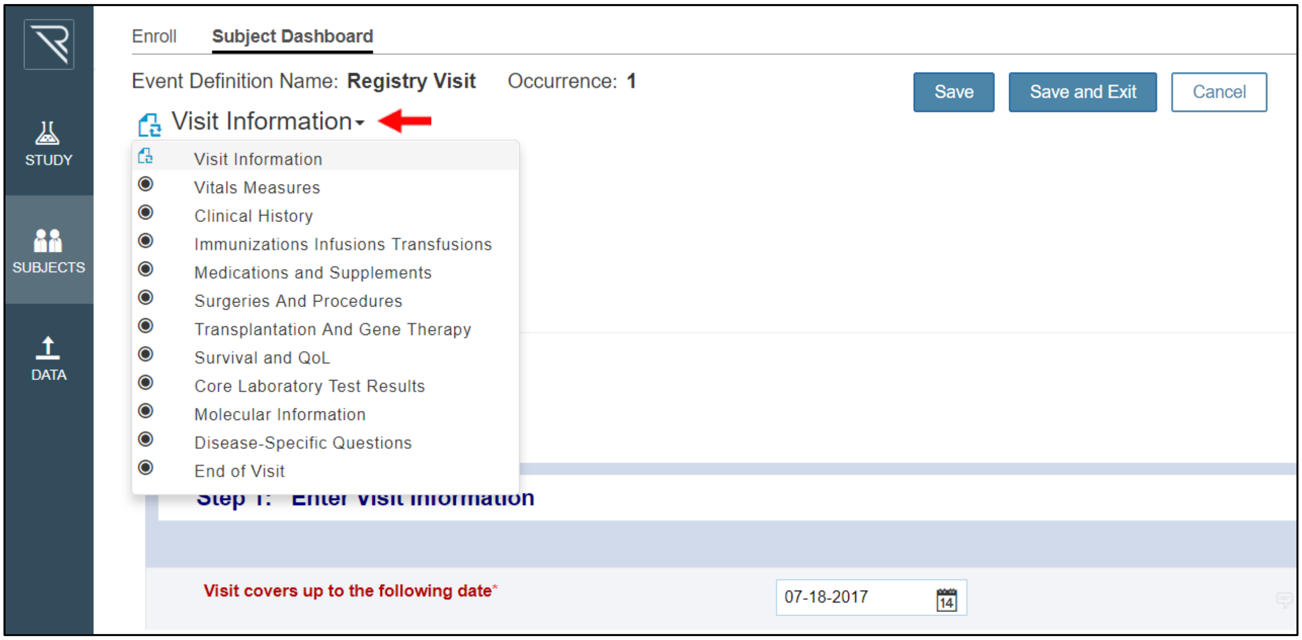
Click **Save and Exit** at any time to return to this screen.



### 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.

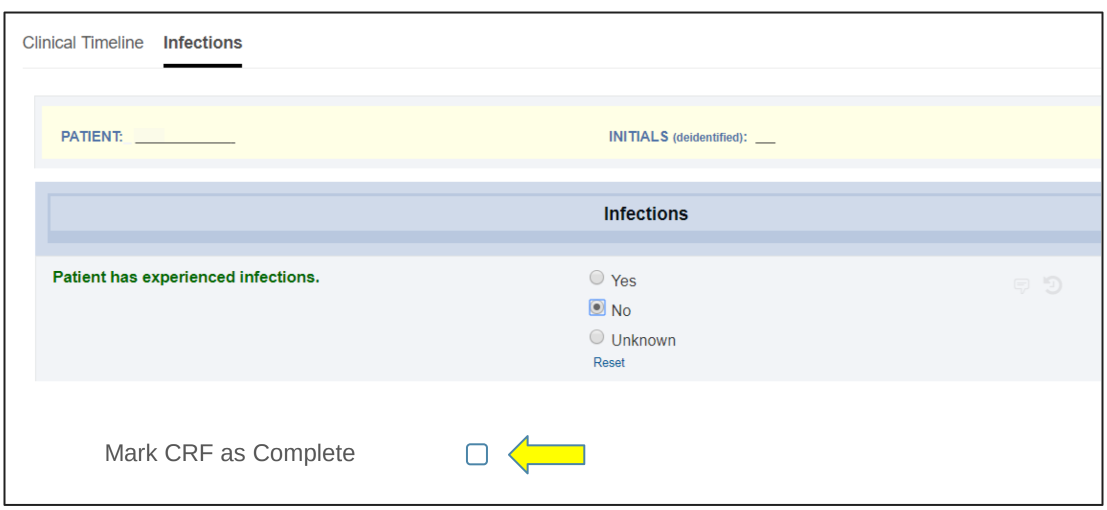
1) Click on the carrot beside the CRF title.
2) You will then see a drop-down of available CRFs.
3) **Save your work before moving from one CRF to another**!
   NOTE: In a Registry Visit event, the *Visit Information* CRF must be completed first.



