REALTIME

CLINICAL TRIAL MANAGEMENT SYSTEMS

CTMS

Administrator Manual

Version 4.4.0

CONTENTS

GENERAL INTRODUCTION

Welcome to the RealTime-CTMS Administration Manual. Quick. Simple. Intuitive. The keys to successfully implementing RealTime-CTMS within your organization successfully are to ensure that the system is set-up properly at the time of deployment and to train key users on the important back-end functions incorporated within the Administration Area of RealTime-CTMS. This Administrator Manual will guide you through the initial set-up process as well as ongoing functions such as: site management, user management, study template creation, study visit tracking, accounting functions, database table management, and reporting.

RealTime-CTMS is designed to integrate the major components of a clinical research site into a cohesive, user friendly, web-based information system that allows for excellent study management and subject tracking.

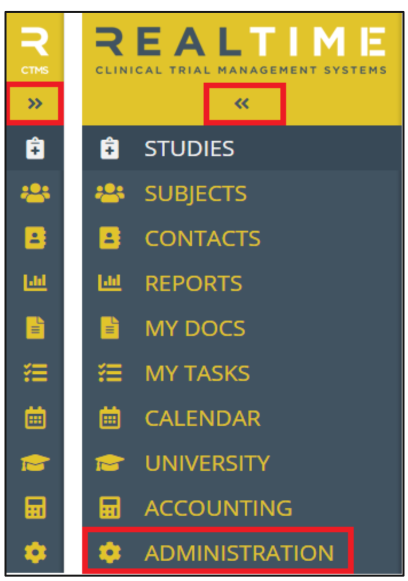
It is important that you read this manual from start to finish ensuring that all other functions within RealTime-CTMS work as designed.

HOW TO USE THIS MANUAL

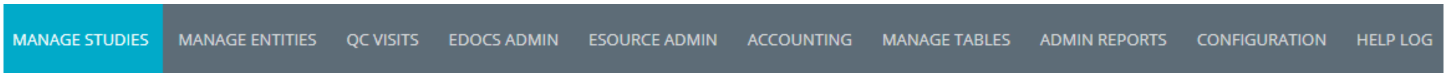
It is recommended that site staff that will be designated as "administrators" familiarize themselves with this entire manual. While most administrator functions are simple and straight-forward, some administrator functions such as study template creation will require careful study of the applicable sections of this manual. An additional User Manual was included with your purchase of this software. The User Manual should always be accessible to site staff as a reference.

GETTING STARTED

The left side of the window contains the side bar which expands by clicking the double arrows. If you have administrative privileges in RealTime-CTMS, simply click on the Administration link at the bottom of the side bar menu.



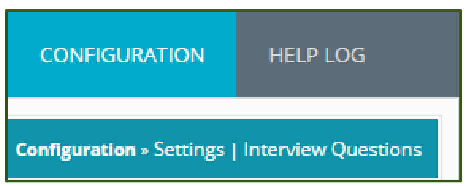
In the Administration section of RealTime-CTMS, users can set up users and their privileges, set up providers and vendors, create and manage new studies and study templates, manage study finances, payments and receivables, track advertising campaigns, and more.



If you have chosen to have RealTime-CTMS integrated with your company website for study recruitment, then you will also be able to manage study postings to the website and track subject study applications. To get started with the implementation of RealTime-CTMS, first you need to ensure that the initial configuration of the software is set-up correctly using the *Configuration* tab and that the database tables are customized to the needs of your particular site using the *Manage Tables* tab. These tabs will be discussed in the next two sections. Please contact RealTime-CTMS Success Team if you need help with this process.

CONFIGURATION TAB

The Configuration tab in RealTime-CTMS will be pre-populated with your site's information by the RealTime-CTMS Success Team. The information contained in each of the following sections should be changed with caution as the changes may affect the functionality/display within RealTime-CTMS. There are two areas to the Configuration section, Settings and Interview Questions.



GENERAL INFORMATION

Basic site information is stored in the General Information section of the Configuration tab. Below are detailed explanations for all configuration options available:

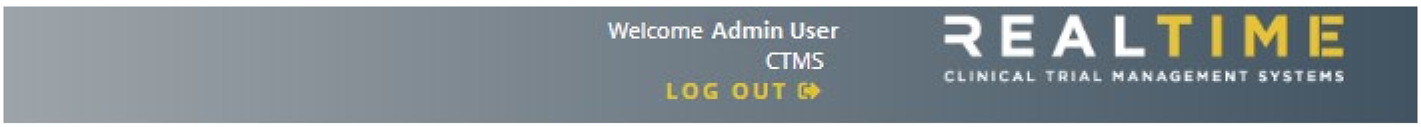
- **Application Name** - Text indicated in this field will display on system banner located at the top of the page. This text will populate in the center of the banner for sites who enable a Custom Logo On System Banner. This text will populate on the bottom left corner of the banner for sites who do not enable the custom logo.
- **Your website URL** - https://www.researchsite.com. This is a field to enter the company website. It is used to preview the website in the Website Information Tab under Manage Studies.
- **Company Name and Address** – Company Name, Address fields, and Phone are added here and are displayed on invoices and patient schedules.

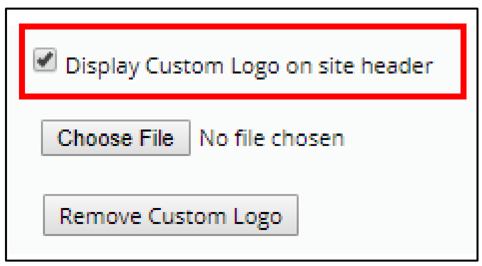
COMPANY LOGO

Upload a company logo to be displayed primarily on invoices. The uploaded image must be a .jpg or .png file. Recommended image size is 467 pixels width x 100 pixels height. Image is sized proportionally to those dimensions when updated. Assistance can be provided by e-mailing a highest resolution logo to successteam@realtime-ctms.com

CUSTOM LOGO ON SYSTEM BANNER

Upload a company logo to customize the display on the system banner. Selected image must be a .jpg or .png file. Recommended image size is 467 pixels width x 100 pixels height. Image is sized proportionally to those dimensions when updated. If you'd like assistance, please e-mail your highest resolution logo to successteam@realtime-ctms.com. Please be advised that if the Custom Logo is selected for use, and no Custom Logo is uploaded, the Company Logo will be used on the System Banner. Update Configuration to see the image on the banner.





PAYABLE INFORMATION ON INVOICES

- Enable this feature to populate an alternate address on invoices. All fields are required when this option is selected.

ADMINISTRATIVE

- **Study Number Prefix** – RealTime-CTMS generates a unique number for each study in the system. The text indicated in this field will pre-populate in front of each unique study number.
- **Password Expiration** – This field will indicate the number of days allowed before a user is prompted to create a new password. The default value of 180 days is recommended to maintain adequate security.
- **Administrative Mail** – Enter an email address into this field that will be utilized for all user inquiries. When a user of the system has a question, they will be able to click 'Contact Admin', located on the top right of their screen, which will automatically generate an email to this email address.

- **Applicant Notification Mail** – This field is related to Web Integration, part of the technology related to having a RealTime-CTMS study listing page on a site's website. Enter the email address into this field that will receive notifications of new study applications received through the website. As soon as a new applicant applies through the website, this address will be notified by email about their application. The email will contain basic patient information as well as their referring URL meaning it will be capable to see how they landed on your website, i.e. Google, Facebook, Craigslist, etc.
- **Accounting Mail** – Enter an email address into this field that will be utilized for inquiries from customers/sponsors regarding accounting-related questions. This email address will appear on invoices generated in RealTime-CTMS.

REALTIME-TEXT

Refer to RealTime-TEXT User Manual

REALTIME-PAY

Refer to RealTime-PAY User Manual

REALTIME-EDOCS

Refer to RealTime-eDocs User Manual

NOTIFICATIONS

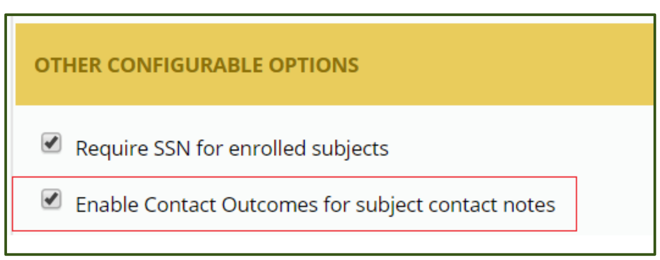
- **Pending Tasks Email Notifications** – When enabled, users will receive an email with an image of their My Tasks section on a weekly basis (every Monday), daily, or not at all. Through the Manage Entities section, individual users may be managed, and the frequency they receive this notification can be set.
- **Calendar Notifications to Users** – This is an overall opt in/opt-out for all site users to receive calendar notifications.

MAILCHIMP EMAIL MARKETING

When enabled, sites will have the ability to sync the subject and/or sponsor mailing lists indicated in RealTime into Mailchimp mailing lists. Sites interested in this functionality must contact Mailchimp and create an account. A MailChimp API key will be necessary to setup the account. Assistance is available when setting up this integration by contacting Realtime-CTMS Success Team at successteam@realtime-ctms.com.

OTHER CONFIGURABLE OPTIONS

- **Require SSN for enrolled subjects** – When enabled, a SSN will be required prior to enrolling a subject into a study.
- **Enable Contact Outcomes for subject contact notes** – When enabled, allows users to categorize the outcome of a contact attempt within the subjects contact notes. Contact Outcomes can be enabled or disabled via the checkbox in the OTHER



CONFIGURABLE OPTIONS section. Enabling Contact Outcomes displays a categorization box in the Contact Notes section of the CONTACT ATTEMPTS page of a subject's profile. Enabling Contact Outcomes provides the ability to report and track recruitment efforts in a more robust manner. To see how this function presents in a user role, see Page 21 in the User Manual.

- **Display Unscheduled Visit tab** – This box will display an Unscheduled visit section within the patient tracking. This visit cannot have financials pre-populated. This section is only to be used under special circumstances. It is strongly recommended to keep unchecked.

THIRD PARTY INTEGRATION

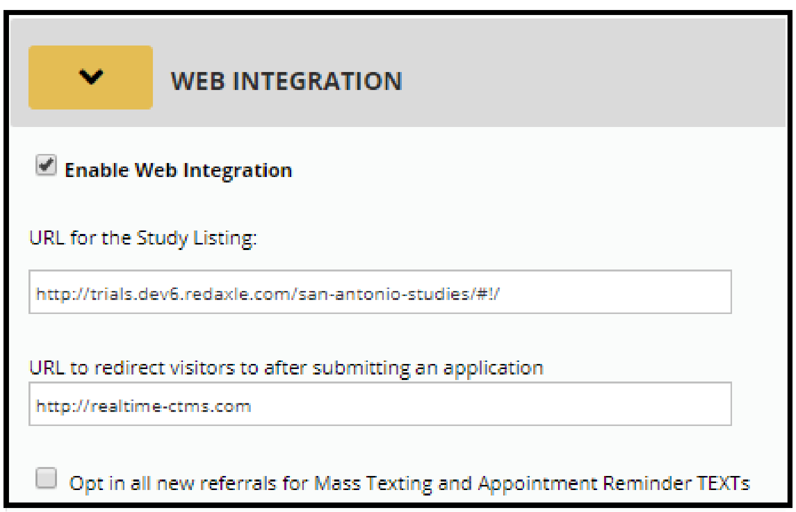
SubjectWell – When enabled, a site must indicate the Site Integration Key provided by SubjectWell. For instructions on how to configure this feature refer to RealTime & SubjectWell Integration Instructions located in the University section. Once fully configured, the checkmark will turn green.

FACEBOOK LEAD FORM INTEGRATION

Clinical Sites can integrate with Facebook for recruitment purposes. Please contact our RealTime-CTMS Success Team for more information.

WEB INTEGRATION

Realtime provides the ability for a site to integrate or connect the site's web page to their instance of RealTime. The integration provides the ability to list studies on the website and have subjects who apply to the listed studies added to the study in RealTime.



Configuration of a sites' website is required to allow this integration. The information needed to modify the web site can be provided by RealTime, or if given access to the website, Realtime can perform the necessary configurations.

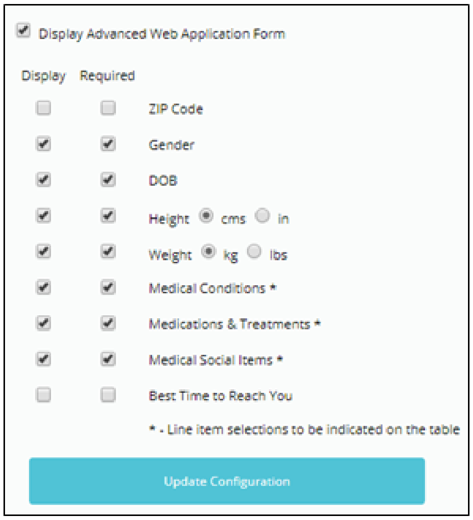
Selecting the Enable Web Integration checkbox enables or turns on the Realtime portion of the integration.

The URL for the Study Listing is a field that would contain the URL or web address of the list of studies being displayed by the integration between the site's website and RealTime. This field needs to be completed for the Preview Study Listing link, on each studies Website Information page, to function properly.

Visitors to a site's website, who apply for a study, can be redirected to an alternative web site upon application completion. Examples of pages that a site may want to re-direct an applicant to are a "Thank You" page created by a site's web support or back to the list of available studies. The ability to re-direct a subject also assists a site when performing website analytics.

Subjects that complete the application to a study, and if the subject is a new referral (new subject in the database) can be opted in for Mass Texting and Appointment Reminder TEXTs if the checkbox is selected.

The standard web application form gathers basic information. Realtime has provided the option to expand the application form to select and gather additional information. ZIP Code, Gender, DOB, Height, Weight, Medical Conditions, Medications, and Social Items are the selectable options.



