Office of Clinical Research

CTMS Reference Guide
Patient Entry & Visit Tracking

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Logging into CTMS

CTMS is web-based. In order to access the application, click the URL provided to you by USF's CTMS Database Administrator.

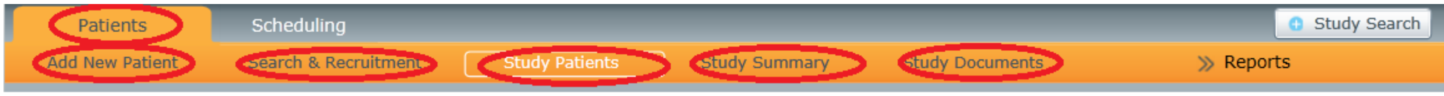
The first time accessing CTMS, you may be prompted to download and install Silverlight, an internet browser plug-in from Microsoft. Installing Silverlight is required in order to use Merge CTMS Investigator. Once Silverlight is installed, your CTMS URL will prompt your internet browser to open the application in a separate, secure browser window.

Enter your login (username) and password and click **Login**. Your username and password for CTMS will always be the same as your USF Health NetID and password. USF requires you to change your NetID password every six months. When you change your NetID password, you must use the new password to log into CTMS.

When a user logs into Merge CTMS, the user is taking responsibility for the data entered into the system. Patient information is confidential regardless of how it is obtained, stored, utilized, or disclosed. Merge CTMS users are required to conduct themselves in strict confidence to all applicable laws and institutional policies governing confidential information.

Patients Module

The Patients module is the area within CTMS where all patient related activities are performed and managed. It is organized into five primary sections:



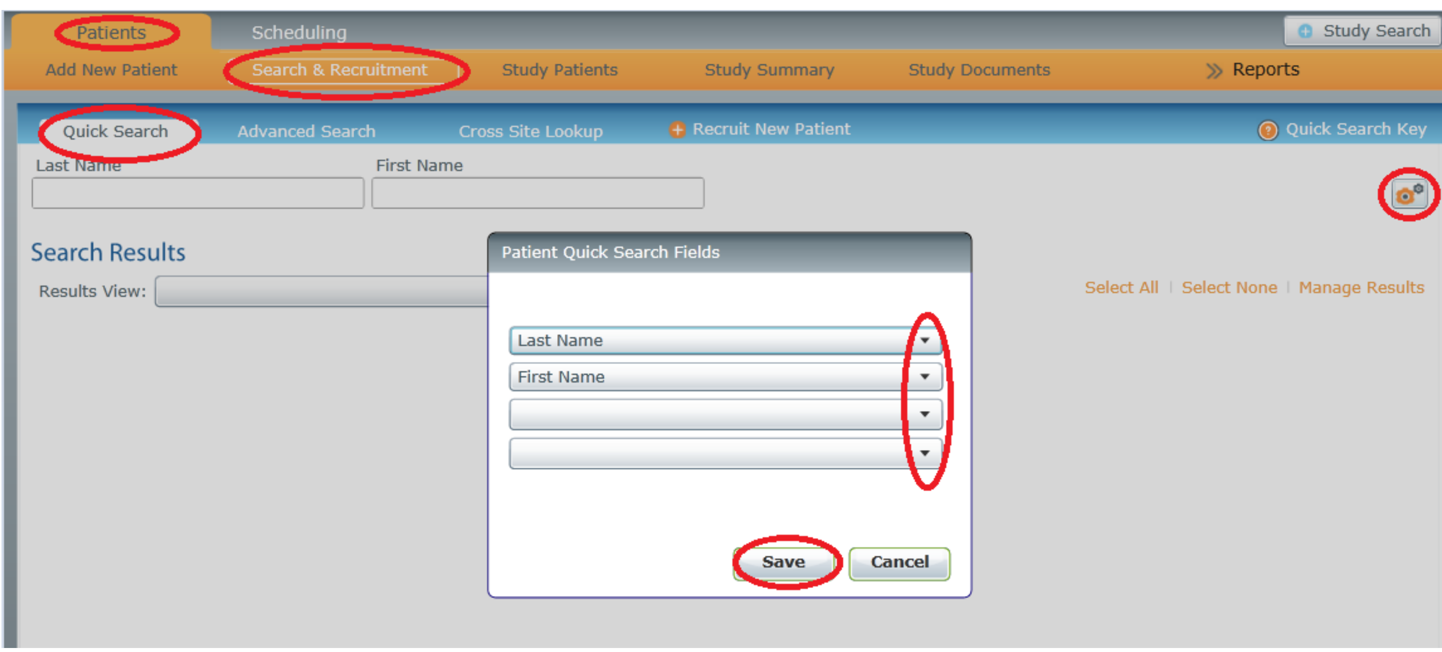
Search and Recruitment / Quick Search

Prior to entering a new patient, you will need to first search for the patient to confirm he/she does not already exist in the database. To do so, you will use the Quick Search tool inside the Search and Recruitment tab of the Patients module.

How to Configure Quick Search Fields

To quickly find patients, choose the fields that best match the search criteria you will want to use.

1. Go to the Patients module and click Search & Recruitment.
2. Click the Quick Search sub-tab.
3. Click the gears icon in the top right corner of your screen.
4. Select the search fields you wish to use from the four available lists.
5. Click Save.



Add New Patient

Quickly add and enroll new patients using the Patient-Entry wizard. Build demographic and enrollment data, optionally build medical history data.

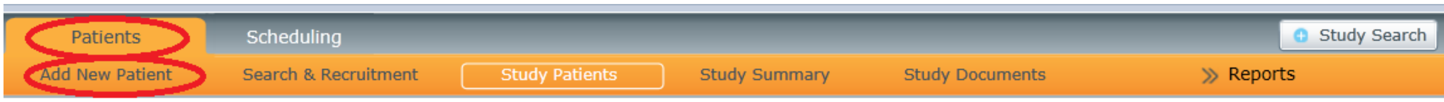
<u>How to Add a New Patient</u>

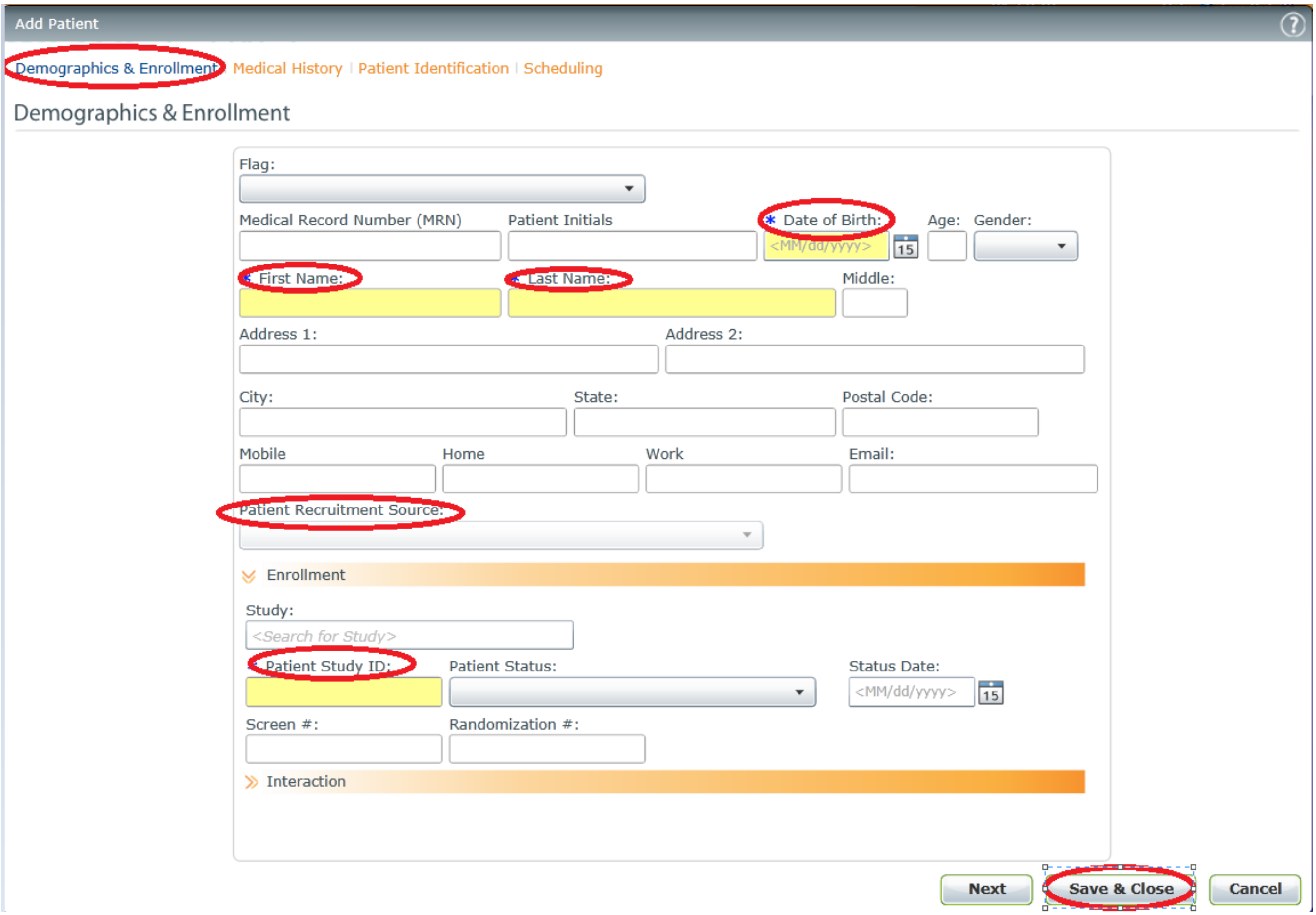
1. Click the Patients tab.
2. Click Add New Patient to display the wizard.
    a. Complete the required as well as any optional fields on the Demographics and Enrollment screen. Fields identified in yellow with blue asterisks are required fields. You cannot save the record until these fields are populated.

    a. You can simultaneously enroll each new patient into a study at the time you create the record by filling in the fields under the Enrollment Information section of the Demographics and Enrollment screen.

    b. If you do not enroll the patient in a study at the time of adding the new patient record to the database using the wizard, you will only have the ability to locate the patient record in the **Search and Recruitment / Quick Search** screen. **Quick Search** does a database wide search of patients regardless of whether or not patients have been enrolled in a study. You will not find the patient in the **Study Patients** screen as this screen only searches for patients that have been enrolled in a study.
3. Click Save and Close to complete the record.

