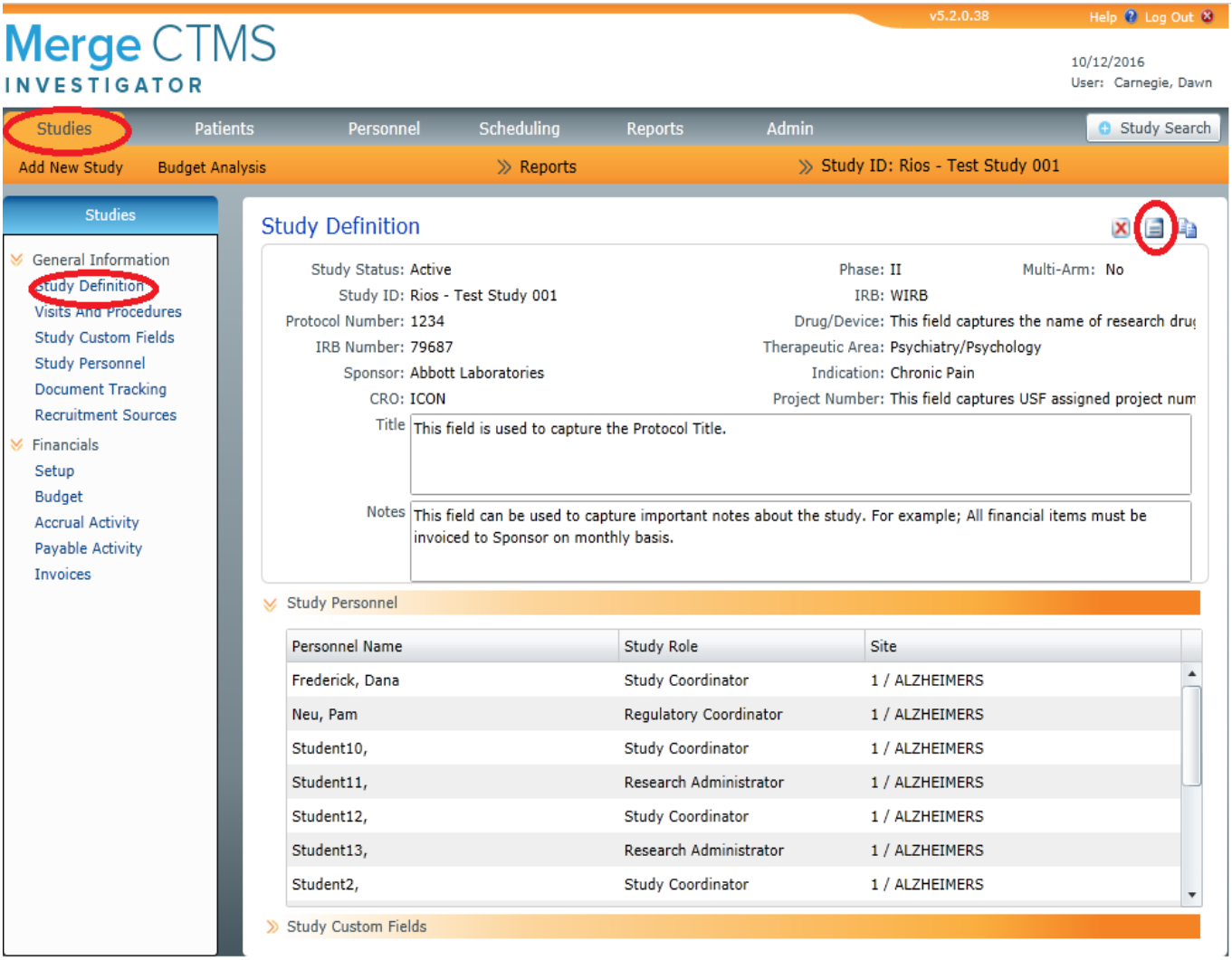
Office of Clinical Research

CTMS Reference Guide
Financial Activity Tracking

Study Definition Screen

The Study Definition Screen is considered the “Front Page” of the study. This screen captures the basic study definition, including study status, study id, study sponsor, therapeutic area indication, phase, title, etc.



Study Status: Captures the current status of the study. Definitions of study status are as follows:

1. **Active:** Study is closed to enrollment, but study is still active with patients being seen as per protocol.
2. **Archived:** Status not used by USF.
3. **Closed:** All study activity is complete. Sponsor has closed study at USF.
4. **Closed / Sent to RFM:** Study is closed and close audit audit is complete by OCRFM.
5. **Contract in** Process: Contract received from Sponsor and is in negotiation.
6. **Enrolling:** Study is open to enrollment.
7. **Inactive:** Status not used by USF.
8. **Pending ATE:** Study has been built in CTMS, but has not been released to study team as Approval to Enroll has not been released.