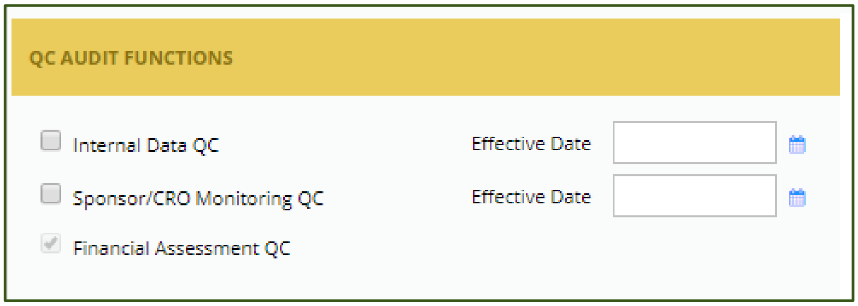
Selecting the checkbox to Display Advanced Web Application Form and selecting Update Configuration makes the optional items available for selection. Items with an "*" are tables in Realtime, and the list displayed on the web application for each item can be determined on each table. (See Managing Tables)

QC AUDIT FUNCTIONS

Quality Control (QC) checks are performed on submitted visits for verifying all information that has been documented completely and properly, as well as verifying and adjusting any financial information.

Realtime provides three types of QC: Financial Assessment, Internal Data, and Sponsor/CRO Monitoring. The Financial Assessment QC section is enabled by default and is not configurable. The Internal Data and Sponsor/CRO Monitoring sections are optional and can be enabled independently. If a section is enabled the corresponding Effective Date is required.

Visits with a Completion Date after the Effective Date will have the selected QC function available at the visit level and will be listed on the selected QC section of the QC Visits tab. See QC Visits for more information.



SYSTEM ACCESS

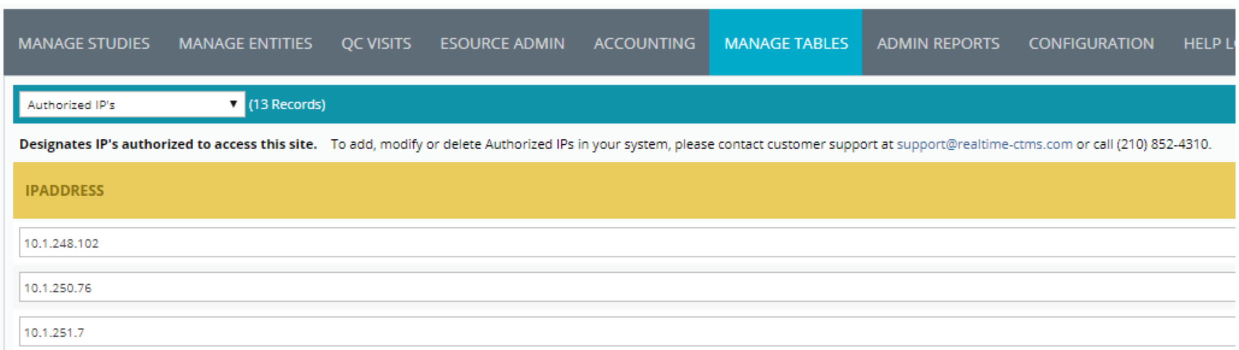
The goal of System Access is to create a layered defense and make it more difficult for an unauthorized person to access RealTime. If one factor is compromised or broken, the attacker still has at least one more barrier to breach before successfully breaking into RealTime.

In addition to a required username and password, access to RealTime can be:

- limited to specific IP addresses and/or ranges
- controlled through Multi-Factor Authentication (MFA).

Authorized IP's

RealTime has a table, Authorized IP's, that contains IP addresses or IP address ranges. Devices accessing the system are placed into one of two groups based on the IP address of the device. A device with an IP address that matches an IP address or falls into an IP range contained in the table are considered Allowed IP's (On Site Logins). A device with an IP address that does NOT match an IP address or does NOT fall into an IP range contained in the table are considered Off Site Logins (Computers with an unknown IP address).



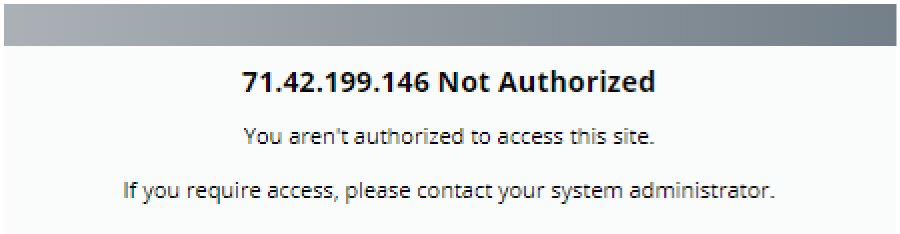
Modifications to the Authorized IP's table is limited to RealTime staff. To add, modify or delete Authorized IP's in the system, contact the Success Team at support@realtime-ctms.com or call (210) 852-4310. Changes to the table are made when requested by an individual verified to request the change.

The values in the table are visible to users with the Administration privilege, under MANAGE TABLES, or under CONFIGURATION>SYSTEM ACCESS.

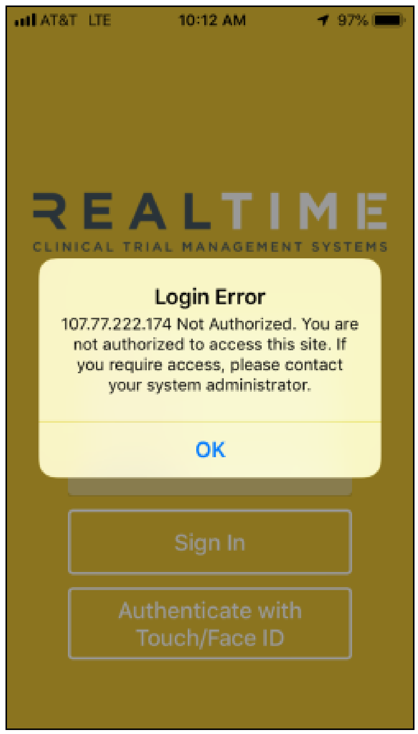
Limit System Access

The ability to limit system access to devices with an IP address that is an Allowed IP or in an Allowed IP range is available by selecting the check box in the middle section of the SYSTEM ACCESS portion of the CONFIGURATION page.

Authorized devices see no change in the login behavior when the checkbox is selected. Devices with an Unknown IP address are not provided any login fields when the logon web page is accessed, only a message that the IP is Not Authorized.



For the RealTime Mobile App, when the user attempts to login a Login Error is displayed.

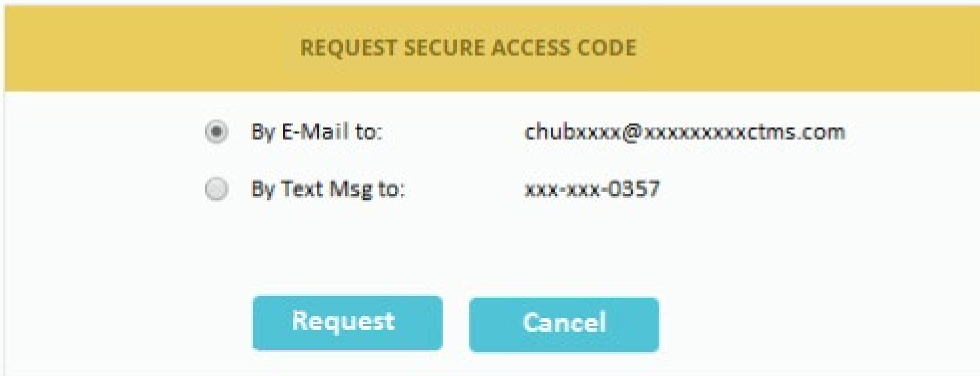


Multi-Factor Authentication (MFA)

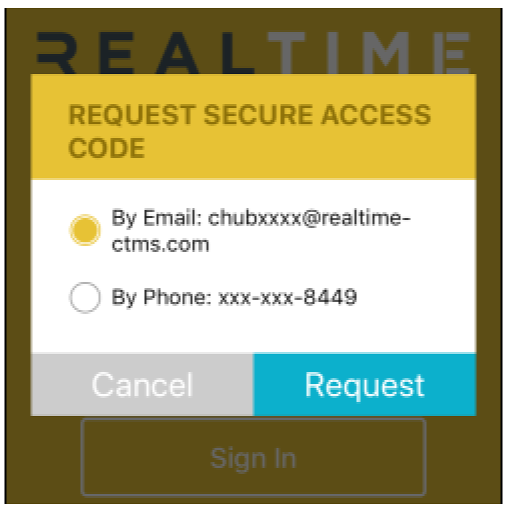
Multi-factor authentication is an authentication method in which a user is granted access only after successfully presenting two or more pieces of evidence to an authentication mechanism. The username/password combination is one piece of evidence, and the Secure Access Code is the second piece of evidence.

Multi-Factor Authentication or MFA is a layer of system access that can be enabled for On Site Logins (Devices with an IP address in the Authorized IP's table), for Off Site Logins (Devices with an unknown IP address), or for both groups.

Devices that have MFA enabled have an additional window displayed after a valid username and password are entered at the login window. The additional window is for the selection of the method a one-time use Secure Access Code will be delivered to the user.



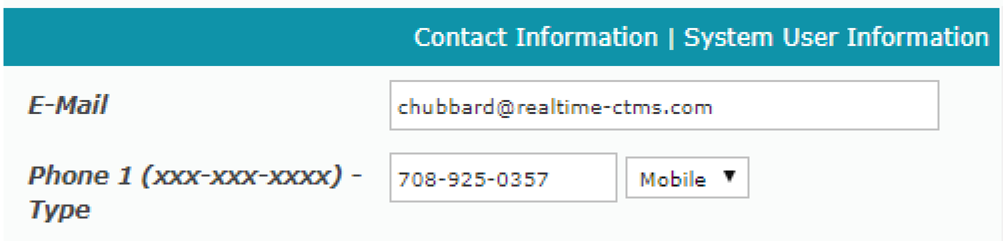
The same prompt is provided in the RealTime Mobile APP.



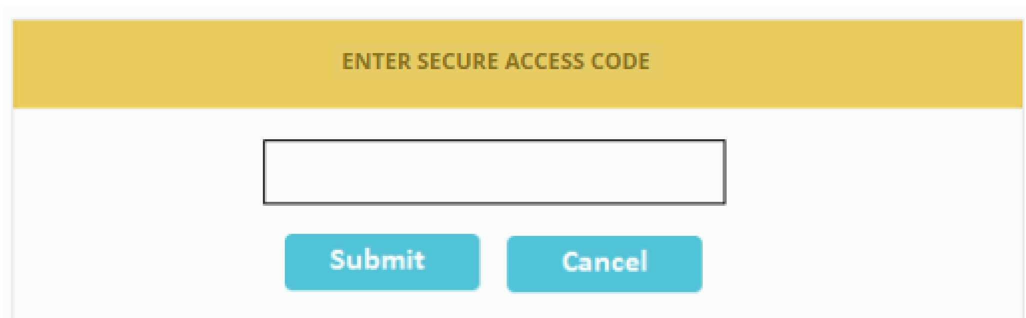
The possible method(s) are based on the user's profile, the information available for the username entered. The possible methods of providing a Secure Access Code are via email or SMS message.

Note: The SMS or text message option is only available if the site has enabled RealTime TEXT.

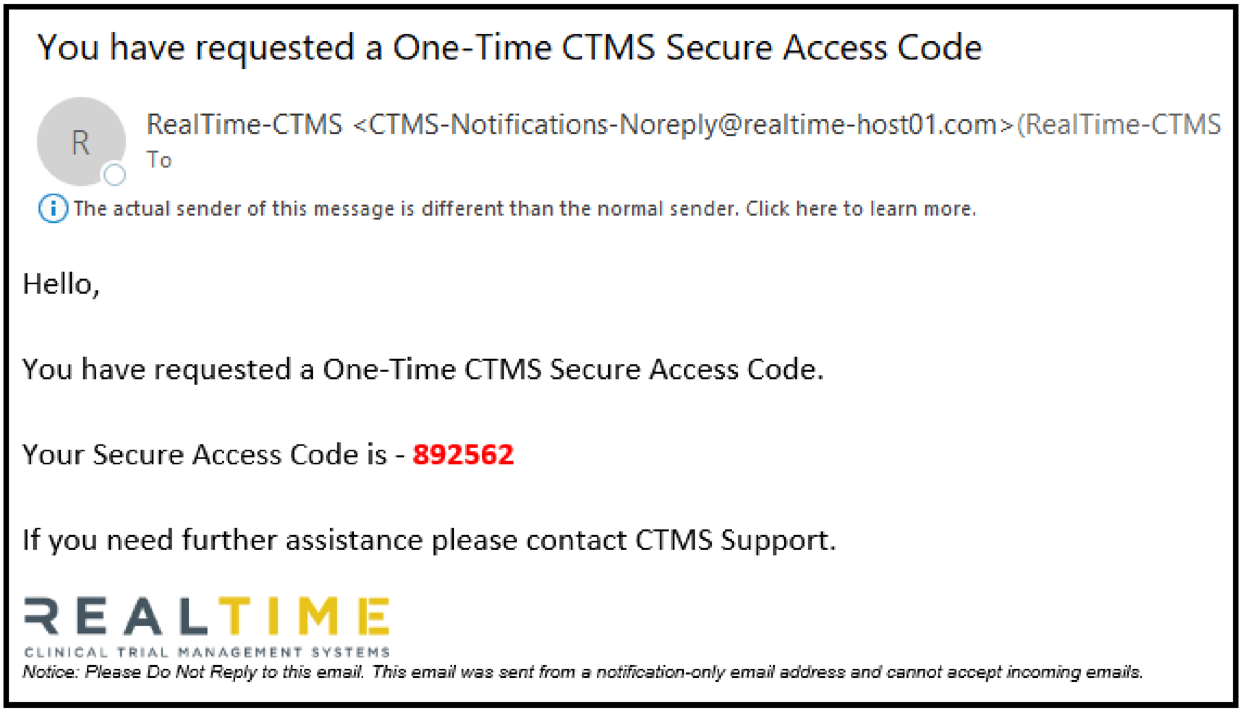
In the user profile, under Contact Information, E-Mail is required and will be populated, and the phone number(s) entered must have the Type selected as Mobile to be used by MFA.