    Note: You are not required to complete any information within the Patient Sites, Medical History, Patient Identification and Scheduling screens within the wizard.





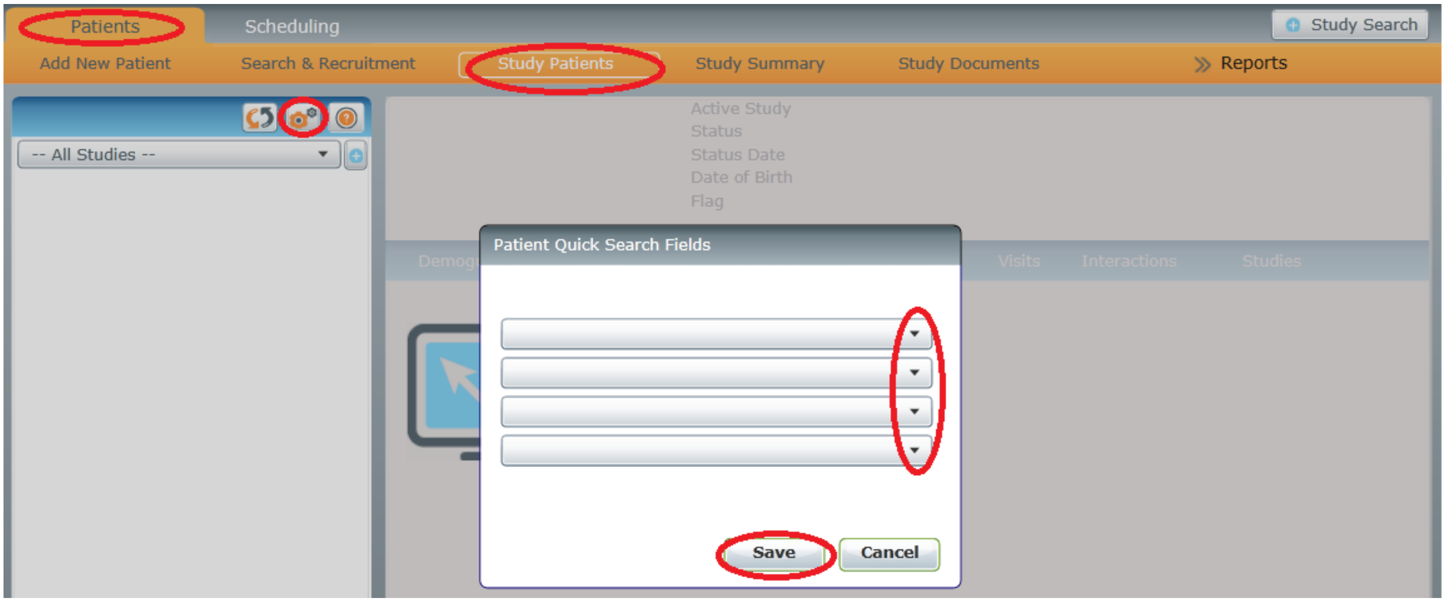
Study Patients

The **Study Patients** section of the **Patients** module provides you with a way to quickly generate a list of patients enrolled in, or associated with a specific study.

You can build search criteria into one or more of the four patient quick search fields to find a specific patient or set of patients. Additionally, these fields can be left blank and you can filter by study to see all of the patients associated with a single study. Once a list of results have been generated, simply select a patient record to quickly add or modify study visits, update enrollment data, demographics, medical history, or any other part of the patient profile.

<u>How to Build Patient Quick Search Fields in the Study Patients Screen</u>

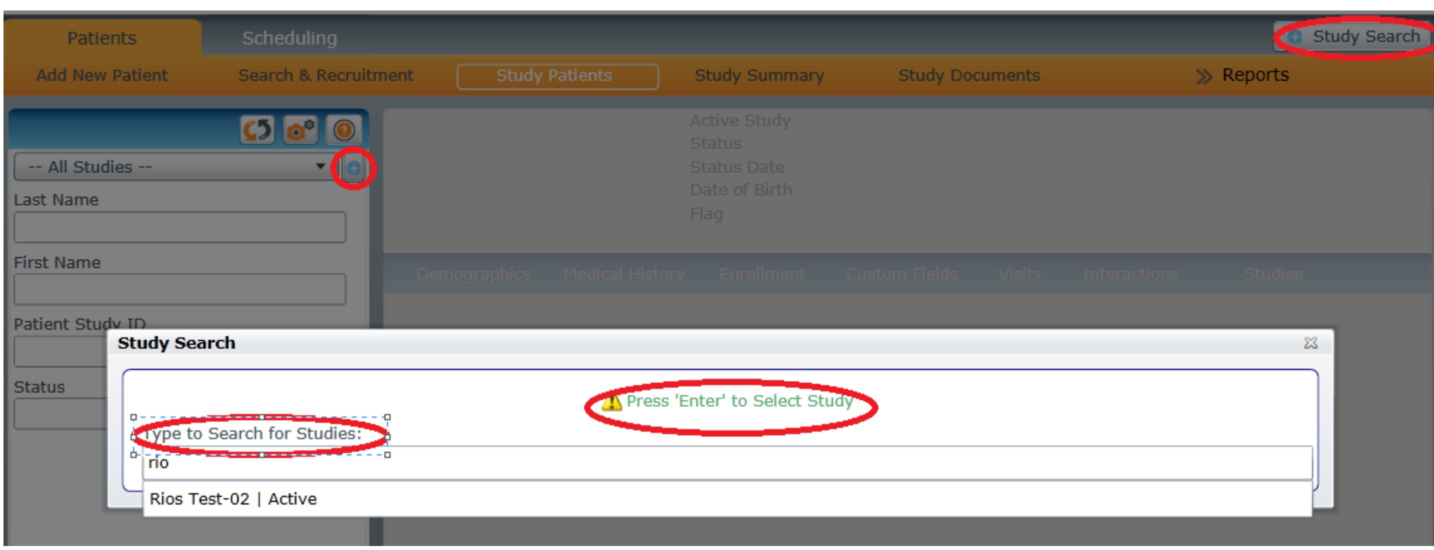
1. Go to the Patients module and click Study Patients.
2. Click the gears icon on the blue bar on the left side of the screen.
3. Select the search fields you wish to use from the four available lists.
4. Click Save.



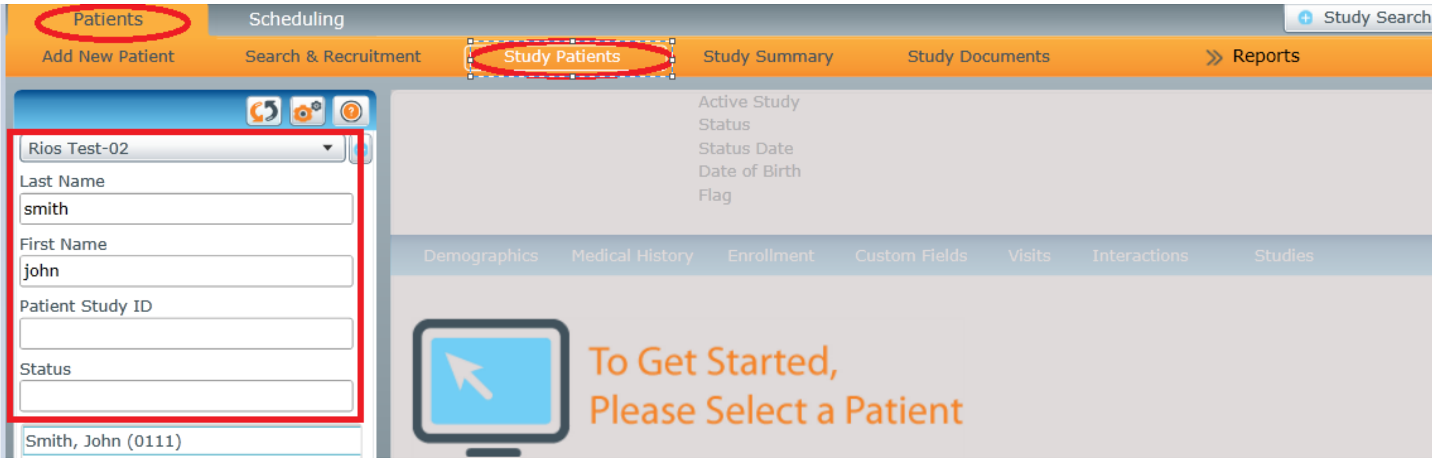
How to Locate a Patient's Profile

1. Go to the Patients module and click Study Patients.
2. Choose the appropriate study from the study list, and if necessary, click the Refresh Patient List icon  to generate a complete list of study patients.