Study ID: Naming convention for Study ID is PI’s Last Name->Sponsor->Protocol #.

Protocol Number: Sponsor assigned number of study.

IRB Number: IRB assigned number of study.

Sponsor: Pharmaceutical company performing and funding study.

CRO: Clinical Research Organization is an organization that provides support to the Sponsor of the study on a contract basis.

Phase: Identifies the clinical phase of the trial. Phase 1-4.

IRB: An Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects. The purpose of the **IRB** is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines. Study can be reviewed by either a "Local" or Central" IRB. Central IRB is the IRB chosen by the Sponsor to review the study, whereas a "Local" IRB would be an IRB outside of the Sponsor's selected IRB.

Drug/Device: The name of the investigational drug/device being studied in the trial.

Therapeutic Area: The medical area being studied in the trial. For example; Internal Medicine, Psychiatry, Ophthalmology, OB/GYN, etc. This is also categorized by the specific USF Health department conducting the trial.

Indication: Defines the disease being studies in the trial. For example; Rheumatoid Arthritis, HIV, Stroke, Burn Injury, Psoriasis.

Project Number: Number assigned by USF's Department of Sponsored Research. This number is used to identify the research project throughout USF's systems.

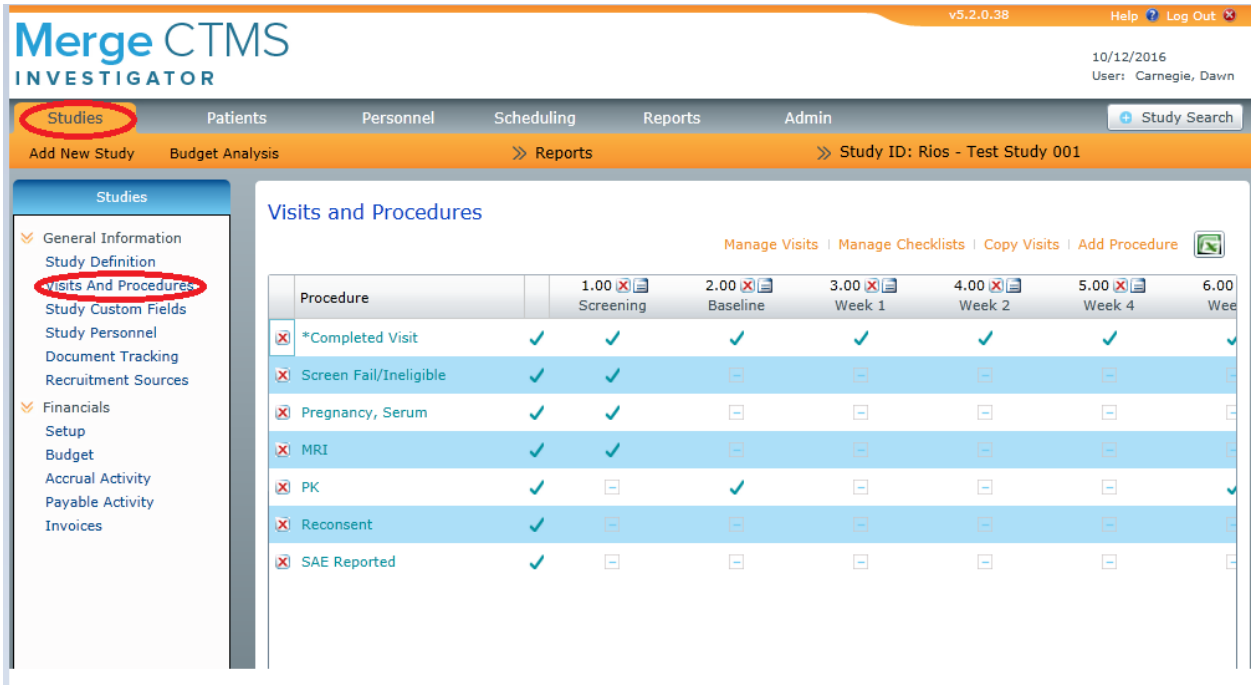
Title: Protocol title assigned by the study Sponsor.

Notes: This field can be used to capture important notes about the study. For example; All financial items must be invoiced to Sponsor on monthly basis.