When a user requests a Secure Access Code, a window to enter the Code is displayed.



The user will receive a message via e-mail or SMS text message, depending on the method selected, that will provide the one-time use Secure Access Code.


You have requested a One-Time CTMS Secure Access Code

RealTime-CTMS <CTMS-Notifications-Noreply@realtime-host01.com>(RealTime-CTMS

To

The actual sender of this message is different than the normal sender. Click here to learn more.

Hello,

You have requested a One-Time CTMS Secure Access Code.

Your Secure Access Code is - **892562**

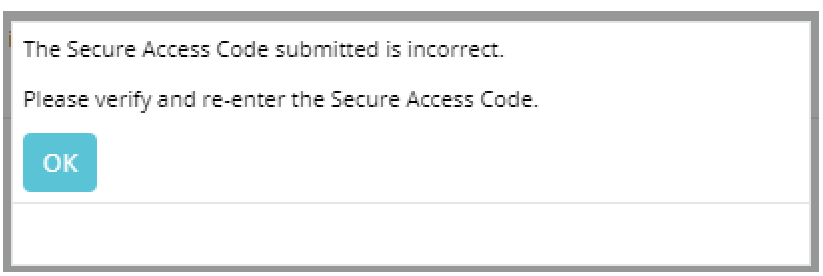
If you need further assistance please contact CTMS Support.

REALTIME
CLINICAL TRIAL MANAGEMENT SYSTEMS

Notice: Please Do Not Reply to this email. This email was sent from a notification-only email address and cannot accept incoming emails.

When the correct Secure Access Code is entered the login process is completed and the home page is displayed.

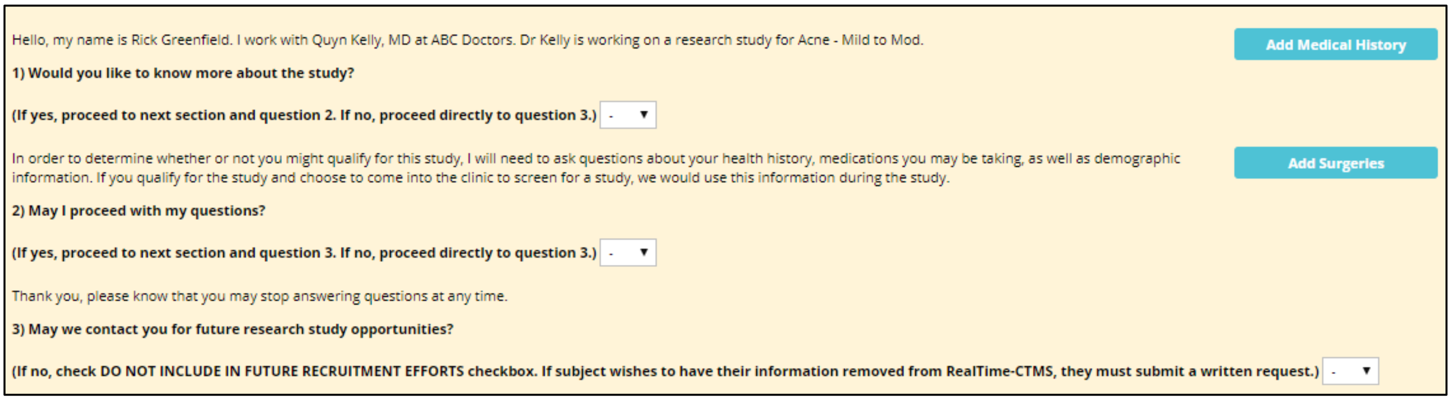
If the incorrect Secure Access Code is entered, a message to verify and re-enter the code is displayed.



If the incorrect Secure Access Code is entered 5 consecutive times, the user account will be locked, similar to 5 consecutive failed login attempts. A user with the Administration and Manage Users privileges assigned can unlock the account, or the user can request a password reset to unlock the account.

INTERVIEW QUESTIONS

You can create subject interview questions (or scripts) display on the subject *Contact Attempts* tab. These interview questions are customizable and can be either global to all subjects and/or study-specific. Global Interview Questions will be displayed on all subject profiles, regardless of study affiliation. An introduction and a question can be set up along with responses. Add button allows for a (i.e. medical history) button to be added next to the interview question so site users can quickly jump to (i.e. medical history) to update the subjects profile. The Study-specific interview questions are specific to a study, so only subjects assigned to a study will have the associated interview questions displayed in their profile.

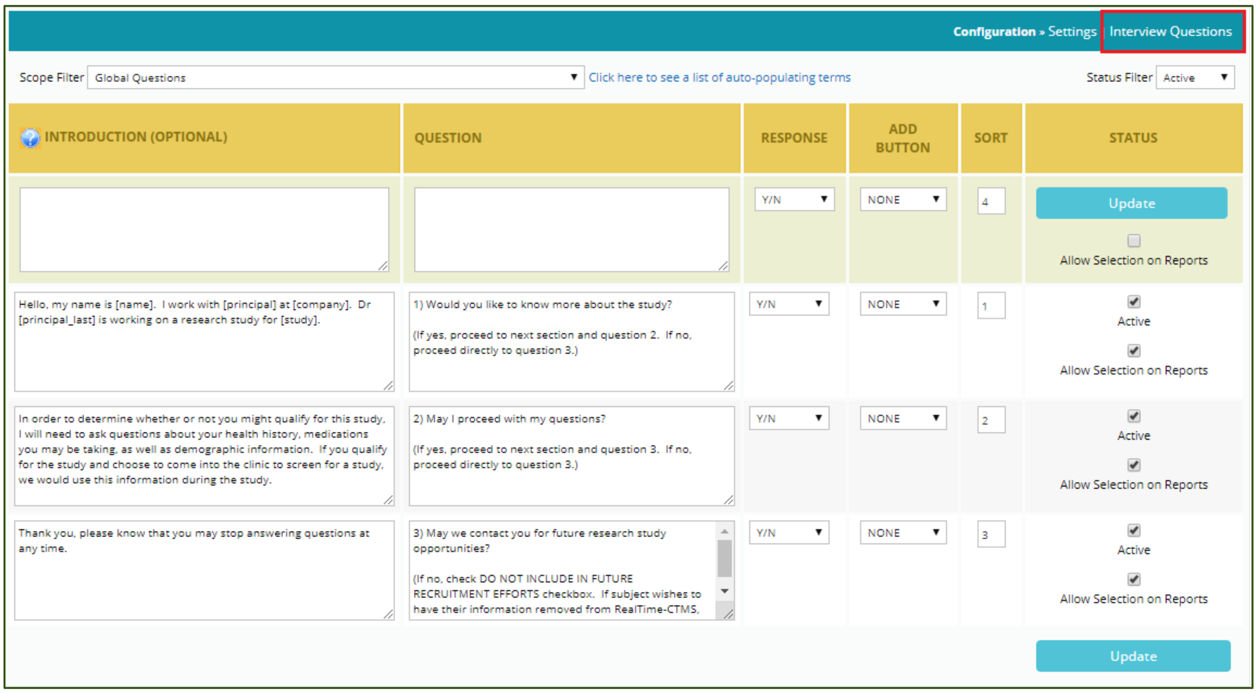


Creating Interview Questions – To create global or study-specific interview questions, first select either 'Global Questions' or the particular study that the questions will be applied to from the 'Scope Filter' dropdown menu. If necessary, you can sort the studies listed in the 'Scope Filter' by the 'Status Filter' on the top right-hand side of the page between All Status, Active, and Inactive studies. Then complete the following fields:

- **Introduction** – Users have the option to create an introduction to your question. An example of an introduction would be: "In order to determine whether or not you might qualify for this study, I will need to ask questions about your health history, medications you may be taking, as well as demographic information."
- **Question** – Type the question that you wish to record an answer for such as, "May I proceed with my questions?"
- **Response** – Users have the option to record a YES/NO ('Y/N') response or a narrative response ('Narrative'). A 'Y/N' response will provide a dropdown for users to select either 'Y' or 'N'. Narrative responses will provide users with a text box to type the subject's verbal response to the question.
- **Add Button** – A button can be added to the question, providing a user the ability to access the selected area, Medical History, Meds and Treatments, Surgeries, or Social items, for the purpose of adding an entry to the subject's record while viewing the CONTACT ATTEMPTS page.
- **Sort** – Users can change the order of the questions by altering the sort numbers of the questions and clicking the 'Update' button.
- **Status** – Users can activate or de-activate each interview question utilizing the 'Active' checkbox. By selecting the 'Allow Selection on Reports,' you can add desired questions to the Interview Questions report located under the Reports link.

Auto-Populating Terms – RealTime-CTMS can also plug in site-specific terms into your global or study questions. An example would be, "Hello, my name is [name]." In this case, RealTime-CTMS will automatically input the name of the current user logged into RealTime. The following terms can be inserted into your questions:

- [name] = User Name
- [principal] = Principal Investigator's Name
- [principal last] = Principal Investigator's Last Name
  [company] = Site Name
  [study] = Study Title
- Update Configuration – as a reminder all changes must be saved by clicking this button prior to moving on to another page, or changes will be lost.



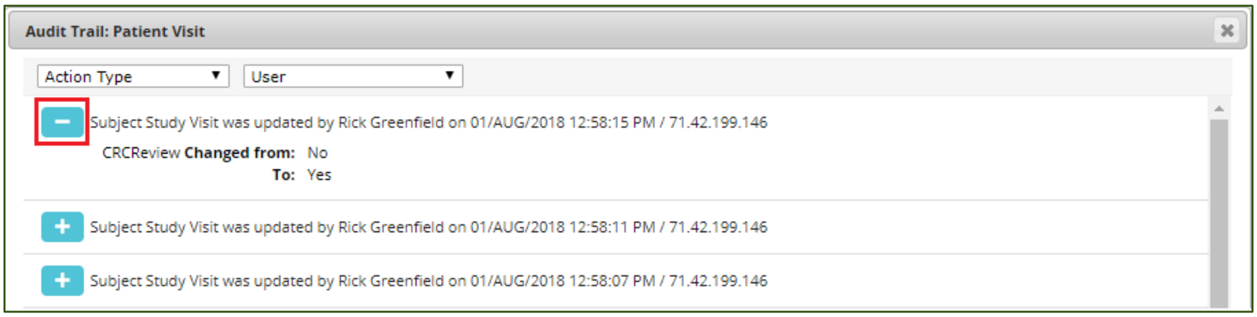
UPDATE CONFIGURATION

As a reminder all changes must be saved by clicking this button prior to moving on to another page, or changes will be lost.

AUDIT TRAILS

View Page History – Users with the "Administration" Privilege have the option to view Page History. This button provides an audit trail and tracks changes and will be located at the bottom left corner of critical pages such as the Contact Attempts, Subject Profile and Medical History pages.

The Audit Trial will differ for each page within the CTMS. Select the + to expand the selection. Username, date, time, and IP address are tracked along with any changes within the page.



MANAGING TABLES

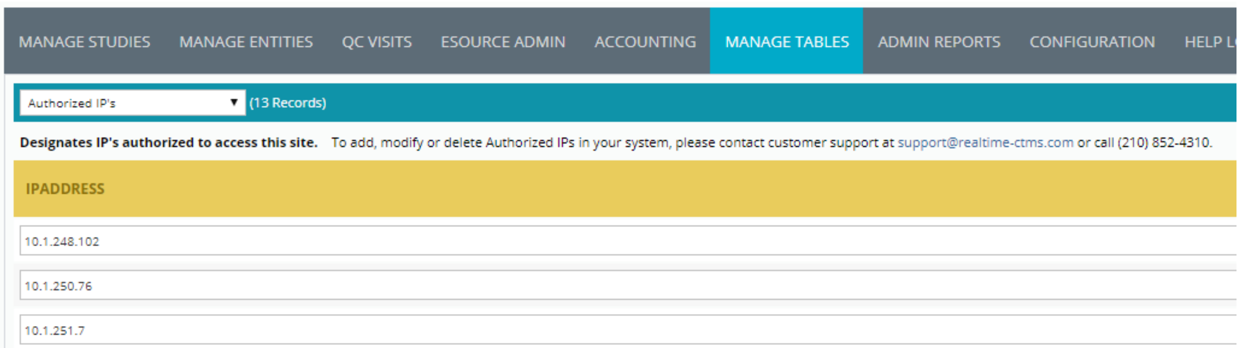
Having the ability to manage tables within RealTime-CTMS allows for customization of RealTime-CTMS for your specific site needs. Table management should also be handled with care as poor table management can lead to duplicate entries, decreased user-friendliness, and overall decreased satisfaction with the performance of RealTime-CTMS. Some tables allow full control, while others have limited edit-ability. If you need a table edited for which you do not have full access to, you will need to contact RealTime-CTMS Success Team.