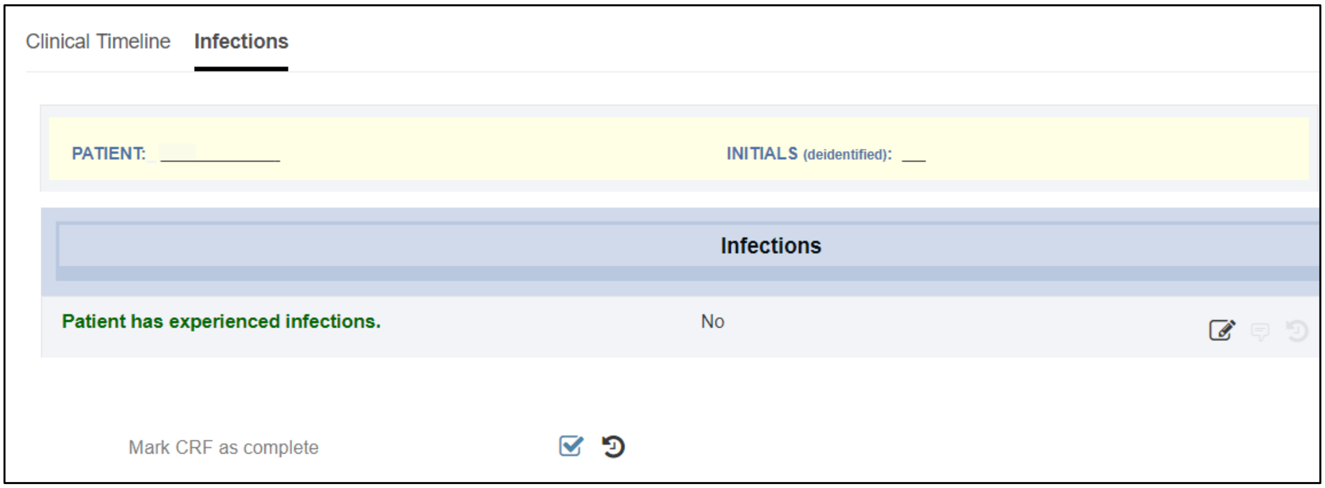

### 4.6.2 Completing a Form

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.