Note: Click the Edit icon  on the top right hand corner of the screen to make modifications to the fields within this screen.

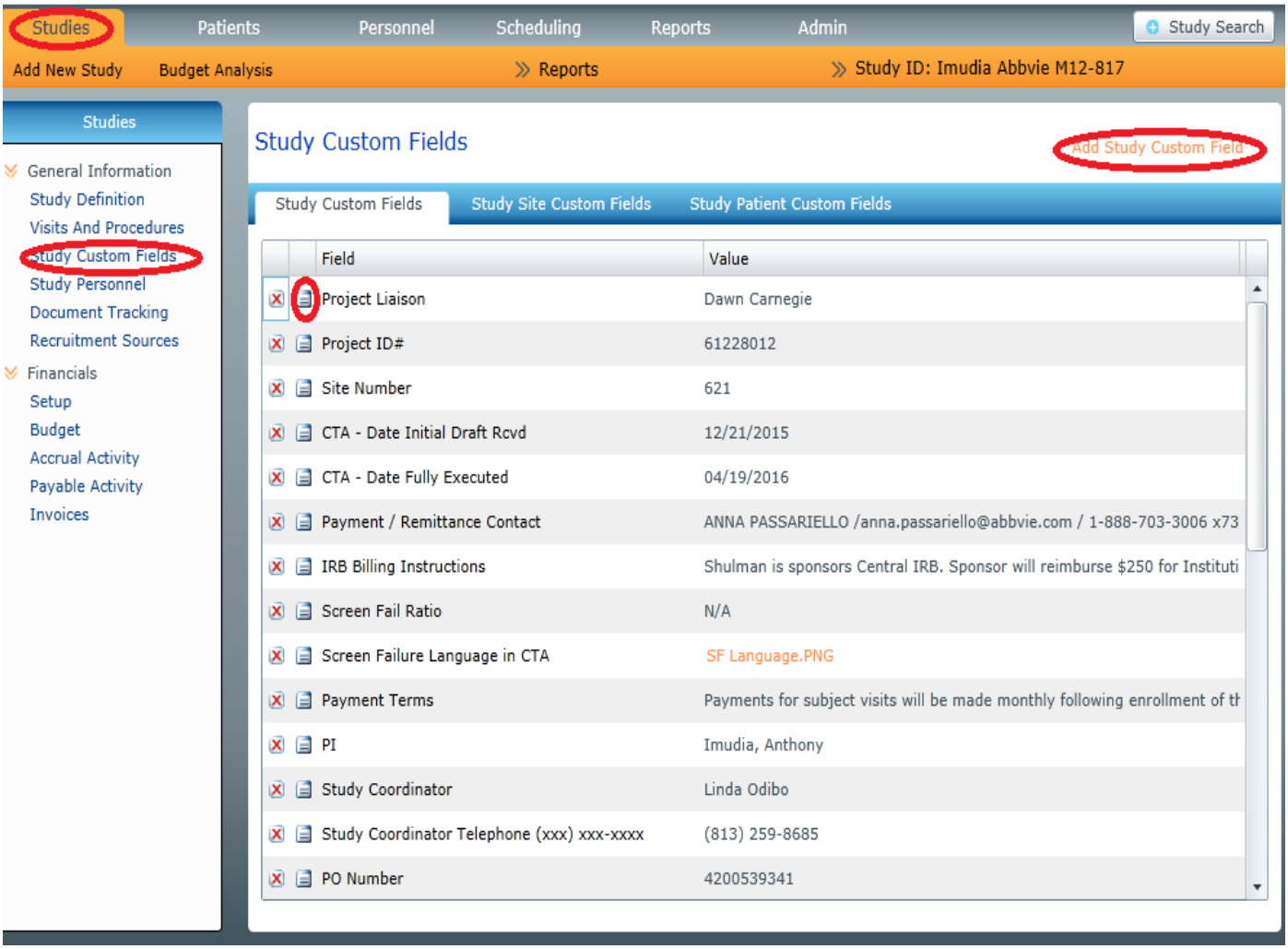
Visits and Procedures Screen

This screen displays the Visits and Procedures within the study as per the study protocol. The procedures run along the left hand side of the screen and the study visits run along the top of the screen. The items seen in this screen translate to the patient visit entry screen study staff utilized to mark study visits complete.



Study Custom Fields

Study Custom Fields allow USF to capture additional study level information based on USF's workflow and business requirements. Custom fields can be used to store information such as the Principal Investigator, contract status, or other benchmarks that USF uses to monitor study progress. USF can create an unlimited number of study custom fields and even upload documents and link to external websites.