   Note: The study list holds the most recent 100 studies your user account has viewed. If your study does not appear in the list, click the **blue plus icon** located to the right of the study list or **Study Search** located at the top right hand side of the screen to locate the study and add it to study list. Studies can be searched by StudyID, Protocol Number, Project Number, Sponsor, CRO, Therapeutic Area, Indication or Study Status.



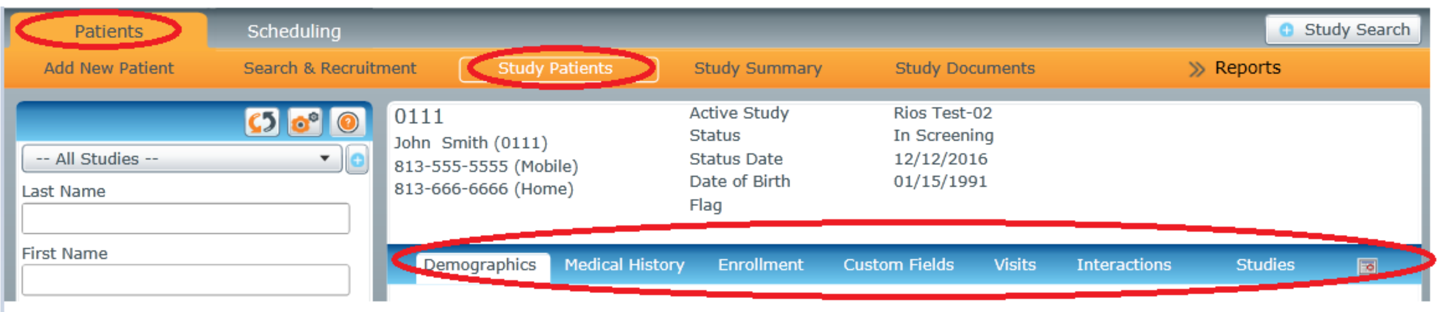
3. If the resulting list of patients is too large, you can enter criteria into one or more of the Quick Search fields to narrow the results of the search.



4. Select the patient from the generated list.

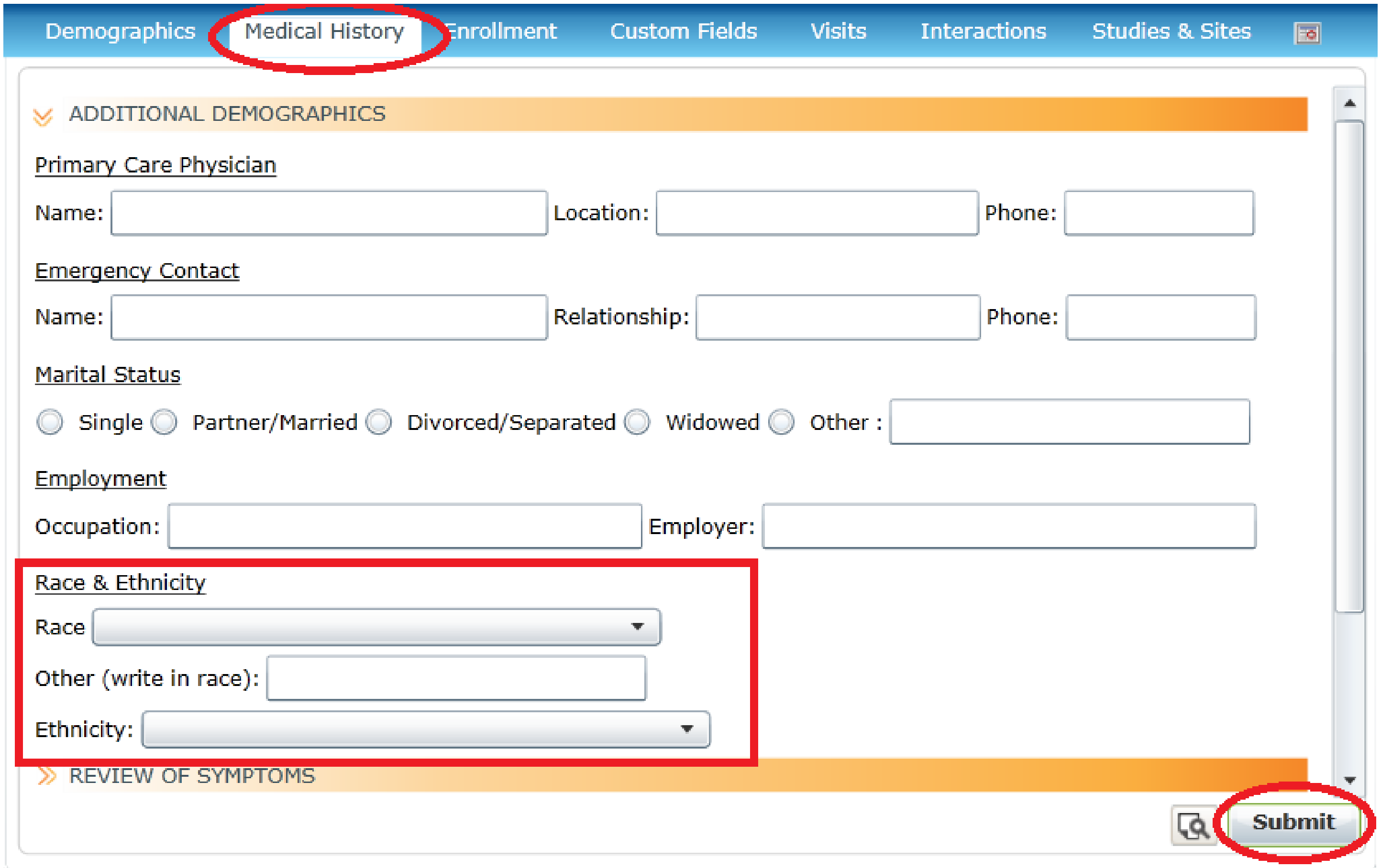
<u>Patient Profile</u>

Within the patient profile, you can manage activities for individual study patients, add or modify study visits, update demographics and medical history, add interactions and review patient study history. Patient related information can be added and/or modified within the various tabs within the patient profile.



1. **Demographics Tab:** Update patient demographics such as patient address, date of birth and phone numbers.
    a. Fields identified in yellow with blue asterisks to the left of the field name are required fields. You cannot save the record if these fields are not populated.

       USF has made the following fields required: First Name, Last Name and Date of Birth. All remaining fields within the demographics screen are optional, although it is highly recommended to complete all fields within the Demographics screen.
2. **Medical History Tab:** Capture medical history information such as medical conditions and medications.
    a. You are required to capture two fields within the Additional Demographics section of the Medical History Screen; Race and Ethnicity. The remaining fields within the Medical History screen are optional. All the data captured within the Medical History screen is searchable and reportable. For example, a report can be generated to show the race and ethnicity of all subjects enrolled in a trial or a query can be built to find existing patients in CTMS with a diagnosis of Asthma.



3. **Enrollment Tab**: Update patient enrollment information such as Patient Study ID, Screening, Number, Randomization Number and Enrollment Status.

   a. **Patient Study ID**: You are required to enter a value in this field. Capture the primary number assigned to the patient by the Study Sponsor in this field. The Patient Study ID appears on invoices generated in CTMS that will be sent to the Study Sponsor for patient related activity.