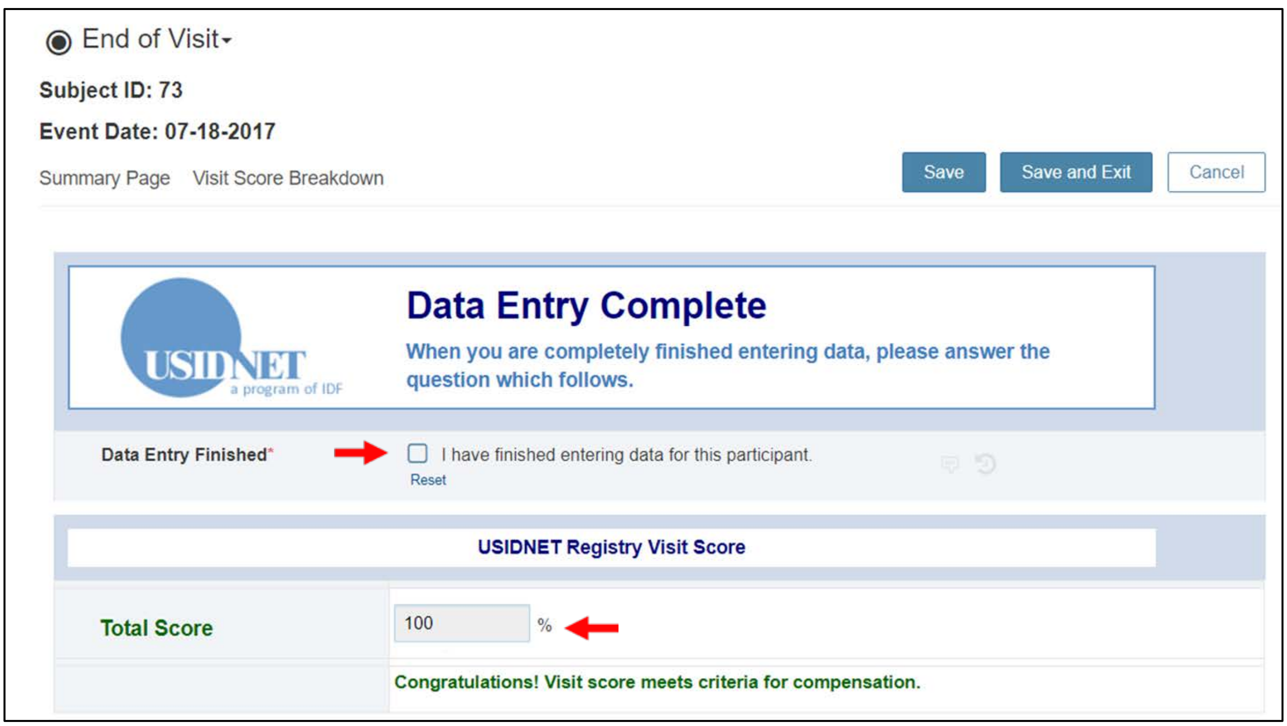
A completed form will look like the form displayed below.