Follow the steps below to add a new Study Custom Field:

1. Click Study Custom Field
2. Click Add Study Custom Field
3. Select Study Custom Field(s) and enter data as appropriate.

   Note: If Custom Field does not already exist, add it by clicking the edit icon next to the list and then clicking the related "Add Study Custom Field" link.

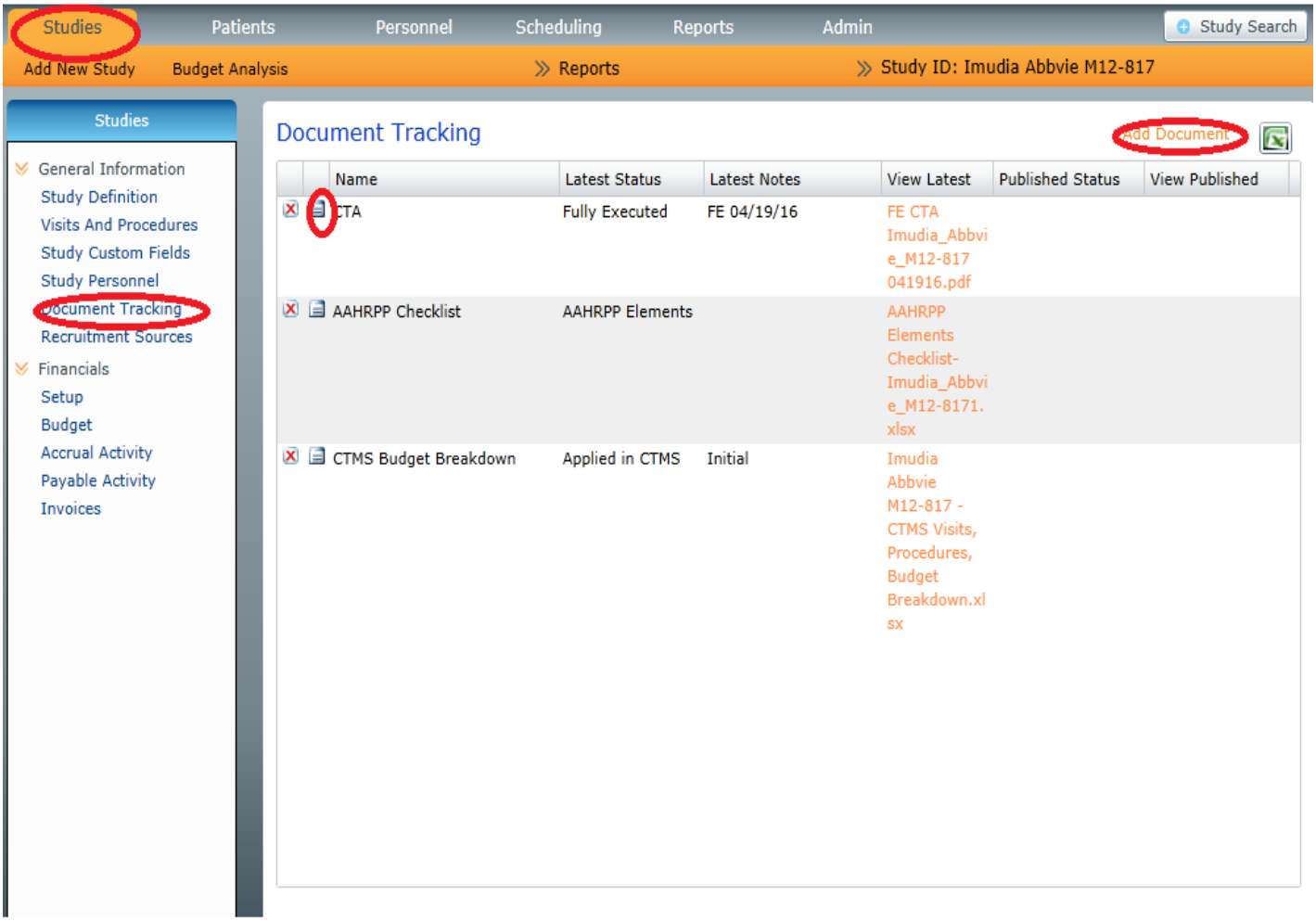
   To modify an existing Study Custom Field, click the edit icon to the left of the existing field and add/edit data as appropriate.

Document Tracking

Managing Study Documents in Document Tracking

The Document Tracking tool in CTMS, located, is intended to provide administrators an opportunity to develop workflows for managing, uploading and publishing key study documentation.