Tables in RealTime:

Advertising Channels
Authorized IP's
Calendar Event Status
Clinical Procedures
Contract Research Organizations
Departments
Entity Expense Items
Event Color Coding
Institutional Review Boards
Medical History Items
Medical Social Items
Medical Surgical Items
Medication Regimens
Medication Routes
Medications and Treatments
Phone Types
Referral Sources
Relationship Types
Resource Calendars
Signature Statements (eDOCS)
Signature Statements (eSOURCE)
Sponsors
Study Contact Titles
Study Decline Reasons
Study Indications
Study Invoice Terms
Study Not Awarded Reasons
Study Phases
Study Progress Note
Categories
Study Revenue Items
Study Roles
Study Status
Subject Enrollment Status
Subject Recruitment Status
Subject's Preferred Language
Therapeutic Areas
User Privilege Description

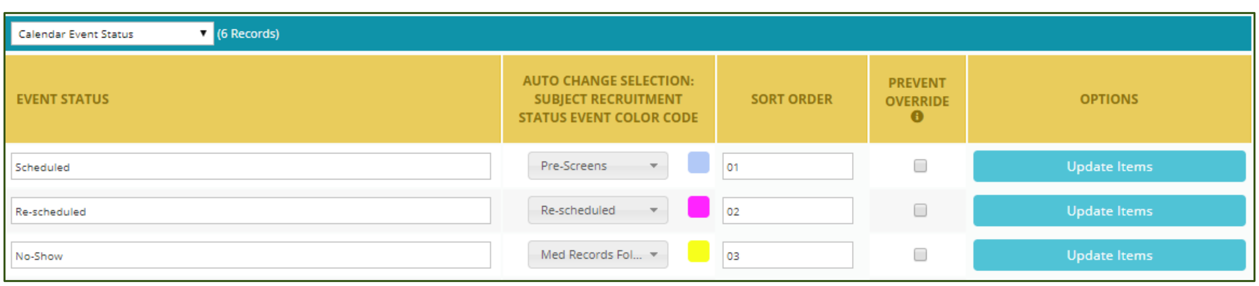
Advertising Channels - Values entered on this table are available for selection in the MANAGE ENTITIES>Advertisers>Advertising Channel association section. (See Managing Advertisers). The table also provide the ability to associate Referral Sources that are Web-enabled to an Advertising Channel.
(See Referral Source table)

Authorized IP's - This is a table that contains IP addresses or IP address ranges. Devices accessing the system are placed into one of two groups based on the IP address of the device. A device with an IP address that matches an IP address or falls into an IP range contained in the table are considered Allowed IP's (On Site Logins). A device with an IP address that does NOT match an IP address or does NOT fall into an IP range contained in the table are considered Off Site Logins (Computers with an unknown IP address).

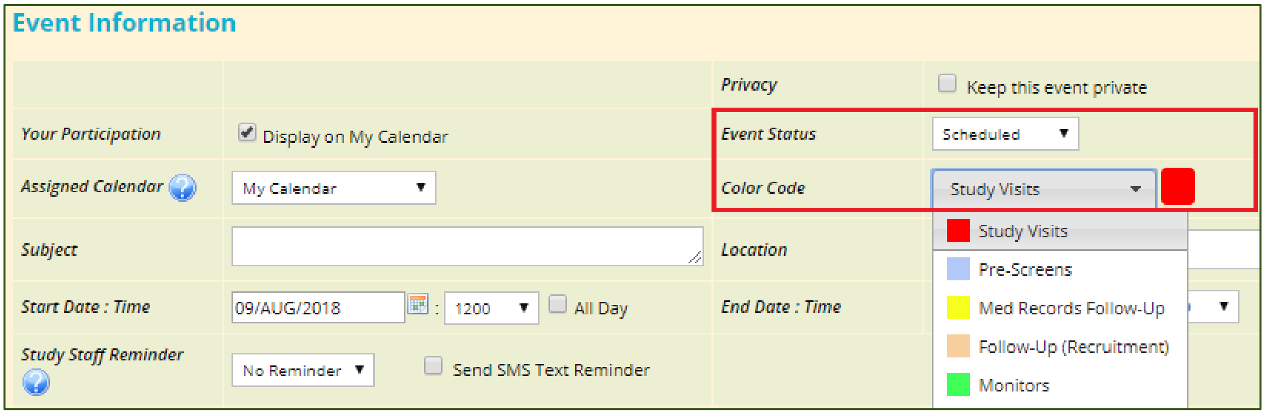


Modifications to the Authorized IP's table is limited to RealTime staff. To add, modify or delete Authorized IP's in the system, contact the Success Team at support@realtime-ctms.com or call (210) 852-4310. Changes to the table are made when requested by an individual verified to request the change.

Calendar Event Status - This table is a list of event statuses and the option to designated color coding for each status. These color-coded statuses allow users to have a visual reference of the status for each event. Users have the option to Auto Change Selection attached to a color code, set Sort Order, Prevent Override and Update Items.



Event Statuses will appear on the 'Event Status' dropdown box in the Calendar section of RealTime-CTMS. The 'Sort Order' will determine the order the Event Status will appear on the 'Event Status' dropdown menu.

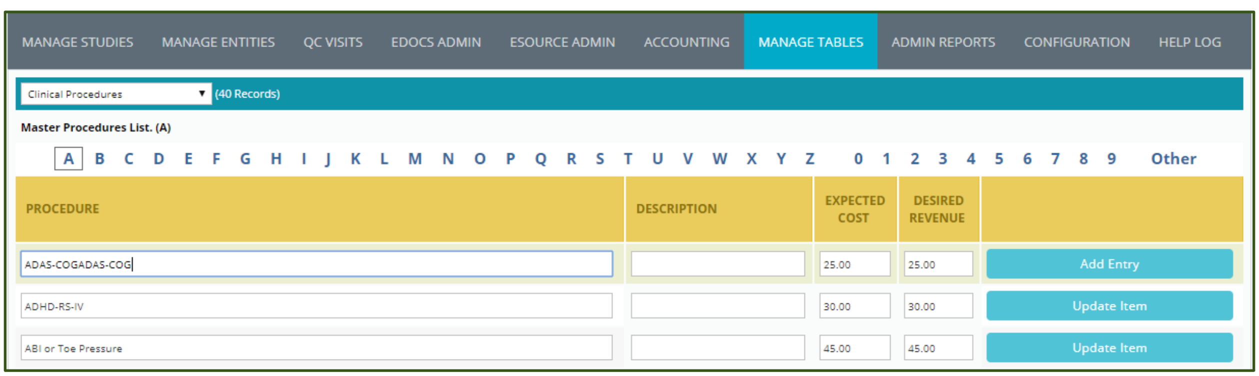


Clinical Procedures – This table is a list of available procedures that may be added to a visit on the visit assessing page or when building a study template.

This table will need to be initially set up prior to implementing RealTime-CTMS. When tracking your visit revenues per procedure, it is important that all the clinical procedures associated with financial revenues/costs are listed in the Master Procedures List prior to creating the study template. Use the protocol visit schedule and/or the study budget to help guide you as to which procedures to add.

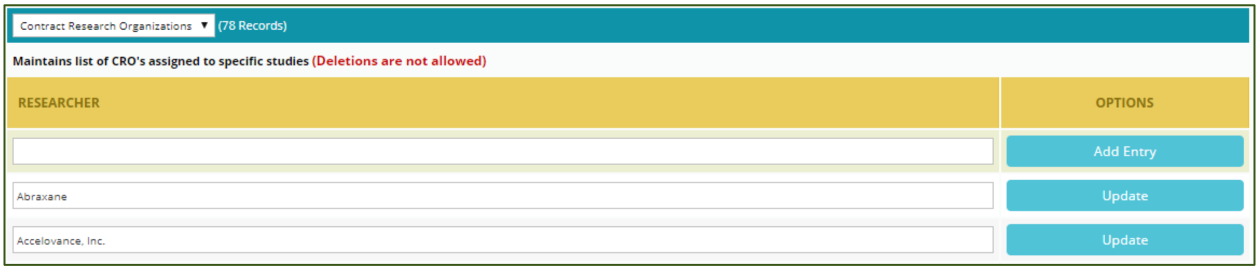
Procedures may be added or edited, but deletions are not allowed since they will have financial costs and revenues associated with them.

To add a procedure simply populate the Procedure field and click 'Update'. You can additionally add a Description, Expected Cost, and a Desired Revenue; however, these fields are not required.

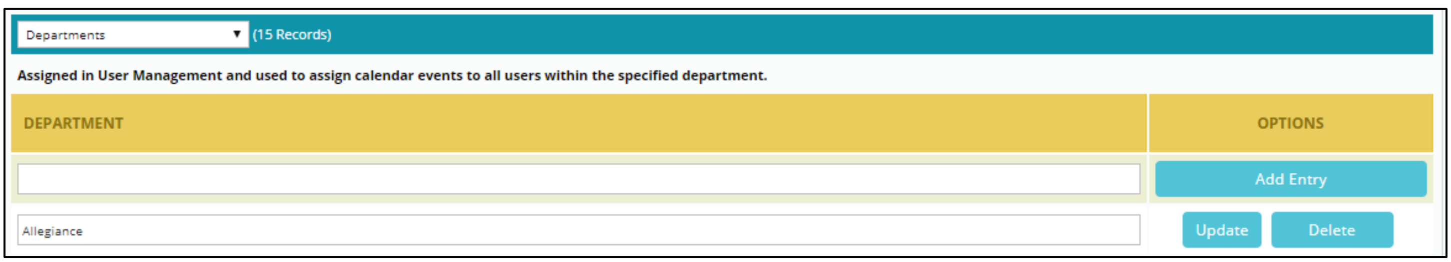


<u>Note</u> *– Any entered Expected Costs and Desired Revenues can be edited when adding a procedure to a study.*

Contract Research Organizations – This table is a list of Contract Research Organizations (CROs) that can be selected for a study when on the Manage Studies tab in the General Information section. This list will also feed into the Sponsor Contact section in the 'Company' dropdown menu, which combines the Contract Research Organizations, Institutional Review Boards, and the Sponsor lists together. To add a CRO, enter a Researcher and click 'Add Entry'.

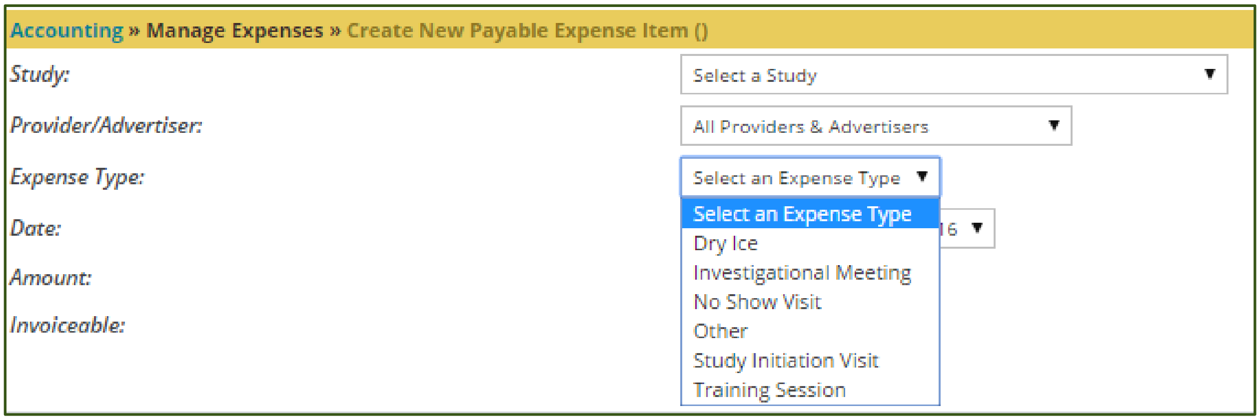


Departments – The Departments table allows a site to establish departments in which to assign users/staff members. Assigning users to departments allows for block scheduling in the RealTime-CTMS calendar.



To add simply populate the Department field and click 'Add Entry'. If your site is not utilizing the department feature in RealTime-CTMS, you can delete departments by clicking the 'Delete' button.

Entity Expense Items – This table is used to categorize payable expense items when creating a payable expense item in the Administration section under the Accounting tab. Example: You need to create an expense for a physician who attended an Investigator Meeting. Entries to this table may be added or edited; however, deletions are not allowed. For more information regarding payable expenses, please refer to the Create Payable Expenses section in this manual.



Event Color Coding – This table is a list of event labels and associated colors. These color-coded labels allow users to have a visual reference of the status for each event. The list of labels and colors can be added to or edited. The color selection is available from the entire color spectrum.

EVENT STATUS	STATUS COLOR	SORT ORDER	OPTIONS
	FFFFFF		Add Entry
Study Visits	FF0000	01	Update
Pre-Screens	B2C9F7	02	Update
Med Records Follow-Up	F7FF1C	02	Update
Follow-Up (Recruitment)	F7D09E	03	Update

Institutional Review Boards – This table is a list of all Institutional Review Boards (IRBs) that may be assigned to studies, and feeds into the 'IRB' dropdown menu in the Manage Studies tab. It also feeds into the Sponsor Contact section in the 'Company' dropdown menu, which combines the Contract Research Organizations, Institutional Review Boards, and the Sponsor lists together. Entries to this table may be added or edited. Deletions are not allowed.