## 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.

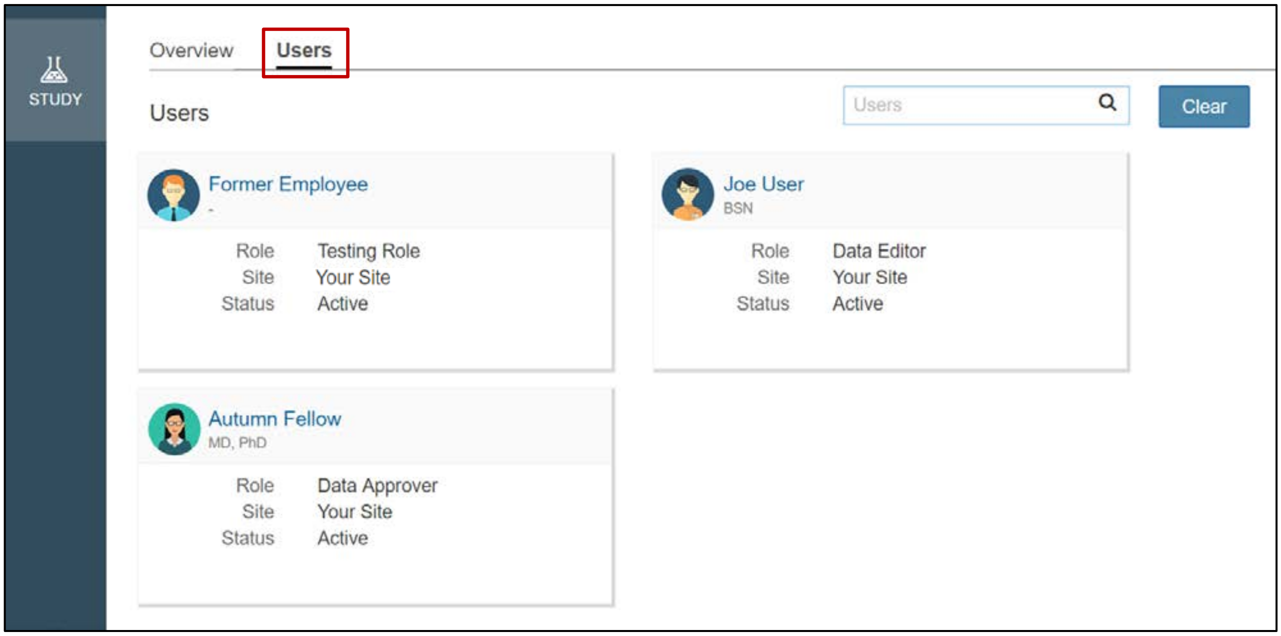


# 5 ADDITIONAL TOOLS

## 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**

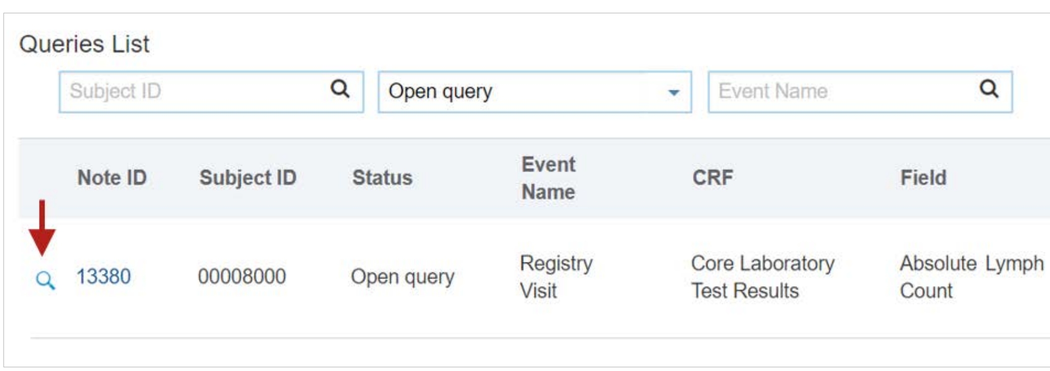



## 5.2 SYSTEM-GENERATED QUERIES

- **Queries** are alerts that notify a user if a certain value falls out of an expected range.
    - o 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.

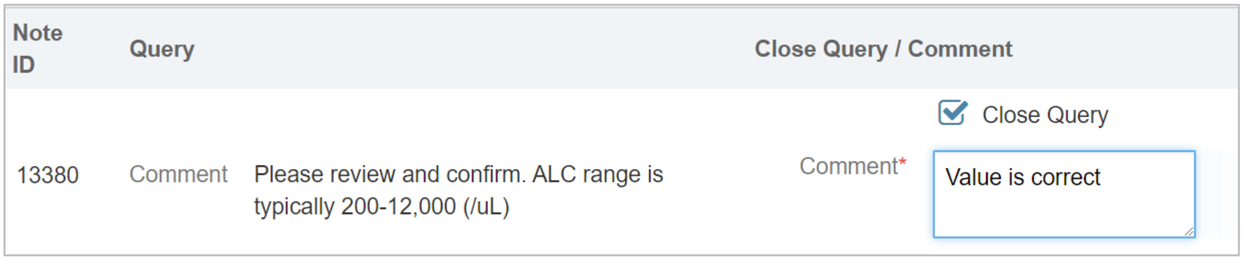


2) A field with an open query will be marked with a **red message icon**. Review the data input.

   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**"




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**.