Uploaded documents oftentimes include:
- Contracts
- Budgets
- CTMS Builds
- Cash Application Notes/Documentation



How to Add Study Documents

1. Navigate to Studies Module.
2. Click Document Tracking.
3. Click Add Document on the upper-right hand side of the screen.
4. Enter document name and select the appropriate document status.
    - Note: If a status that you wish to apply does not already exist, click the Add Document Status icon to the right of the Select Status list, then click Add Study Document Status in the upper-right corner of the pop-up window. Enter the status name and click Save.
1. If you wish to make the document available to other users, check Set As Published Document.

- Note: Published documents are available in the Study Documents section of the Patients module. Anyone with access to the specific study, as well as that module, will be able to view the published document.

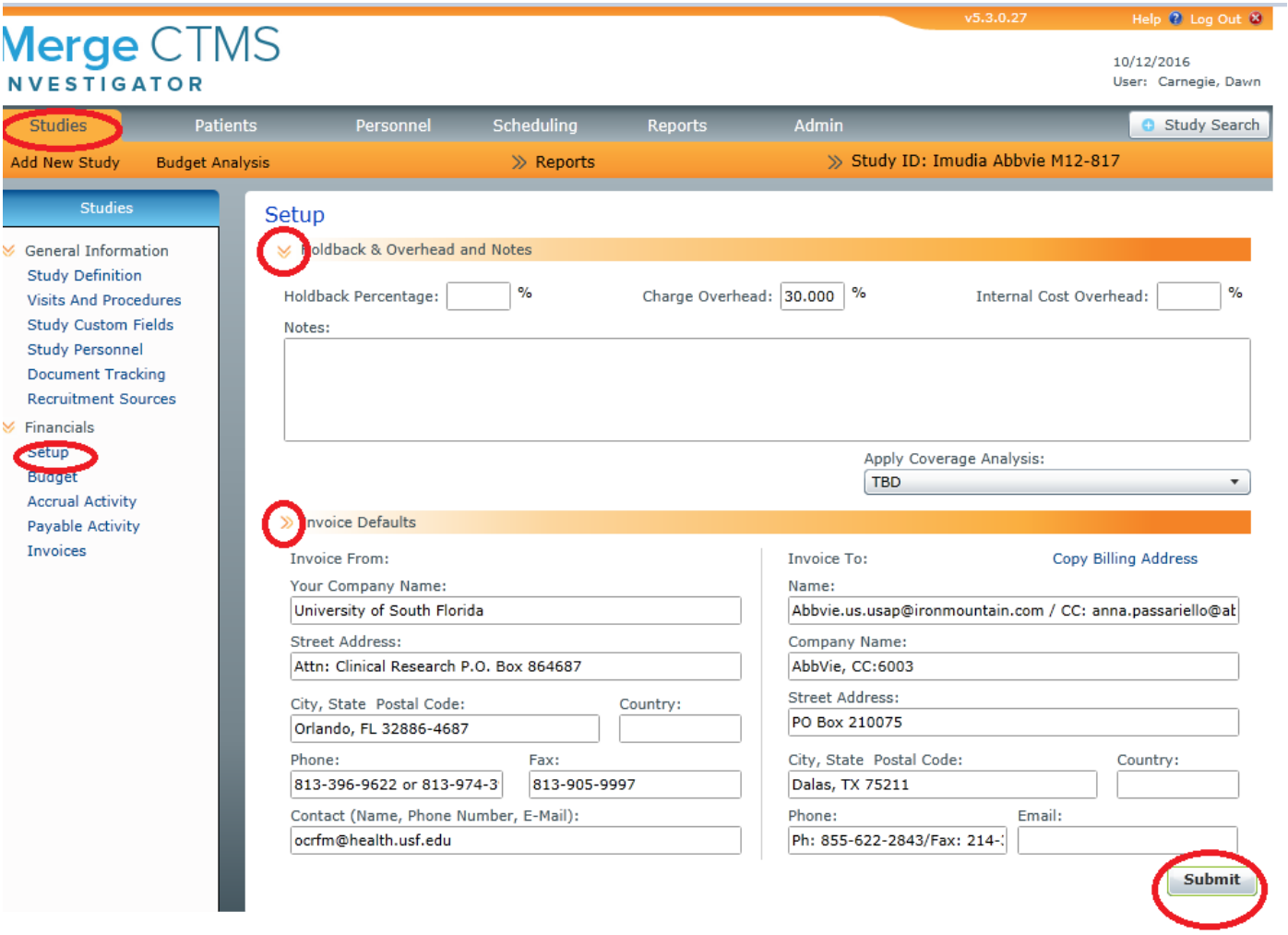
2. Optionally Add Notes. (i.e. Clinical Trial Agreement Execution Date)
3. Click the upload document icon to locate electronic copy of the file, change the file type as necessary, navigate to the folder location, select the file and click Open.
4. Click Save.