Institutional Review Boards (23 Records)

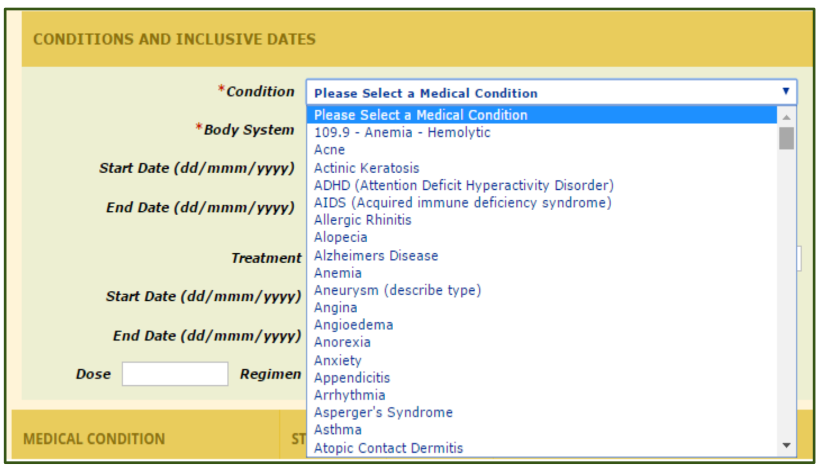
Institutional Review Boards (Deletions are not allowed)

REVIEWBOARD	OPTIONS
	Add Entry
Asentral, Inc. IRB	Update
Aspire IRB	Update

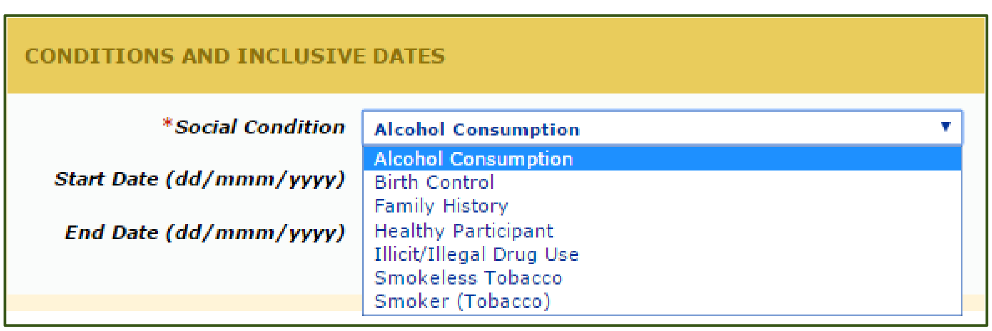
Medical History Items – This table is a list of medical conditions to be applied to subject's medical history. Entries may be added or edited from this table. By checking or un-checking the 'Active' checkbox, you are telling the system to display or not to display the entry in the 'Condition' dropdown menu. Items within this table cannot be deleted once created. This prevents items which are assigned to a subject's record from being deleted in their medical history. So, if you no longer wish to use a certain medical history item, simply uncheck the 'Active' checkbox and that item will no longer be an option for users to select.

Duplicate entries or similar entries may adversely affect subject matching when searching the RealTime-CTMS database for potentially qualified subjects. An example of this would be to have two separate entries such as "High Blood Pressure" and "Hypertension". Only one of these should be used. You may want to name this entry "Hypertension (High Blood Pressure)" to incorporate both common descriptions into a single entry. Additionally, each medical history item must be coded to its applicable body system to allow RealTime-CTMS to auto-code body systems as 'Abnormal' in the System Assessment section. It is strongly suggested that you designate one key administrator to manage this table.

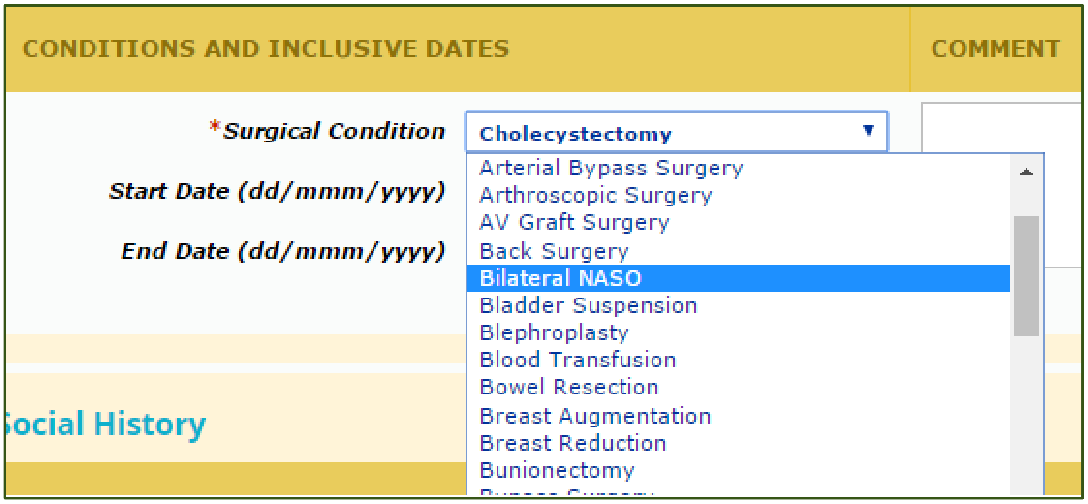
All conditions listed on this table (active and inactive) will be included on the Subject Matching report search criteria.



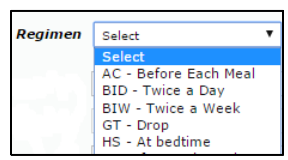
Medical Social Items – This table is a list of social history items to be applied in a subject's Social History section located in the *Medical History* tab. Items within this table cannot be deleted once created. This prevents items which are assigned to a subject's record from being deleted in their medical history. If you no longer wish to use a certain medical social item, simply uncheck the 'Active' checkbox, and that item will no longer be an option for users to select. All social conditions listed on this table (active and inactive) will be included on the Subject Matching report search criteria.



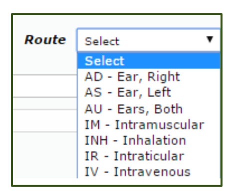
Medical Surgical Items – This table is a list of surgeries, procedures and hospitalizations to be applied in a subject's Surgeries, Procedures and Hospitalizations section in the *Medical History* tab. Items within this table cannot be deleted once created. This prevents items which are assigned to a subject's record from being deleted in their medical history. If you no longer wish to use a certain medical history item, simply uncheck the 'Active' checkbox, and that item will no longer be an option for users to select. All surgeries, procedures and hospitalizations listed on this table (active and inactive) will be included on the Subject Matching report search criteria.



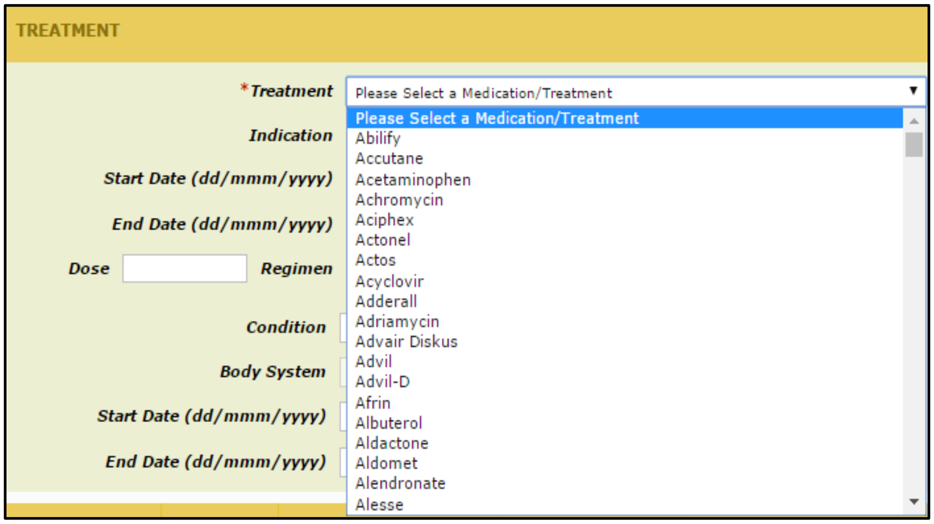
Medication Regimens – This table is a list of medication regimens available for treatment entries. Items in this table can be edited by modifying the present text and clicking 'Update,' or to add an additional medical regimen, populate the 'Regimen' field and click 'Add Entry'. Deletions are not allowed.



Medication Routes – Medication Routes table lists possible routes for treatment administration. This list is available when entering treatments on a patient's *Medical History* or *Meds & Treatments* tabs. Items in this table can be edited by modifying the present text and clicking 'Update,' or to add an additional medication route, populate the 'Regimen' field and click 'Add Entry'. Deletions are not allowed.



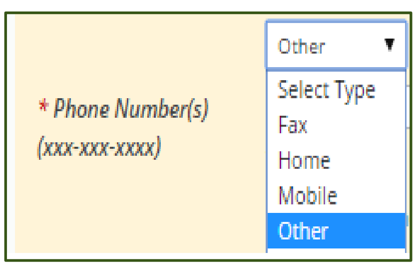
Medications and Treatments – This table is a list of medication names and treatments that can be used while collecting a subject's medical history. Entries to this table may be added or edited. Deletions are not allowed to prevent items which are assigned to a subject's record from being deleted in their medical history. To remove a medication or treatment from the 'Treatment' dropdown box, simply uncheck the 'Active' checkbox on this table.



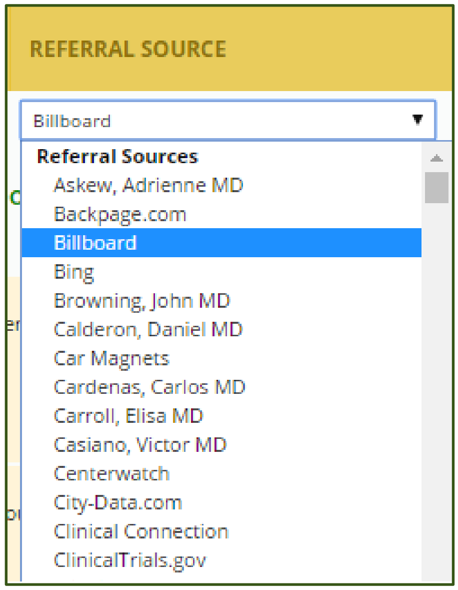
As with the Medical History Items table, it is suggested that a site designate one key administrator to manage the items within this table. Duplicate entries or similar entries may adversely affect subject matching when searching the RealTime-CTMS database for potentially qualified subjects. An example of this would be "Tylenol" and "Acetaminophen". Depending on the site, trade names or generic names or a combination may be preferred.

All medications and treatments listed on this table (active and inactive) will be included on the Subject Matching report search criteria.

Phone Types – This table manages the list of phone type descriptions when collecting telephone numbers for subjects. Entries may be added or edited, but deletions are not allowed.

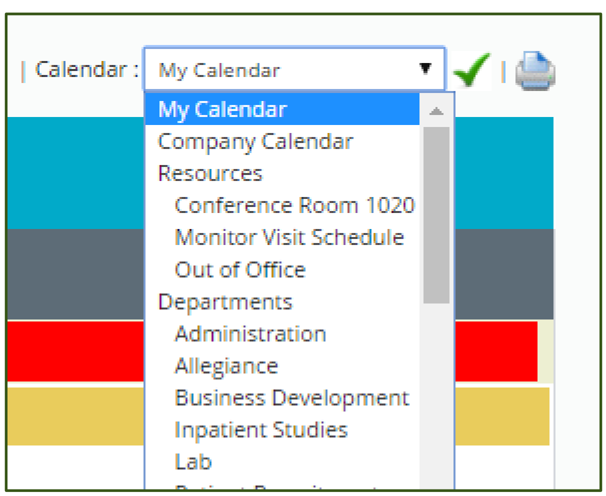


Referral Sources – This table will manage a list of referral sources to be used when identifying a subject's referral source. Local newspapers, radio stations, referring doctors, etc. can be added to this list. Entries may be added or edited, but deletions are not allowed. For instructions on adding specific advertising campaigns (i.e., a one day run in the local newspaper) refer to the Recruitment Campaign Manager section of this manual.



Relationship Types – This table keeps a list of relationships between the subjects and their emergency contact(s). Entries in this table may be added or edited, but deletions are not allowed. To delete an entry, call/email RealTime-CTMS Success Team.

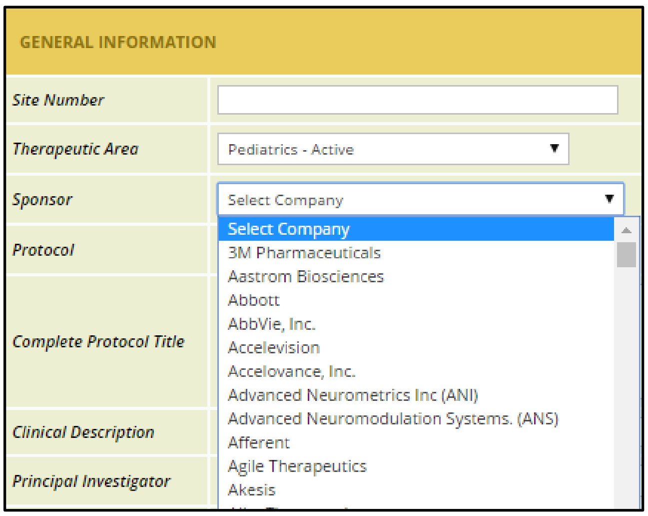
Resource Calendar – This table is a list of site resources that require an individual calendar (i.e. Conference Room, Monitor Rooms, Exam Rooms, etc.) in the *Cal*endar section. Entries to this table may be added or edited; however, deletions are not allowed.

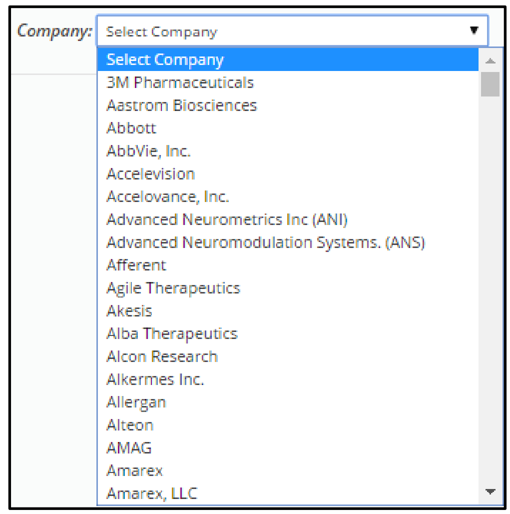


Signature Statements (eDOCS) – This table provides predefined statements, available for selection via a drop down list, when a user is signing an eDOCS related document.

Signature Statements (eSOURCE) – This table provides predefined statements, available for selection via a drop down list, when a user is signing an eSOURCE related document.