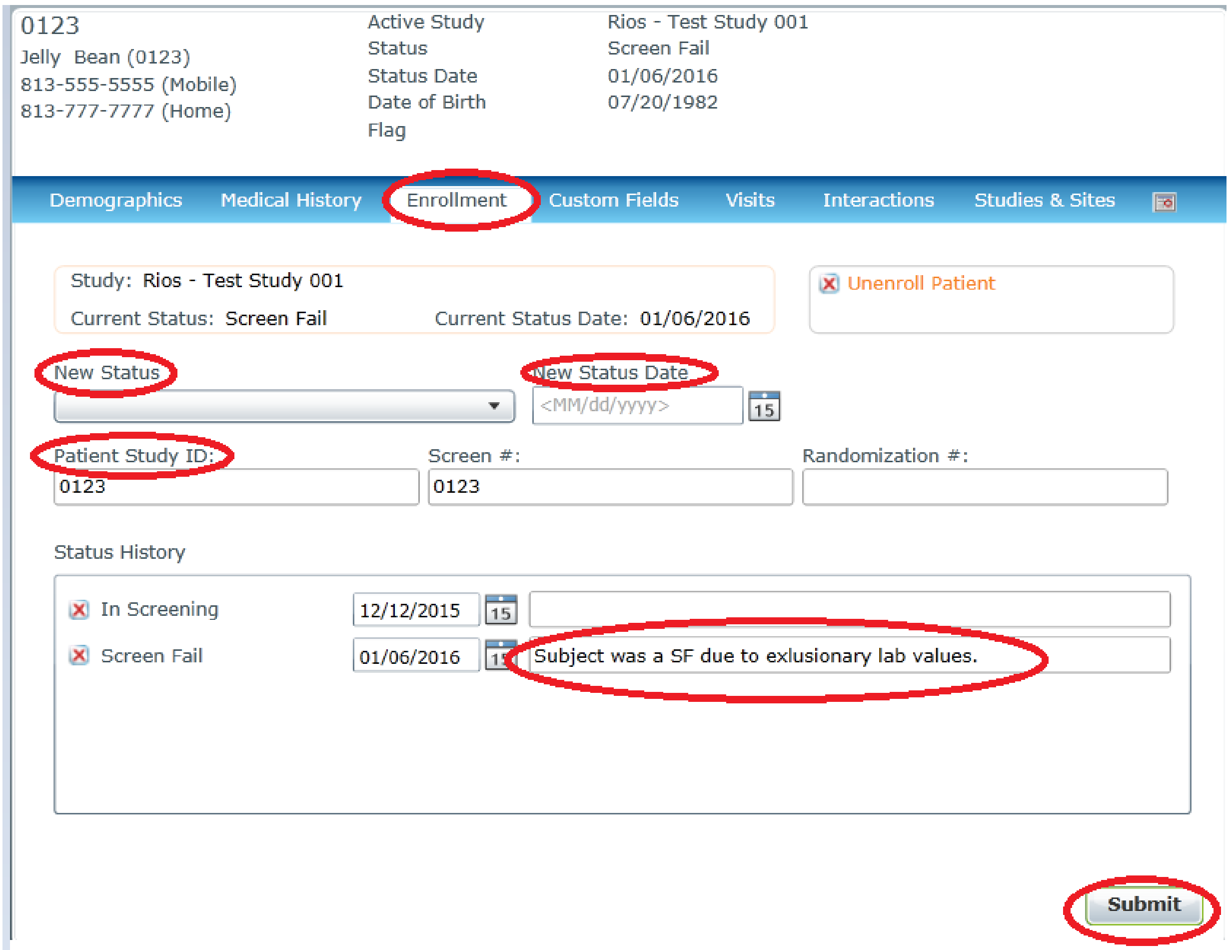
   b. **Enrollment Status**: You are required to update patient enrollment status and status dates as patients' progress through the study. The following enrollment statuses can be assigned to patients.

      - **In Screening** – Assign when patient has signed consent and has begun the screening process.
      - **Screen Fail** – Assign when patient has been identified as a screen failure.
      - **Enrolled** – Assign when a subject has successfully completed the screening process. Note, if the study does not have a screening visit (e.g., Registry and Chart Reviews), Enrolled will be the first status assigned to the patient.
      - **Discontinued** – Assign when patient has been discontinued from the study before study completion (e.g. lost to follow up, withdrawn, or transferred).
      - **Completed –** Assign when patient has completed the study as per the protocol.

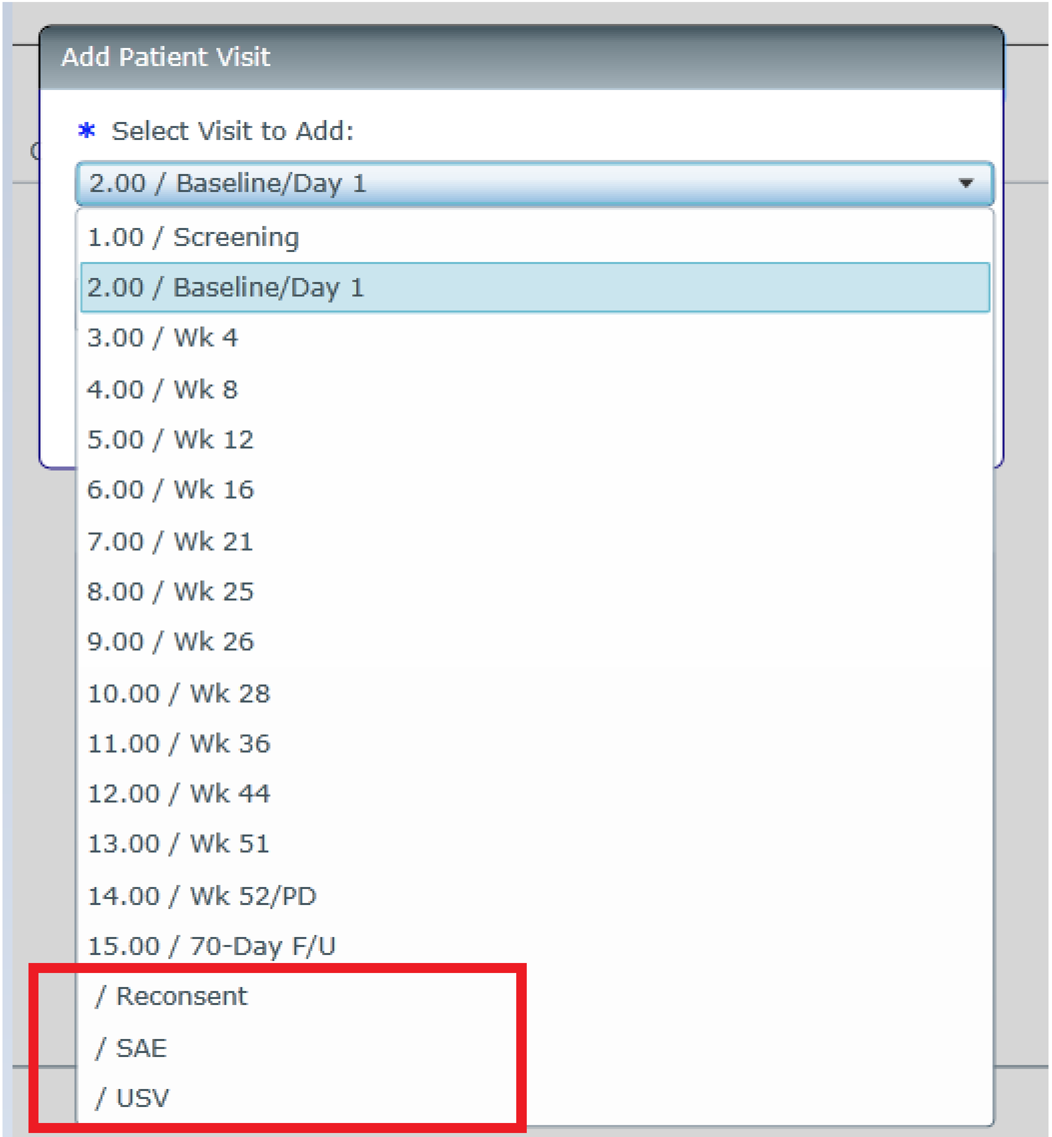
   Examples of the flow of enrollment status assignments are below.

   - In Screening -> Screen Fail
   - In Screening -> Enrolled -> Discontinued
   - In Screening -> Enrolled -> Completed

Note: Enrollment Status notes can be captured in the text box to the right side of the enrollment status date. It is highly encouraged to note in this field the reason why a subject screen failed or discontinued study.

