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**.

![Participant Information](image)

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

![Schedule Events](image)

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.

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:

<table>
<thead>
<tr>
<th>Icon</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>✗</td>
<td>No event created</td>
</tr>
<tr>
<td>🕒</td>
<td>Event created, Data entry not started</td>
</tr>
<tr>
<td>🕒</td>
<td>Data entry started</td>
</tr>
<tr>
<td>✔</td>
<td>Complete</td>
</tr>
</tbody>
</table>

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.

![Image of Subject Dashboard]

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.

![Image of Clinical Timeline and Infections]

Mark CRF as Complete
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.
  - 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"

![Close Query Example](image)

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 Tool](image)

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

![Dataset Properties](image)

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.