Sponsors – This table manages the list of sponsors available in RealTime-CTMS. This list will feed into the *Manage Studies* tab where you can select the desired sponsor in the General Information section. It will also feed into the Sponsor Contact section in the 'Company' dropdown menu, which combines the Contract Research Organizations, Institutional Review Boards, and the Sponsor lists together.





Study Contact Titles – This table is a list of possible job titles for study contacts. Study contacts are saved in the study *General Information* section of the Manage Studies Tab.

Study Decline Reasons – On the STUDY PROGRESS tab for a study, when a date is entered for Study Declined, a window is displayed with a drop down selection for the Reason Study was Declined. This table provides values available for selection in the drop down list.

Study Indications – The Study Indications table stores a list of study indications which are selected in the *General Information* section of the Manage Studies tab. It is useful when searching for studies by indication. Entries may be added or edited, but deletions are not allowed. If a deletion is necessary, call/email RealTime-CTMS Success Team for assistance.

Study Invoice Terms – This table is a list of Payment Terms that can be selected when creating an invoice. To clarify, these are the payment terms that your site wishes the sponsor/CRO pay you within.

Study Not Awarded Reasons – On the STUDY PROGRESS tab for a study, when a date is entered for Study Not Awarded, a window is displayed with a drop down selection for the Reason Study was Not Awarded. This table provides values available for selection in the drop down list

Study Phases – By default your system is delivered with the four main phases of research: I, II, III and IV. You can add additional phase by using this table.

Study Progress Note Categories – This table populates the Progress Note Category dropdown found on the STUDY PROGRESS tab of a study. When a study Progress Note is being entered, the CATEGORY selection is optional, and changes to the list are made in this table.

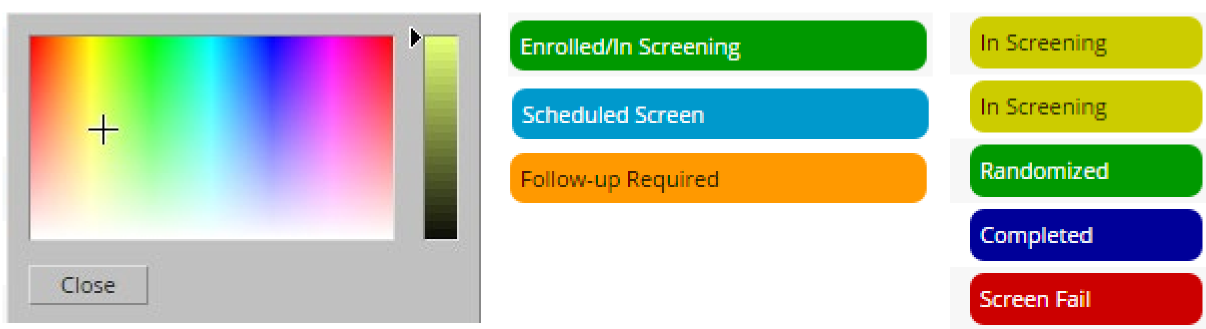
Study Revenue Items – This table is a list of Revenue Items that can be selected when adding a non-visit-based revenue item to a study (See Managing Study Revenue Items). Examples include: Study Start-Up, Record Storage and Pharmacy Fees.

Study Roles – This table provides role selections for eSOURCE purposes.

Study Status – This table provides the ability to add or change available study statuses for selection on the MANAGE STUDIES>GENERAL INFORMATION page (See Managing a Study). A study status can be assigned to a category, enabled as a web page driving study, and the sort order or placement in the drop down list can be set.

Subject Enrollment Status – This table lists available enrollment statuses that can be applied to subjects who are assigned to a study arm. These are "On Study" statuses that may vary in terminology from site to site. Enrollment Statuses may be added or altered, but no deletions are allowed. Enrollment Statuses will appear in the 'Enrollment Status' dropdown box located on a subject's On Study tab. Use the 'Sort Order' field to manually alter how you would like the statuses displayed in the 'Enrollment Status' dropdown menu.

Click the 'Color' field to assign a color to an enrollment status using the hexadecimal color system. The selected colors will be reflected on the Enrollment Roster tab and the Visit Tracking tab.



Selecting the check box for a status under the VISITS ON MY TASKS column determines that if a subject is assigned the selected status and has a visit that is overdue, then the visit is displayed on MY TASKS.

Ending statuses (i.e. Completed, Dropped, Screen Fail, etc.) should have the 'Ending Status' box checked.

Selecting Collate as Randomized triggers RealTime-CTMS to include the numbers for this Enrollment Status in reports and on the Home Page randomization tallies. This should be checked for randomization and all statuses following randomization.

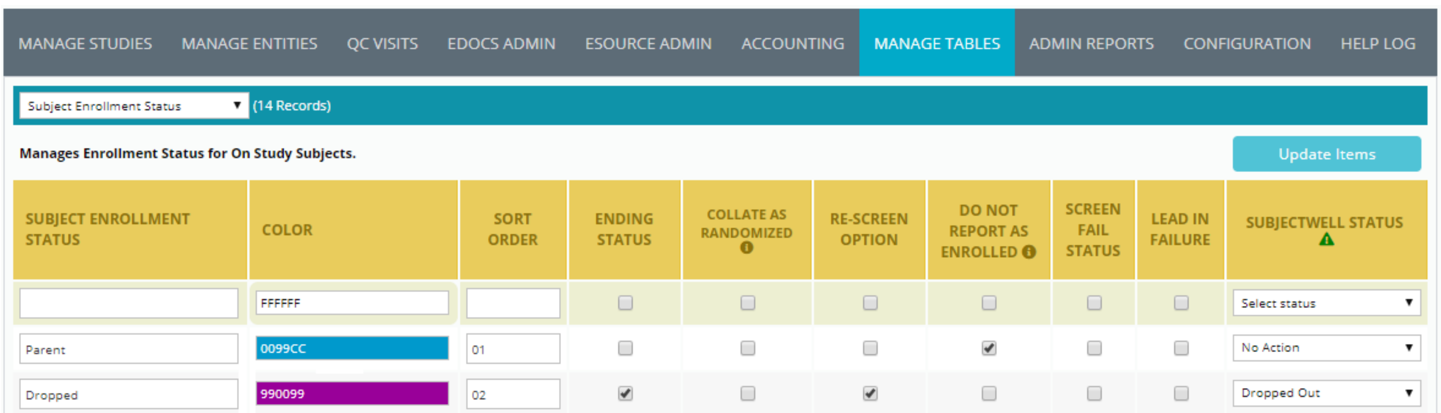
Selecting the Re-screen Option will allow a patient to be re-screened when that particular status is appended to their profile. When a status with the re-screen option is selected for the patient, a “Re-screen” button will display on their Contact Attempts page where a re-screen profile can be created.

The DO NOT REPORT AS ENROLLED selection provides the option to have subjects assigned to a status NOT be reported as Enrolled in study metrics or reports. This option would be applied to a status assigned to individuals considered caregivers (parent, spouse, adult child), that while not participating in the study, must be enrolled in the study. A status with the DO NOT REPORT AS ENROLLED option selected will have the selection indicated on the ENROLLED ROSTER.

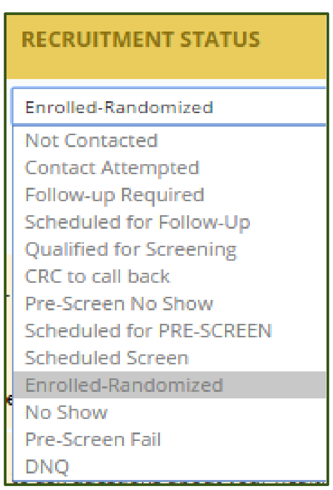
Any status that a site desires to have considered a Screen Fail or Lead In Failure can be selected as such using the checkboxes in the respective column.

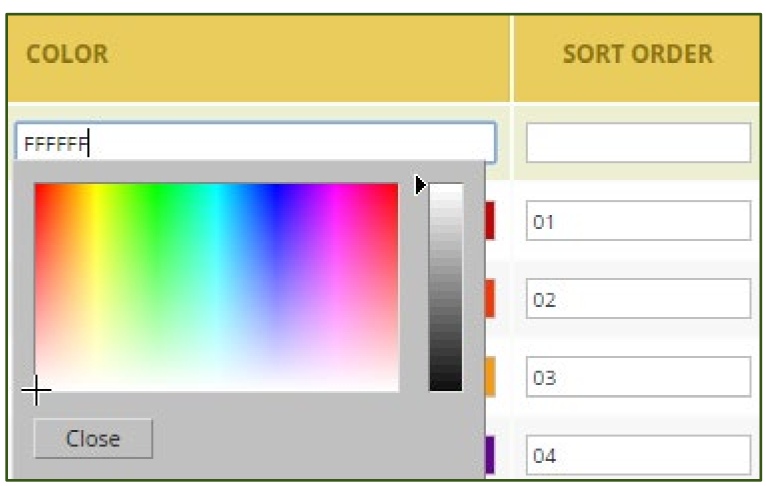
RealTime makes it easy to connect your CTMS to SubjectWell recruitment campaigns allowing automated recruitment leads to funnel from SubjectWell directly into your study recruitment roster.

Hovering over the Ending Status, Collate as Randomized, Re-Screen Option, Do Not Report As Enrolled, Screen Fail Status, and Lead In Failure sections or their check boxes will provide you with a brief description of the function.

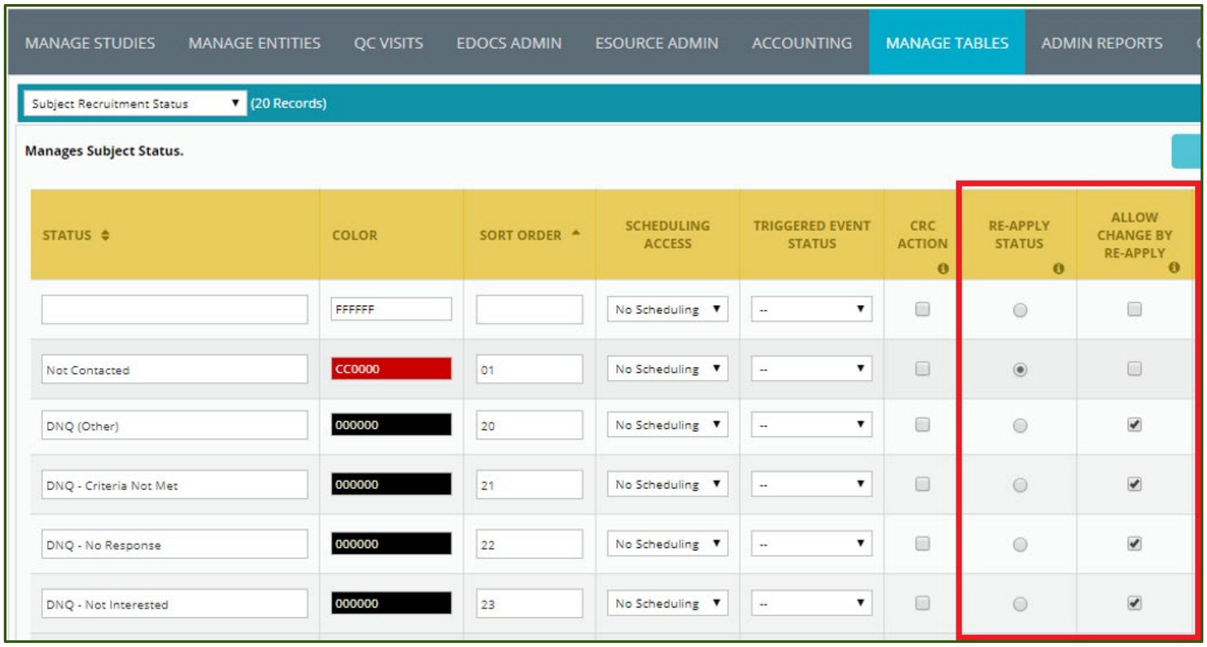


Subject Recruitment Status – This table is a list of Subject Recruitment Statuses. These are the subject statuses that are set for each study on the subject’s “Contact Attempts” page.

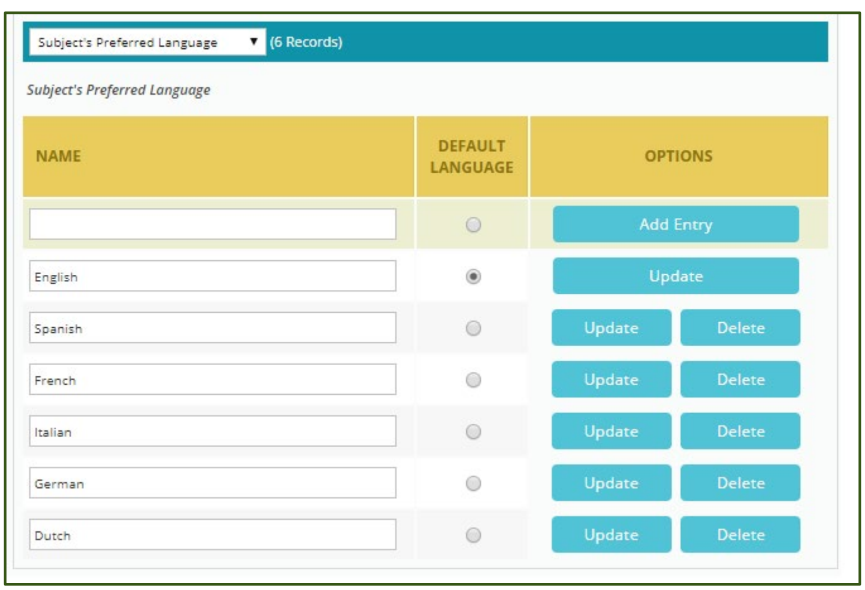




Statuses may be added or edited, but not deleted. Status colors use the hexadecimal color system. Use the Sort Order field to manually alter how statuses display in the final dropdown menu. Realtime provides the option to configure if and how a subject's "Re-Application" can change the subject's current status for the study. Recruitment statuses can be selected to Allow Change, meaning a subject with the indicated status can have their status changed by a re-application. A single status is selected to be the new status, the Re-Apply Status, as a result of the re-application.