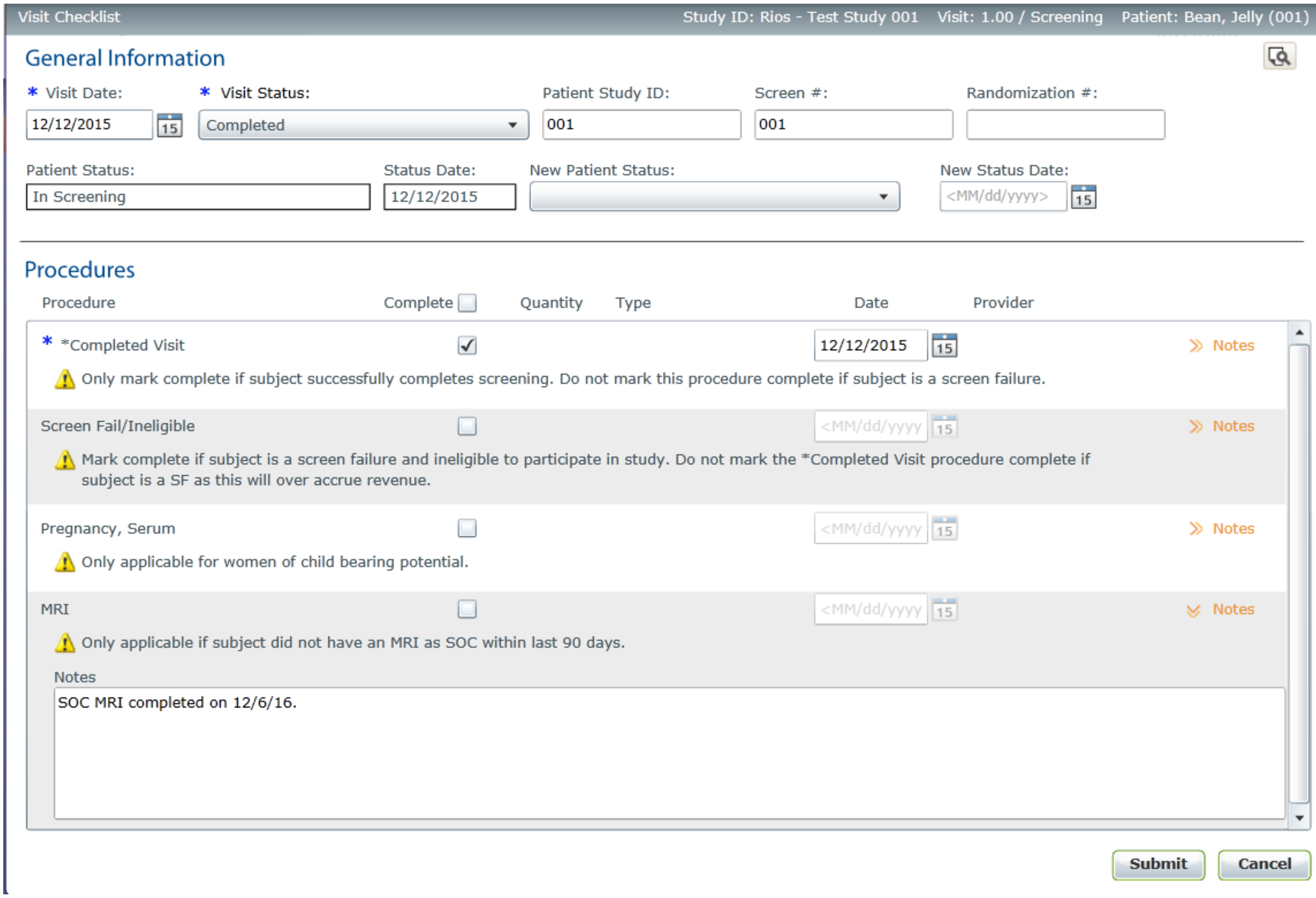


4. **Visits Tab:** Add or modify study visits. Study visits are required to be entered into CTMS in a timely manner (within 72 hours of visit). Delayed entry of study visits in CTMS has a direct impact on the study financials.
    a. To add a new visit, click Add Visit. Select the visit you wish to add from the list of available visits. Set the Visit Date and Visit Status and Click Submit.
        - Become familiar with all of the visits within the visit list. Oftentimes, there are additional visits at the bottom of the visit list that are above and beyond the standard visits within the protocol. These "additional" visits are used to track various items being reimbursed by the study sponsor (e.g. Reported SAE, Unscheduled Safety Visit and Reconsent). It is imperative these visits are tracked accordingly so the financial accruals tied to these visits are triggered and collected from the study sponsor.



b. The visit checklist will open once the visit has been selected from the dropdown list. The visit checklist is a critical component of the CTMS workflow, driving much of the study, patient and financial information stored by the application. The data entered within the visit checklist directly correlates to the financial accruals.

- The first section of the visit checklist allows user to quickly update enrollment information such as Screening Number, Randomization Number and Enrollment Status.
- The second section of the visit checklist lists the visit's procedures. It is imperative the procedures in the visit checklist are tracked accurately to ensure the appropriate financial accruals are triggered.
- Required procedures are indicated with a blue asterisk. Notes are required for mandatory procedures that are not marked as completed.
- The icon identifies a note has been added to the procedure by the study builder. Pay careful attention to these notes as they provide important information regarding the procedure.
- If an individual procedure within a visit occurs on a different date than the visit date, adjust the procedure date accordingly.
- The notes field allows you to capture notes specific to the procedure.


Visit Checklist   Study ID: Rios - Test Study 001   Visit: 1.00 / Screening   Patient: Bean, Jelly (001)

General Information

* Visit Date: 12/12/2015
* Visit Status: Completed
Patient Study ID: 001
Screen #: 001
Randomization #:
Patient Status: In Screening
Status Date: 12/12/2015
New Patient Status:
New Status Date: <MM/dd/yyyy>

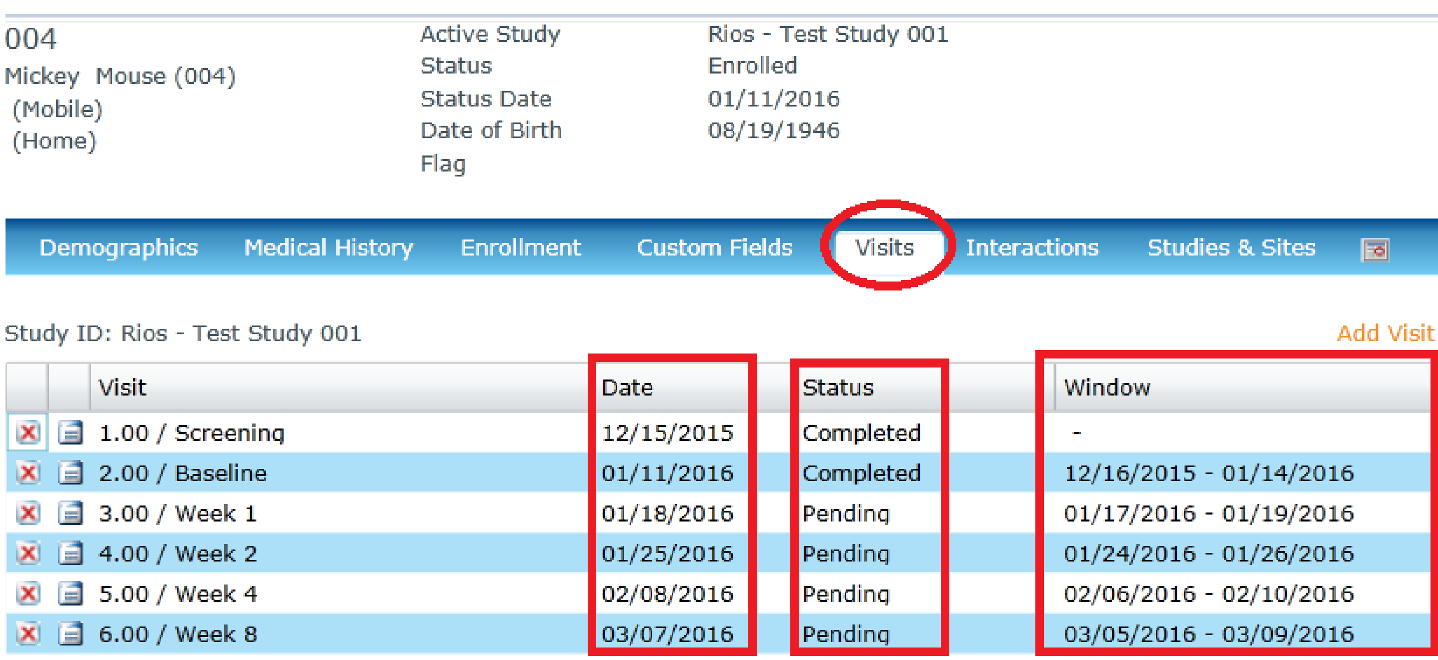
Procedures

Procedure	Complete	Quantity	Type	Date	Provider	
* *Completed Visit	☑			12/12/2015		Notes
Only mark complete if subject successfully completes screening. Do not mark this procedure complete if subject is a screen failure.						
Screen Fail/Ineligible	☐			<MM/dd/yyyy		Notes
Mark complete if subject is a screen failure and ineligible to participate in study. Do not mark the *Completed Visit procedure complete if subject is a SF as this will over accrue revenue.						
Pregnancy, Serum	☐			<MM/dd/yyyy		Notes
Only applicable for women of child bearing potential.						
MRI	☐			<MM/dd/yyyy		Notes
Only applicable if subject did not have an MRI as SOC within last 90 days.						

Notes
SOC MRI completed on 12/6/16.

Submit   Cancel

c. Visit Timelines are built by the study builder. Once the initial visit is marked complete in CTMS, the upcoming pending visits in the study will populate in the Visits tab. The screen will show the target dates of the future visits, the visit status of pending, and the window of the study visits based on the study protocol.


004
Mickey Mouse (004)
(Mobile)
(Home)

Active Study: Rios - Test Study 001
Status: Enrolled
Status Date: 01/11/2016
Date of Birth: 08/19/1946
Flag

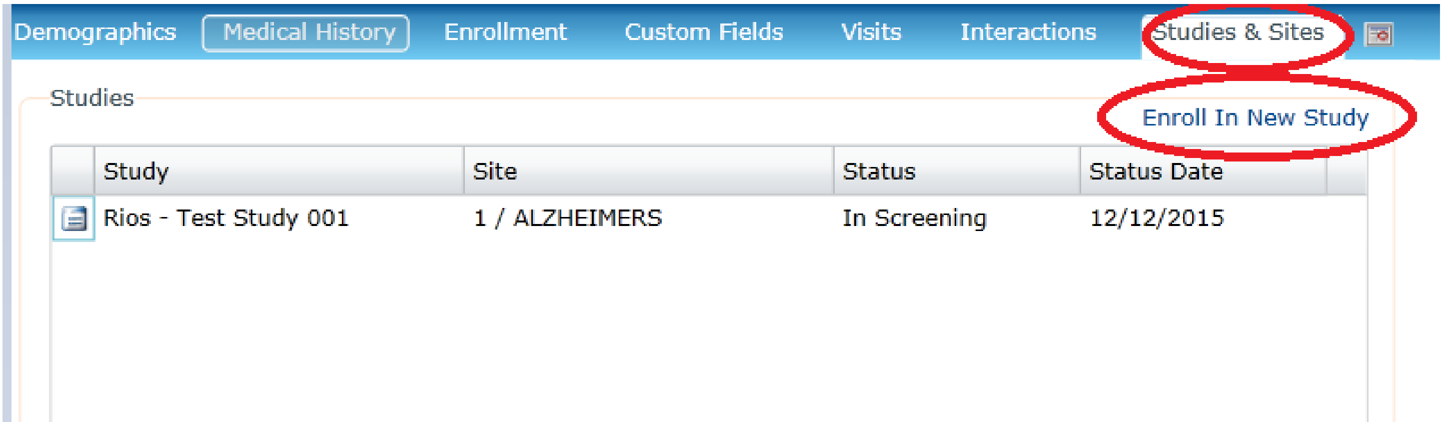
Demographics | Medical History | Enrollment | Custom Fields | Visits | Interactions | Studies & Sites

Study ID: Rios - Test Study 001   Add Visit

Visit	Date	Status	Window
1.00 / Screening	12/15/2015	Completed	-
2.00 / Baseline	01/11/2016	Completed	12/16/2015 - 01/14/2016
3.00 / Week 1	01/18/2016	Pending	01/17/2016 - 01/19/2016
4.00 / Week 2	01/25/2016	Pending	01/24/2016 - 01/26/2016
5.00 / Week 4	02/08/2016	Pending	02/06/2016 - 02/10/2016
6.00 / Week 8	03/07/2016	Pending	03/05/2016 - 03/09/2016

5. **Interactions Tab:** You are not required to enter data in this tab. This screen is optional. Interactions are intended to record contact or other information about patients stored within CTMS.