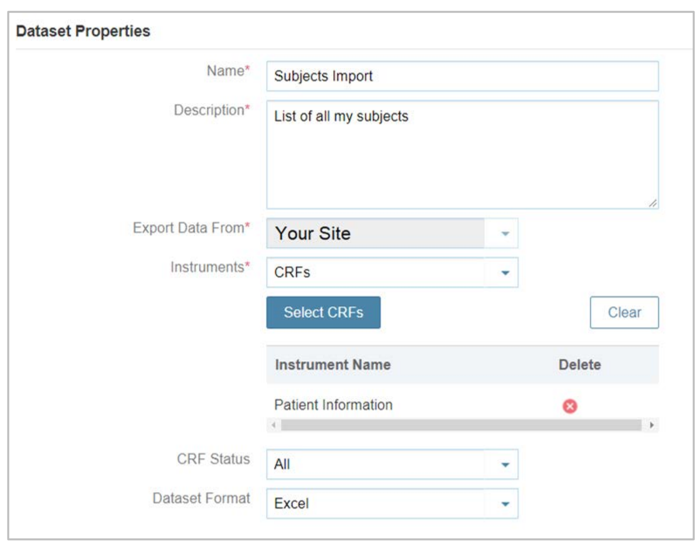
1) Click the **+Add** button to start a new export.


2) **Select the following**

   a. Instrument (Subject, CRF, etc.)

   b. CRF Status

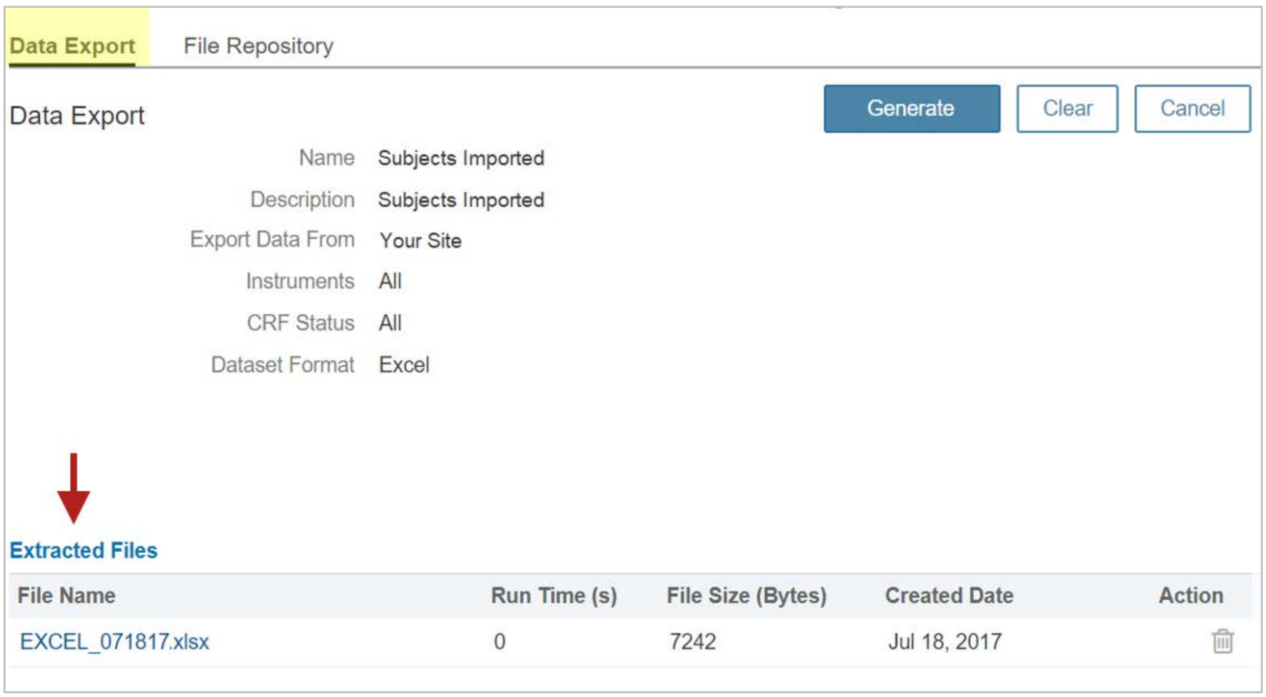
   c. Dataset Format




3) Click **Save and Exit**

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


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




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