Financials – Set Up

The Financial Set-Up Screen is used to capture important budgetary information for this study such as Holdback %, Overhead %, and Invoice Defaults.

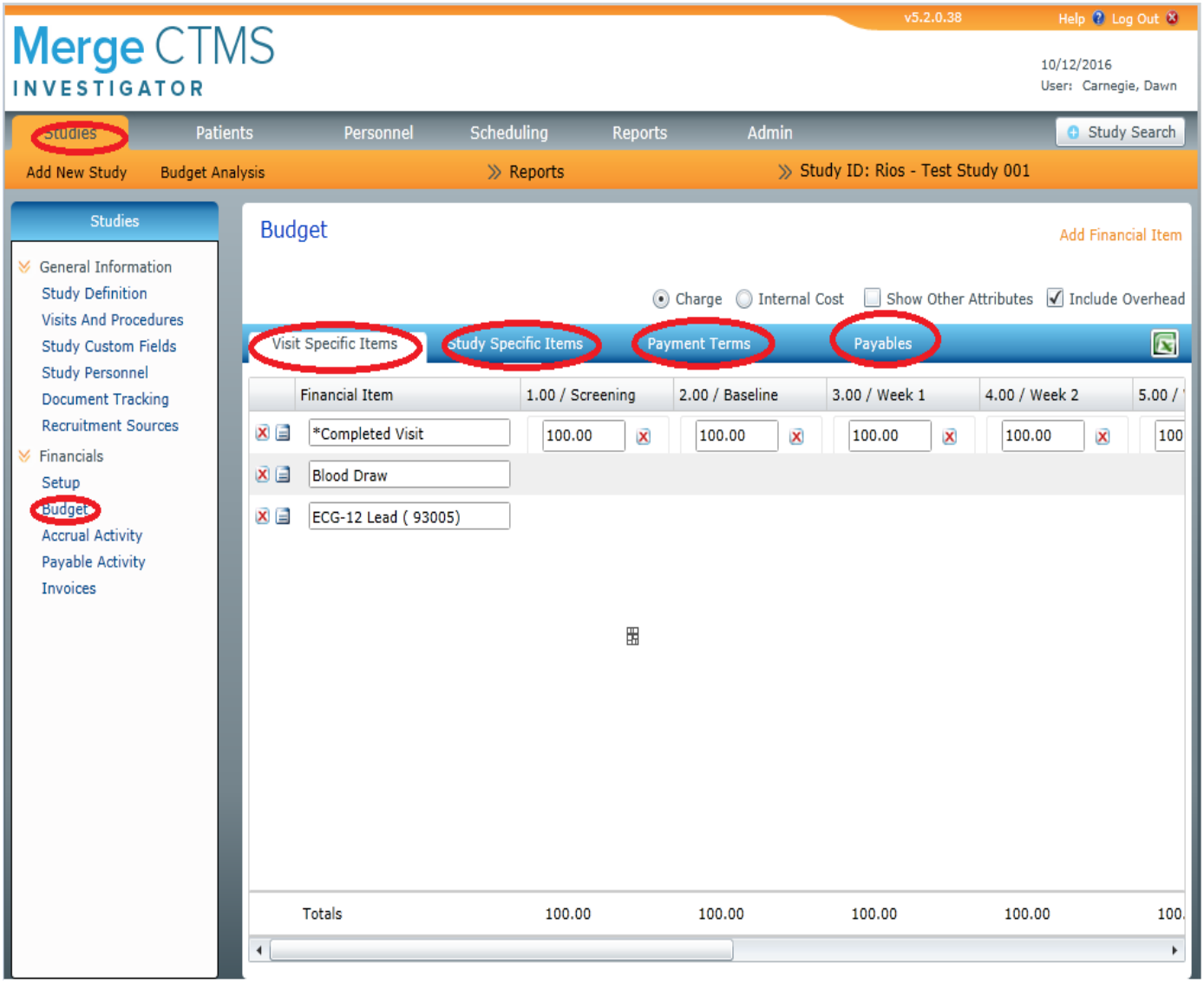
If changes are made to this screen click the “Submit” button located at the bottom right hand corner to save changes.