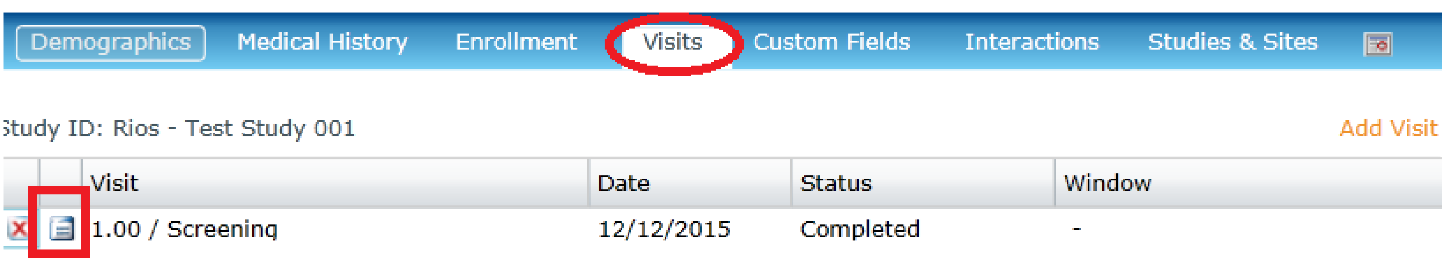
6. **Studies & Sites Tab:** Provides a list of studies the patient has been enrolled in, as well as the current enrollment status and status date. Within this screen, you can enroll an existing patient in CTMS into a new study by clicking Enroll in New Study.

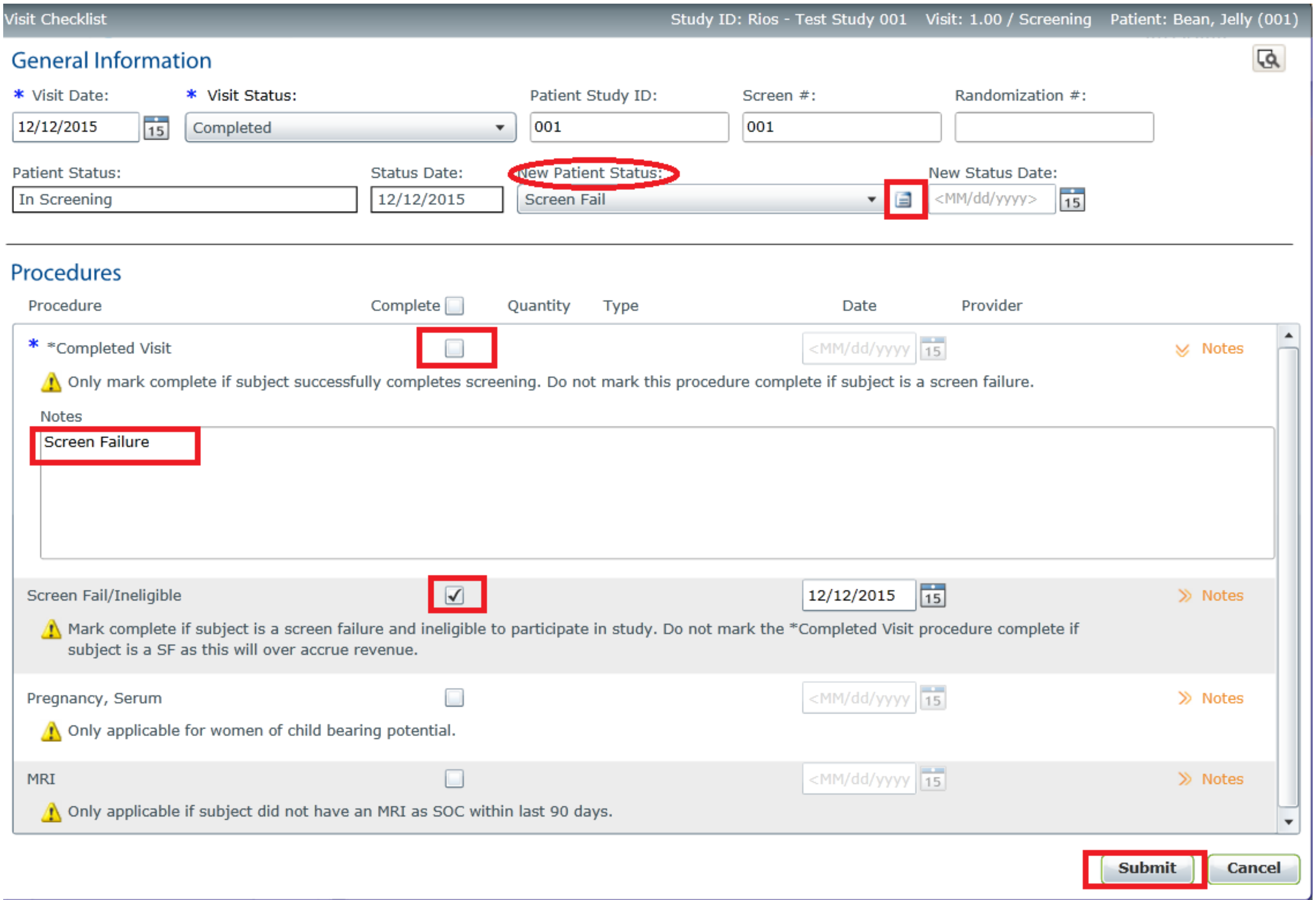


How to Track Screen Failures

Follow the steps below upon receiving notification a patient has screen failed.

1. Locate the patient record in Study Patients.
2. Click on the visits tab.
3. Click the edit icon to the left side of the Screening visit to open the Screening visit checklist.
4. Select New Patient Status as Screen Fail and capture a status note indicating why the subject was a screen failure by clicking the edit icon to the right of New Patient Status.
5. Uncheck the "*Completed Visit" procedure and make a note in the notes field that the subject was a screen failure.
6. Check the Screen Fail/Ineligible procedure.
7. Click Submit.



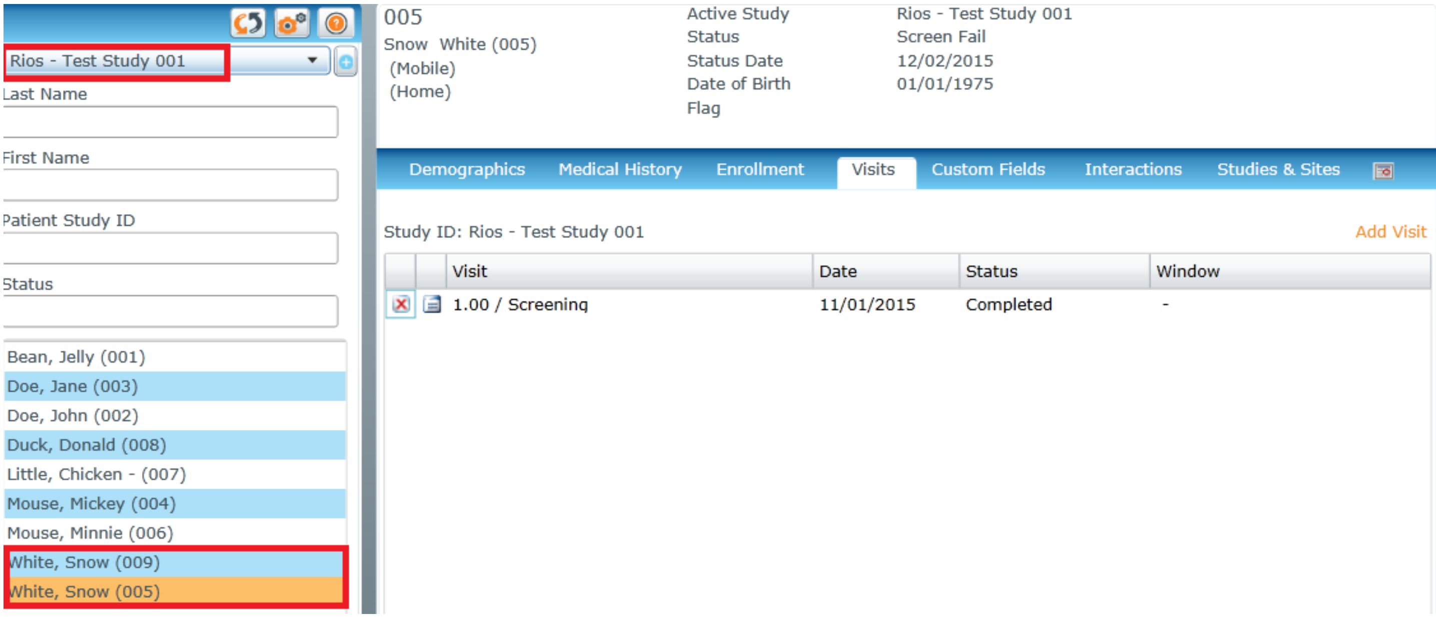


How to Track Rescreens

Follow the steps below when a patient is a screen failure and is later rescreened for the same study.