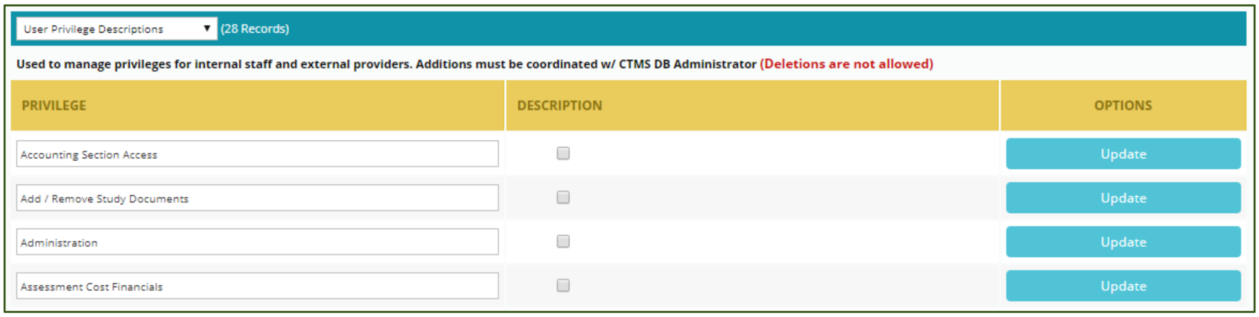
Subject's Preferred Language – This table manages the list of languages available for section under the Preferred Language drop down of the Subject Profile tab. The table can select a default language, so that any subjects added to the database will have the preferred language preselected. Entries to this table can be added or edited, but deletions are not allowed.



Therapeutic Areas – This table manages the list of therapeutic areas that pulls into the *Manage Studies* tab, General Information section. Entries to this table can be added or edited, but deletions are not allowed.

Additionally, if your site is utilizing website integration capabilities, RealTime-CTMS will use the assigned therapeutic areas to categorize your studies on your website. To have your studies listed by therapeutic areas on your website, enter '1' into the Active on Website field.

User Privilege Description – This table is a list of the privileges in the system and a description of each privilege. The tool tip / hover description that is displayed when a cursor is placed over the privilege comes from this table.



MANAGING ENTITIES AND USERS

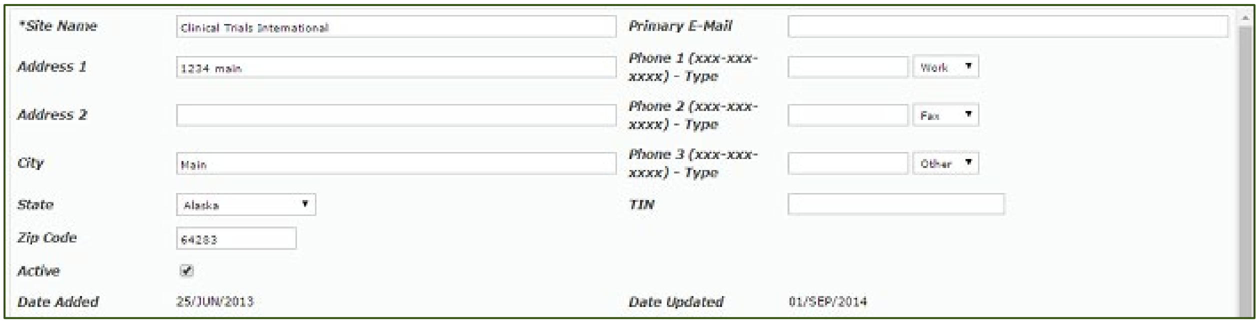
There are three internal sections in the *Manage Entities* tab, Company Site Locations, Study Providers, and Advertisers. These three internal sections will allow you to easily manage the site along with all of the entities that you contract with to conduct your business.

COMPANY SITE LOCATIONS

Within the Company Site Locations section, you will be able to manage your site's location, as well as your users, being able to add, assign/modify permissions, and inactivate your users. If you would like to manage multiple site locations and upgrade to RealTime-CTMS Enterprise, contact your RealTime-CTMS sales representative.

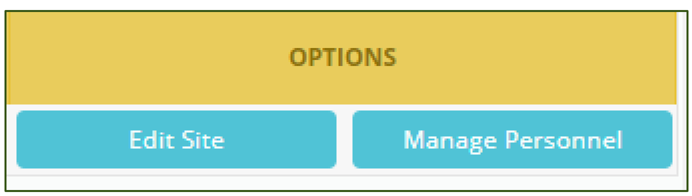
MANAGING SITE(S)

The information that was provided to RealTime-CTMS Success Team during the purchase of your software will already be entered into the system for you. By clicking on the 'Edit Site' button, you can view the entered site information. If an update is required, simply make the desired change and click 'Update Entity' to save your changes. To close the window without making any change click 'Close'. The site information that is populated into this field is only to help you manage your site location(s) and does not appear on reports or invoices.

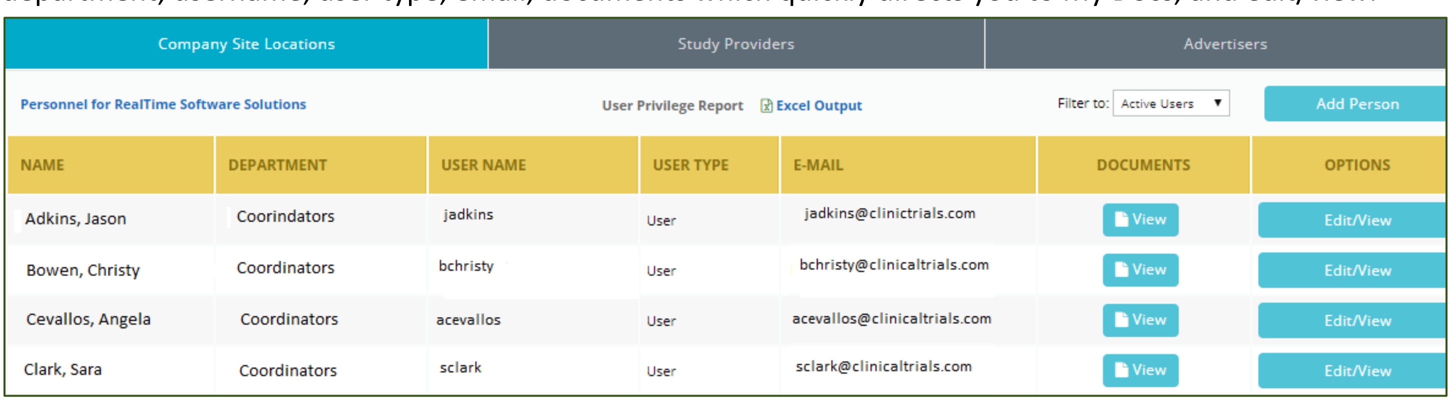


MANAGING SITE USERS

To access site personnel, click the 'Manage Personnel' button. You will be directed to the personnel management page.

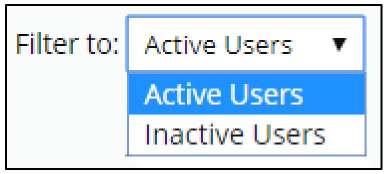


To go back to the site management page, click the 'Personnel for your site' link or the 'Company Site Locations' link, located in the upper left side of your screen. A table of all staff will be listed here to include name, department, username, user type, email, documents which quickly directs you to My Docs, and edit/view.



NAME	DEPARTMENT	USER NAME	USER TYPE	E-MAIL	DOCUMENTS	OPTIONS
Adkins, Jason	Coorindators	jadkins	User	jadkins@clinictrials.com	View	Edit/View
Bowen, Christy	Coordinators	bchristy	User	bchristy@clinicaltrials.com	View	Edit/View
Cevallos, Angela	Coordinators	acevallos	User	acevallos@clinicaltrials.com	View	Edit/View
Clark, Sara	Coordinators	sclark	User	sclark@clinicaltrials.com	View	Edit/View

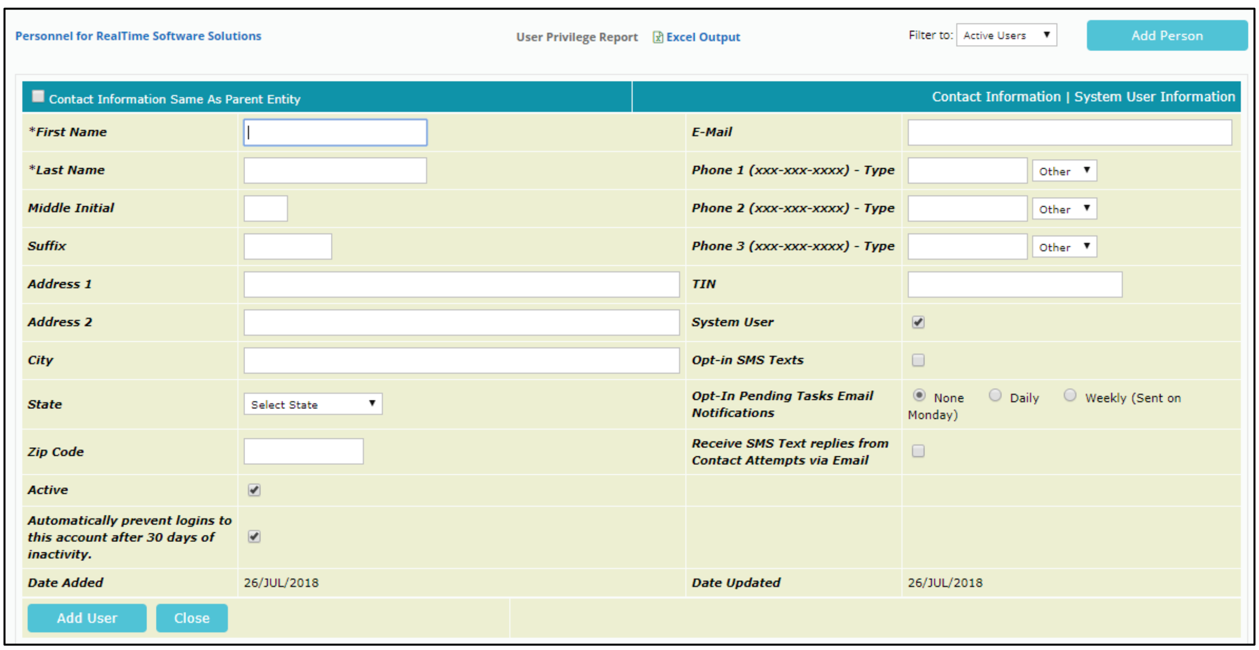
Visible users can be filtered by Active Users and Inactive Users. Once created, user accounts cannot be deleted from RealTime-CTMS due to system data associated with that user.



ADDING USERS

To add additional users to your site location, click the 'Add Person' button. An entry box will appear on your screen. On the top right side of the entry box you will see it contains two links, the Contact Information link and the System User Information link. The entry box automatically opens onto the Contact Information section, allowing you to populate the new user's contact information. If the contact information is the same as the parent entity a quick check of the 'Contact Information Same as Parent Entity' box will pull in the same mailing address and phone numbers as the parent site.

All required fields are indicated with an asterisk (*). In addition to adding their first and last name, be sure to include their e-mail address, which will be utilized to send calendar invites and study notifications. System users are required to have an e-mail address populated.

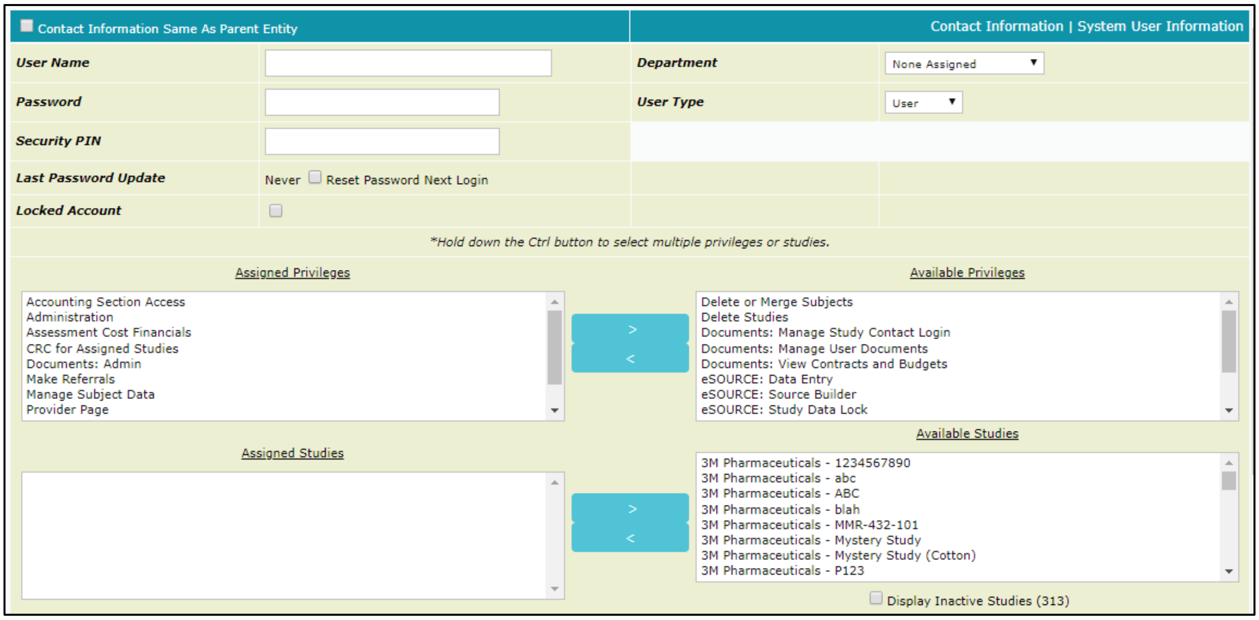


If the individual you are adding does not require access to your RealTime-CTMS be sure the 'System User' check box is not checked and click 'Add User'. A scenario of this occurring at your site is if you have a company employed sub-investigator who minimally fills in for the principal investigator. The sub-investigator will need to add him to the system, so he can be selected from the visit assessment page as a provider, but you do not need to grant him access to your system. If the individual you are adding will be a system user, meaning that they will need access to your RealTime-CTMS, then the 'System User' checkbox should be checked, and the System User Information will need to be completed prior to being allowed to save the user.