Note: Click the orange chevrons » to expand or collapse the two sections in this screen.



Financials – Budget

The budgeting tools available in CTMS allows USF to build each study budget based on the final signed sponsor contract. The financial items built in the budget drive both accrual and payable activity within CTMS as actions such visit entry, visit completion and other related events take place on a regular basis. The Budget screen is divided into four distinct sections, shown below. Each section represents a different area of the budget and contains unique features and functions.



- **Visit Specific Items** – Captures financial items expected to accrue for each study at the visit level tied to patient related activity. Financial items automatically accrue when the financial items are marked as complete within a study visit in the Patients Module.
- **Study Specific Items** – Captures financial items USF expects to accrue at the study level, for example, non-refundable start up fees, advertising fees, document storage, etc.
- **Payment Terms** – USF does not use this tab.
- **Payables –** Captures payable items USF expects to accrue for each study. Setting up payables allows USF to effectively, and in real time track payments to vendors, third-party providers, internal providers (e.g. PI payments) and patient related reimbursements (stipends).

Financials: Accrual Activity

View Activity

As users add patient visits into the database and trigger other study level fees, CTMS will automatically generate study specific accruals based on what was built inside of the study budget. Accrual Activity is a screen that allows users to monitor study financials on a per study basis.

In Accrual Activity, users can set different filters to quickly generate real time information to show the amount of overall revenue accrued, how much (if any) is currently being held back, amount that is currently receivable (AR), and amount that has been paid. In addition, users can generate real time aging reporting.

Applying Payments

CTMS provides users with the ability to apply incoming sponsor payments (checks) to patient visits and other study level fees in an effort to generate up to date A/R reporting.

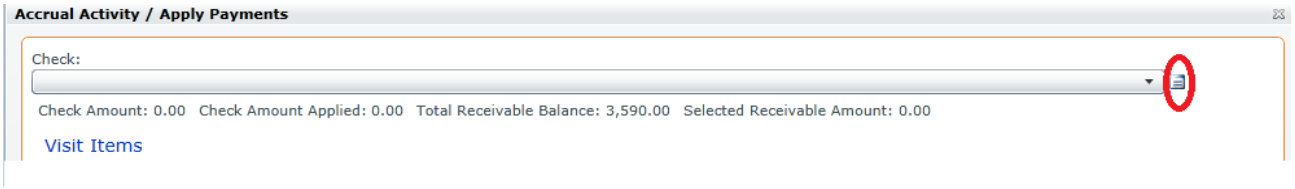
Payments can be applied using one of four different receivable views:

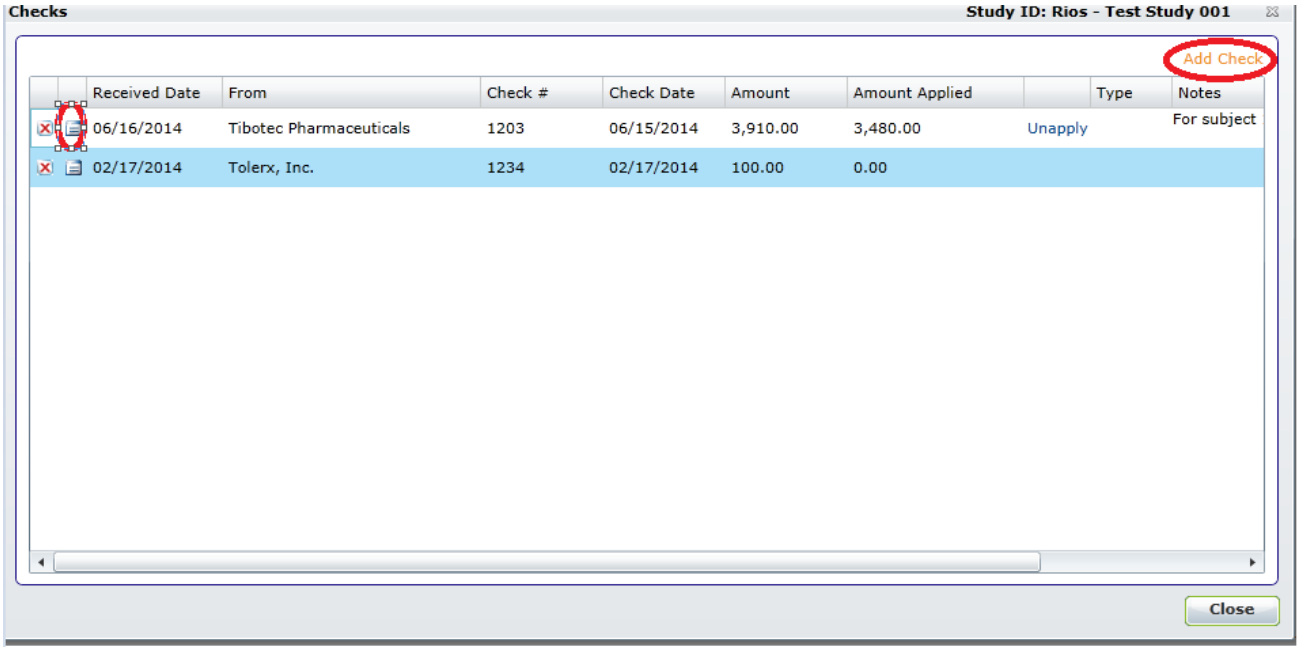
- Budget Summary - Visits: Apply payments to Visit Specific Items with a receivable balance. This option allows users to quickly post payments to individual study visits and provides the most efficient and detailed means of reconciliation.
- Budget Summary – Study Specific: Apply payments to Study Specific Items with a receivable balance such as; IRB Fees, Start-Up Fees and so on. Users can apply payments to any items that were added to the Study Specific section of the budget, have been accrued and as a result, are receivable.
- Flat Payment - FIFO: Apply payments to the oldest receivable balance. This option is the least detailed and is useful when the sponsor provides little, or no supporting information with a payment and a user simply wants to apply a payment to the entire study. It is not possible to create procedure/visit level A/R reporting using this method.
    - **Note: USF does not use this tool to apply payments in CTMS.**
- Activity List: Apply payments to specific financial activities. This option is useful for tracking and applying payments to optional and/or invoiceable procedures that are paid separately from the standard visit payment.