1. Locate the patient record in Study Patients.
2. Click on Studies & Sites Tab within the patient's profile.
3. Click on Enroll in New Study.
4. Select study from study list and capture new Study ID and Screening Number assigned by study sponsor.
5. Click Save.

*Note: The patient's name will now appear twice within the study list. One represents the screen failure and the other represents the rescreen.



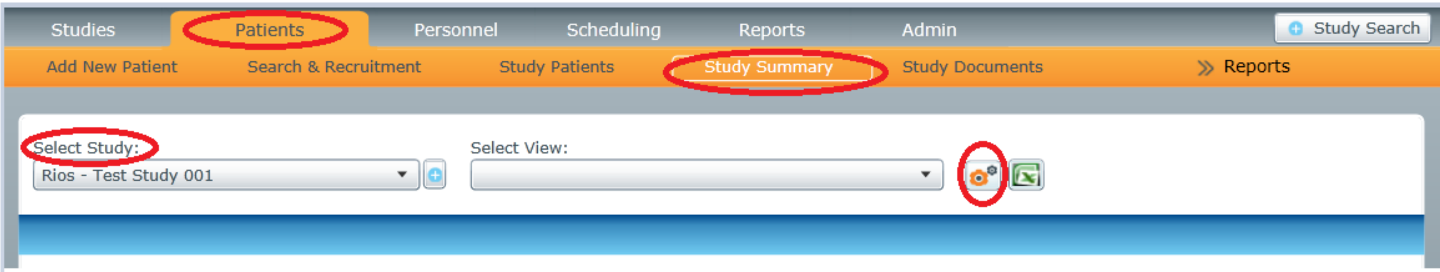
Study Summary

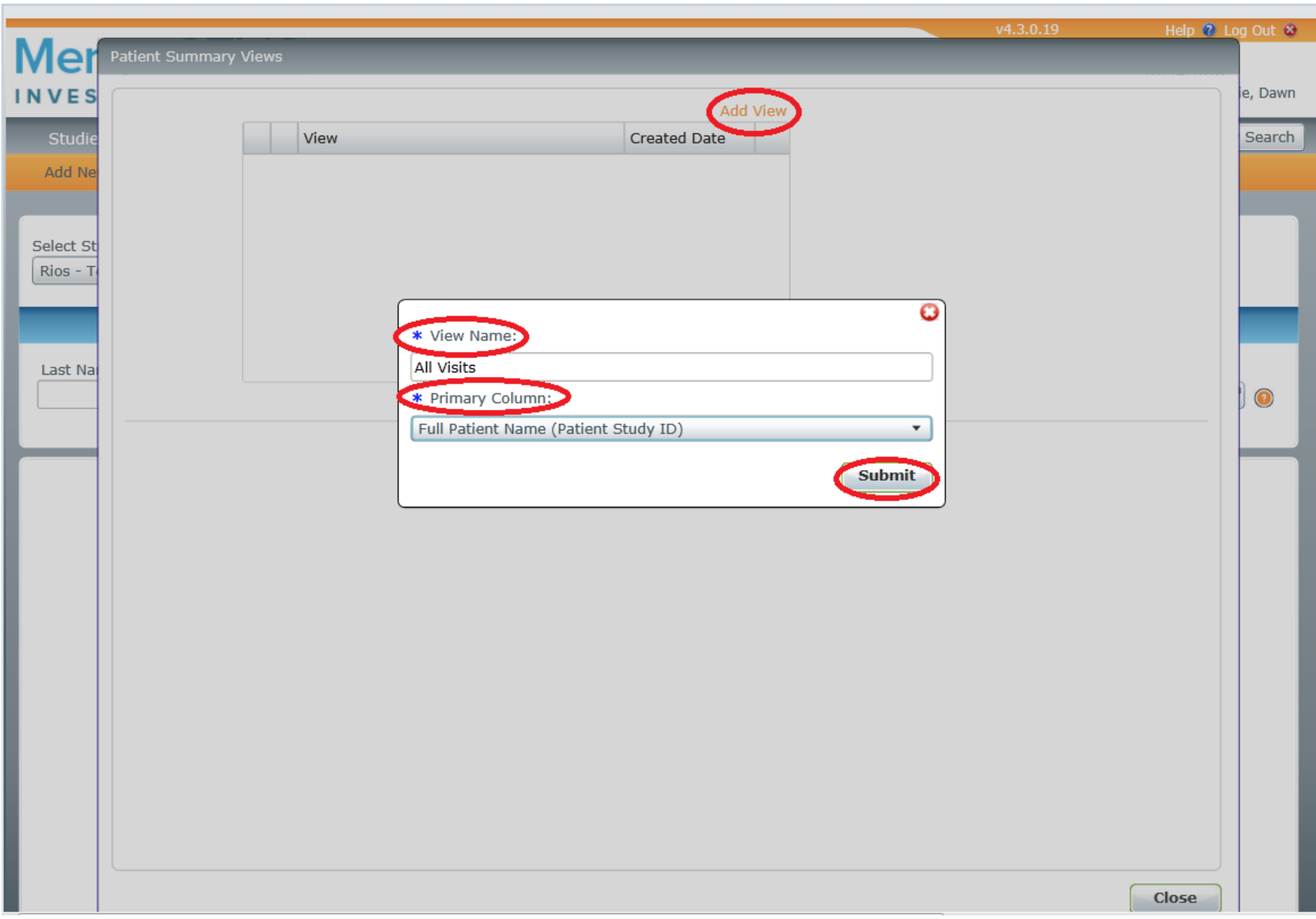
The **Study Summary** section of the **Patients** module allows you to create summary style views for patients enrolled in specific trials. You can create an unlimited number of custom views to display study related information (e.g. Visit Log, Screening Log, and Patient Contact Information). You can show all patients or look up individual patients by entering criteria into one or more of the four configured patient quick search fields.

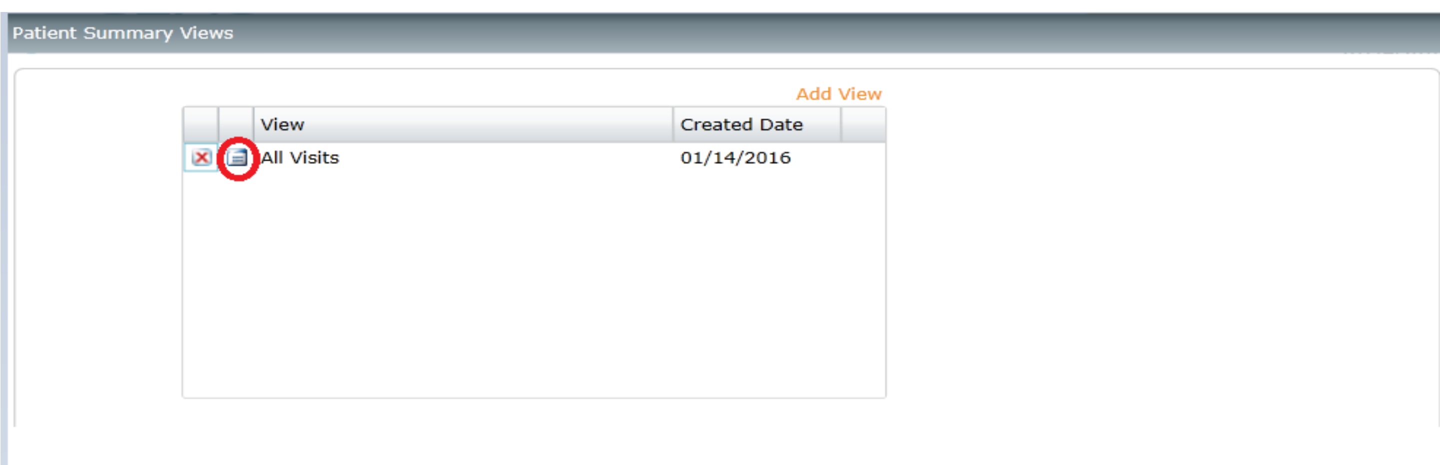
Once a list of results has been generated, you can employ any number of actions depending on the way you've set up your view. You can export the results to Excel by clicking the Export to Excel icon , or add, delete or modify study visits, sort by status or simply click on an individual patient record to pull up the related profile.