Before applying incoming sponsor payments to individual studies, users need to add the checks to the database.

How to Add a Check

1. Log into Merge CTMS Investigator and go to the Studies module.
2. Select the ID of the study for which the check is paying.
3. Under Financials, click Accrual Activity.
4. In the Accrual Activity screen select the option to Apply Payments.
5. Select the view (e.g. Budget Summary - Visits, etc.) you wish to apply the payment towards and click Next.
6. Click the manage check icon on the upper right-side of the screen.
7. Click Add Check.
8. Fill-in the check number, amount, check date and received date along with any check notes, and click Submit.
9. Repeat the process to add more checks, or click Close.





How to Apply a Check

1. Go to the Studies module.
2. Select the study that the payment will be applied to.
3. Under Financials, click Accrual Activity.
4. In the Accrual Activity screen select the option to Apply Payments.
5. Select the view (e.g. Budget Summary - Visits, etc.) you wish to apply the payment towards and click Next.
    a. *Note: You cannot apply payments unless the receivable (A/R) balance is greater than zero.
6. Select the check you wish to apply from the available list.
7. Select (click or check) the item(s)/visits you wish to apply the payment towards.
8. Click Apply Payment when you are have applied some, or all of the selected check amount.

How to Create an Invoice

1. Go to the Studies module.
2. Under Financials, click Accrual Activity.
3. In the Accrual Activity screen, click the option to "Create Invoice" and click Next.
4. In the Invoiceable Activity screen select the item(s) to be added to the invoice on the left, and then click the orange arrow in the middle of the screen.

5. Choose one of the available options (the second option provides the most detail) and then click Submit.
6. Click Generate Invoice and add an invoice number and description.
7. Click Continue and then Open.
8. The invoice data is pulled from within CTMS and output as a Word document. Double-click "SMi_Invoice" to open up the Word file.
9. You can edit, print or email using any of Word's native functionality.
    a. Note: Any changes made to the invoice from within Word will not be saved with the original invoice stored in Investigator CTMS.
    b. All invoices generated for a study can be viewed at any time in the “Invoices” screen found in the Studies module.

How to Adjust Accruals

1. Go to the Studies module.
2. Under Financials, click Accrual Activity.
3. In the Accrual Activity screen, click the option to "Adjust Accruals" and click Next.
4. In the Adjust Accruals screen, adjust accrual amounts by entering enter new values in the editable box for the “Accrued” column.
    a. Users can adjust as many financial items at once, as needed.
    b. If a financial item that has already been paid is to be adjusted, users cannot add new accrual amounts that are less than the amount in the paid column.
5. Once the Accrual values have been updated, enter adjustment notes and then click Submit.