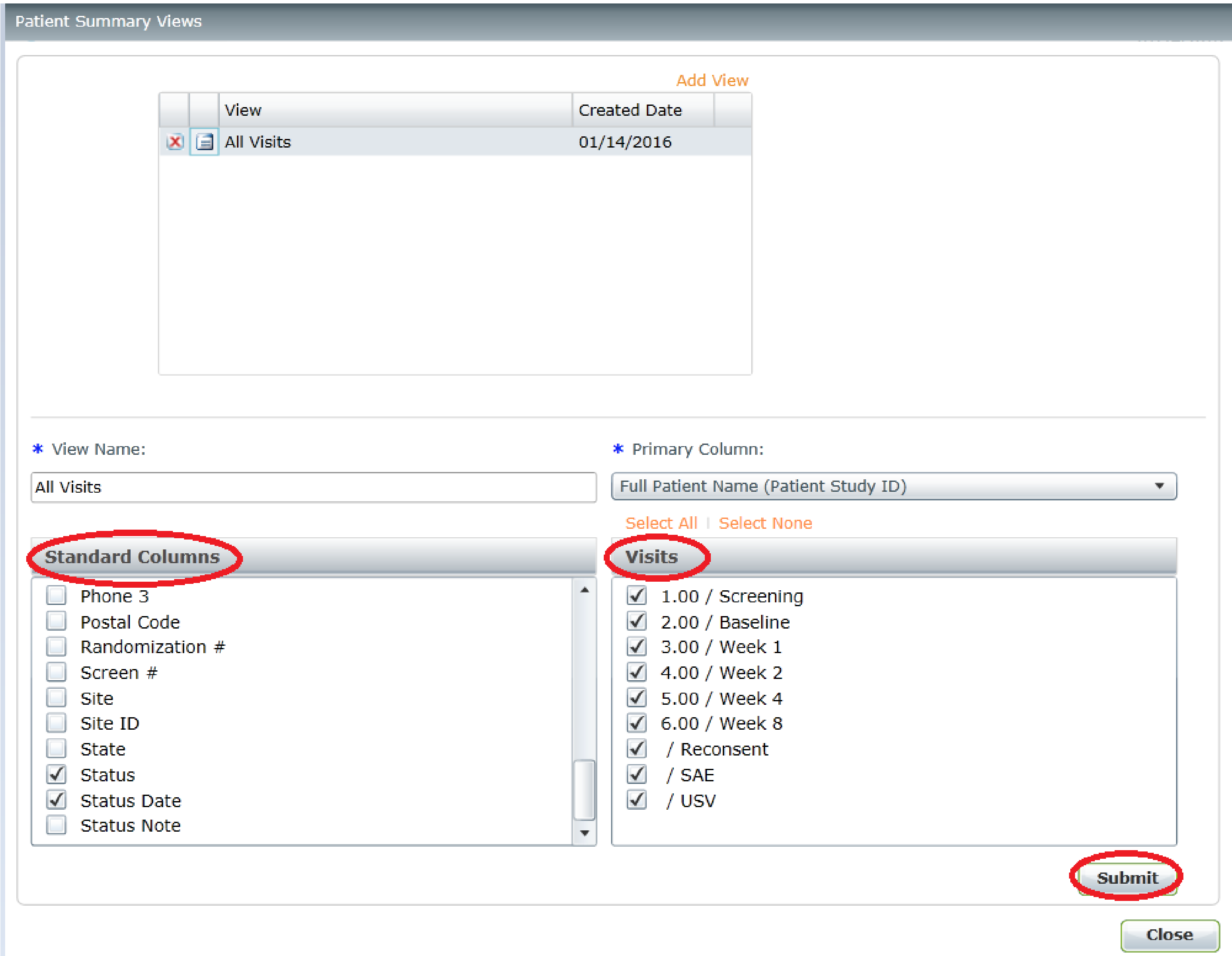
How to Create a Study Summary View

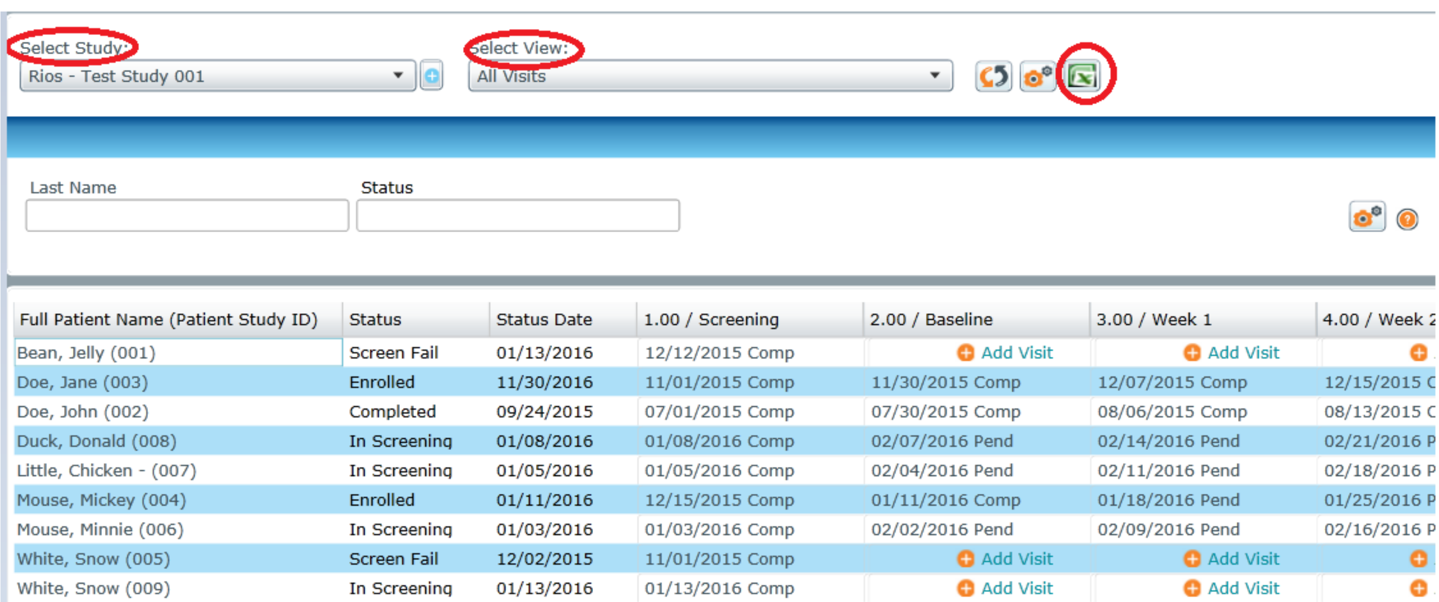
1. Go to the Patients module and click Study Summary.
2. Click the Manage Views icon to display the Patient Summary Views window.
3. Click Add View and type the name of your view (e.g., All Visits) in the View Name field.
4. Choose a Primary Column from the list of available options.
    a. The Primary Column is fixed on the left-hand side of the resulting summary view.
5. Click Submit.
6. Click the Edit Summary View icon next to the View Name you created.
7. Select (check) the study visits you wish to display on the right side of the screen.
8. Select (check) any additional columns you wish to include in the resulting summary view (e.g., Status, Patient Study ID, etc.)
9. Click Submit and Close.
10. To generate view results, select a study and then select the view you wish to apply.


Studies
Patients
Personnel
Scheduling
Reports
Admin
Study Search
Add New Patient
Search & Recruitment
Study Patients
Study Summary
Study Documents
Reports
Select Study:
Rios - Test Study 001
Select View:


v4.3.0.19
Help
Log Out
Patient Summary Views
Add View
View
Created Date
* View Name:
All Visits
* Primary Column:
Full Patient Name (Patient Study ID)
Submit
Close


Patient Summary Views
Add View
View
Created Date
All Visits
01/14/2016


Patient Summary Views
Add View
View
Created Date
All Visits
01/14/2016
* View Name:
All Visits
* Primary Column:
Full Patient Name (Patient Study ID)
Select All | Select None
Standard Columns
Phone 3
Postal Code
Randomization #
Screen #
Site
Site ID
State
Status
Status Date
Status Note
Visits
1.00 / Screening
2.00 / Baseline
3.00 / Week 1
4.00 / Week 2
5.00 / Week 4
6.00 / Week 8
/ Reconsent
/ SAE
/ USV
Submit
Close


Select Study:
Rios - Test Study 001
Select View:
All Visits
Last Name
Status
Full Patient Name (Patient Study ID) | Status | Status Date | 1.00 / Screening | 2.00 / Baseline | 3.00 / Week 1 | 4.00 / Week 2
Bean, Jelly (001) | Screen Fail | 01/13/2016 | 12/12/2015 Comp | Add Visit | Add Visit
Doe, Jane (003) | Enrolled | 11/30/2016 | 11/01/2015 Comp | 11/30/2015 Comp | 12/07/2015 Comp | 12/15/2015 C
Doe, John (002) | Completed | 09/24/2015 | 07/01/2015 Comp | 07/30/2015 Comp | 08/06/2015 Comp | 08/13/2015 C
Duck, Donald (008) | In Screening | 01/08/2016 | 01/08/2016 Comp | 02/07/2016 Pend | 02/14/2016 Pend | 02/21/2016 P
Little, Chicken - (007) | In Screening | 01/05/2016 | 01/05/2016 Comp | 02/04/2016 Pend | 02/11/2016 Pend | 02/18/2016 P
Mouse, Mickey (004) | Enrolled | 01/11/2016 | 12/15/2015 Comp | 01/11/2016 Comp | 01/18/2016 Pend | 01/25/2016 P
Mouse, Minnie (006) | In Screening | 01/03/2016 | 01/03/2016 Comp | 02/02/2016 Pend | 02/09/2016 Pend | 02/16/2016 P
White, Snow (005) | Screen Fail | 12/02/2015 | 11/01/2015 Comp | Add Visit | Add Visit
White, Snow (009) | In Screening | 01/13/2016 | 01/13/2016 Comp | Add Visit | Add Visit