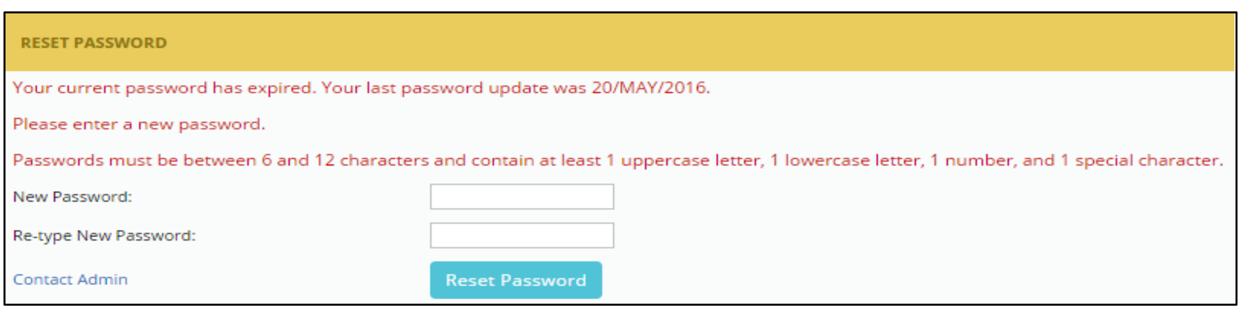
If your site is participating in the RealTime-TEXT program, you will see an option to opt-in the user to receive reminder text messages for appointments. Refer to the RealTime-TEXT user manual for additional instructions.

SYSTEM USER INFORMATION

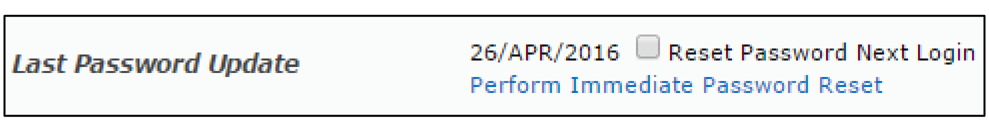
The System User Information section is where you can quickly manage system user's profile, from establishing the user to assigning/editing the user's privileges and studies.



When adding a new user, populate the 'User Name' and 'Password' fields. The username will be the first initial of the user's first name and their complete last name (for example: jsmith). Please note that usernames are not case sensitive. RealTime-CTMS requires that passwords contain 6-12 characters, an uppercase letter, lowercase letter, symbol, and a number. By checking the 'Reset Password Next Login' checkbox you are telling the system to have the user create or re-create their password at the user's first or next login.



A user will be locked out of the system after five failed log-in attempts. In order to unlock the account, an administrator will need to uncheck the Locked Account checkbox. Clicking the Perform Immediate Password Reset will email the user a temporary password.



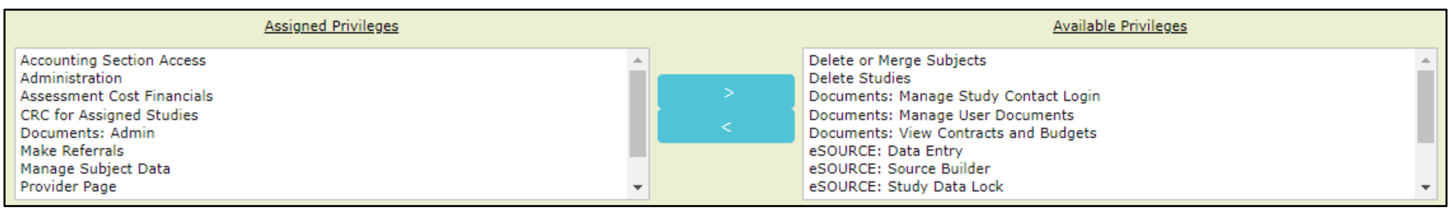
Each user should be assigned to a department. This will be helpful when utilizing the Calendar section of RealTime-CTMS. If the desired department is not listed, please refer to the Manage Tables section of this manual.

Each user will need to be established as either a 'Provider' or a 'User'. When determining which users are "Providers" and which are "Users". Use the following definitions to help you.

- **Provider** – A provider of services who will be paid for specific procedures and/or are completing study related procedures like physical exams, determining subject eligibility, and rating scales (investigators and raters).
- **User** – A system user who will be completing study related activities but does not meet the requirements of a "Provider".

ASSIGNING PRIVILEGES TO USERS/PROVIDERS

Each site user/provider should be assigned privileges to allow access to specific areas and functions within RealTime-CTMS. Assign or remove privileges for users/providers by simply moving privileges in and out of the 'Available Privileges' box and 'Assigned Privileges' box by clicking on the directional arrows.



To move multiple privileges, hold down the Ctrl button on your keyboard. Hover your mouse over a desired privilege for a quick description of its controls. To save changes to a user profile, the 'Add User' button must be pressed.

USER/PROVIDER PRIVILEGES

A detailed description of each privilege is defined below:

Accounting Section Access – Gives user access to the Accounting tab in RealTime-CTMS. The user must also have the Administration privilege along with this privilege.

Documents: Admin: Allows Users/Providers to add or remove documents in and out of each study-specific document repository.

Administration: Gives user access to the Administration area (add/remove studies, build study visit templates, manage sites, run administrative reports, etc.)

Assessment Cost Financials: Allows users to view financial information when performing visit assessments and submissions (i.e., the cost per procedure, or the revenue from the visit).

CRC for Assigned Studies: Designates the user as a study coordinator which adds them to CRC menus within RealTime-CTMS and adds their email to CRC notifications built into RealTime-CTMS.

Delete or Merge Subjects: Allows users the authority to delete or merge existing subject profiles. Special caution should be given to this privilege, as deletion of subject's medical histories is not to be taken lightly.

Delete Studies: Allows users with Administrative privileges to delete all data associated with a study from the RealTime-CTMS database. Very important information can be deleted, so proceed with caution.

Make Referrals: Allows users to add subjects to studies.

Manage Subject Data: Allows users to edit subject data.

Provider Page: Gives providers the ability to view financial data associated with their provider profile. If you have a doctor that only wants to see financial information that is related to them, then give them this privilege. They will not be able to see what other doctors in the practice have earned.

Red Flags: Allows users the ability to add "Red Flag Comments" to subject profiles.

Site Manager: Allows a provider to view financial data for the entire site with which they are associated. This allows the doctors access to their site's financial data, not of the entire research practice.

User Management: Allows an administrator to add and edit user information, including passwords, and system privileges.

View Study Subjects: Allows users to view study subject information.

ASSIGNING STUDIES TO USERS/PROVIDERS

Selecting studies for Users/Providers is as simple as moving studies from the 'Available Studies' box to the 'Assigned Studies' box using the arrows. When setting up a new User/Provider it is required that the user is assigned to at least one study. If no studies are created in RealTime-CTMS that apply to a user, then the study labeled 'RealTime-CTMS – Future Candidates' can be used. This is a "dummy" study set up in RealTime-CTMS to allow for this situation. To save changes to a user profile, the 'Add User' button must be pressed.

INACTIVATING A USER

Once created, user accounts cannot be deleted from RealTime-CTMS due to system data associated with the user. In the situation where an employee has departed or been terminated by your site, you will need to remove their access to RealTime-CTMS by inactivating them immediately. To inactivate a user's account, click the 'Inactivate' button or uncheck the 'Active' checkbox and click 'Update User' button in their profile.

STUDY PROVIDERS

Within the Study Providers section, you will be able to manage all contracted entities and establish how you will pay each provider, whether you will pay directly to the providers themselves or to their associated entities. All individuals or companies who perform study related procedure(s) for your site and are not employees of your site (i.e., contracted imaging facilities, local labs, dry ice vendors, and physicians) will need to be entered into this section.

MANAGING STUDY PROVIDER PAGE

The Study Provider Management Page will list all entered contracted providers, displaying their company name, location, quick identification of whether they are the "Primary Payee," and their status 'Active' or 'Inactive'.

ADDING STUDY PROVIDER ENTITIES

To add a provider entity, click the 'Add Study Provider' button. An entry box will appear on the screen. The 'Provider Name' should reflect the name of the contracted company. If you are working with a physician who is not associated with a specific entity, you should enter the physician's name as the 'Provider Name'. Populate all required fields (indicated with an asterisk*) and the remaining information as necessary.

*Provider Name		Primary E-Mail	
Address 1		Phone 1 (xxx-xxx-xxxx) - Type	Other
Address 2		Phone 2 (xxx-xxx-xxxx) - Type	Other
City		Phone 3 (xxx-xxx-xxxx) - Type	Other
State	Select State	TIN	
Zip Code		Primary Payee	☑
Active	☑		
Date Added	20/MAY/2016	Date Updated	20/MAY/2016

The 'Active' checkbox determines whether or not a contracted entity is active or inactive. If you are currently conducting business or will conduct business in the future be sure the 'Active' checkbox is checked. Once created, contracted entities cannot be deleted from RealTime-CTMS due to the corresponding data that entity is associated with in the system.

When utilizing contracted entities there is always a "Primary Payee," which is determined by how you will pay for the contracted services. For instance, a group of radiologists provide radiological procedures for your research site, the payee may be the individual radiologist (Dr. Exray) who performs the procedure, or the payee may be the name of the group (Radiology Consultants, PA) that the radiologist is affiliated with. If you are paying the group or company for the contracted services, the 'Primary Payee' checkbox should be checked. If you are paying individual providers for their contracted services, the 'Primary Payee' checkbox should be unchecked.

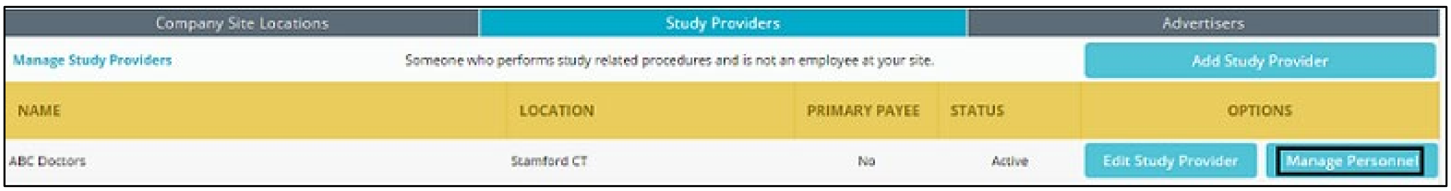
Once all of the applicable information is populated, click 'Save Entity'.

EDITING STUDY PROVIDER ENTITIES

To edit or view any previously entered information for an entity that is listed on the Study Provider Management Page click on the 'Edit Study Provider' button. If an update is required, make the desired change and click 'Update Entity' to save your changes. To close the window without making any change click 'Close'.

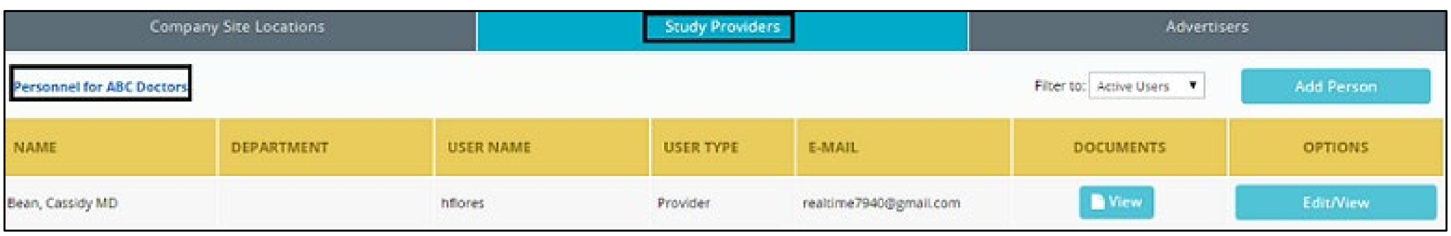
MANAGING PERSONNEL WITHIN ENTITIES

Each contracted entity entered into RealTime-CTMS should have at least one provider associated with their company. To add a provider, click the 'Manage Personnel' button located on the study provider management page.

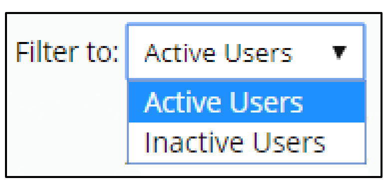


You will be directed to the personnel management page for that specific entity.

To go back to the study provider management page click the 'Personnel for Provider Entity' or the 'Study Providers' links.



Visible provider entity personnel can be filtered by 'Active Users' and 'Inactive Users'. Once created, provider accounts cannot be deleted from RealTime-CTMS due to the corresponding data that provider may be associated with in the system.



ADDING PROVIDERS WITHIN A STUDY PROVIDER ENTITY

To add a provider to a study provider entity, click the 'Add Person' button. An entry box will appear on your screen. On the top right side of the entry box you will see it contains two links, the Contact Information link and the System User Information link. The entry box automatically opens onto the Contact Information section, allowing you to populate the new user's contact information.

If the contact information is the same as the parent entity a quick check of the 'Contact Information Same as Parent Entity' box will pull in the same mailing address and phone numbers as their parent site. All required fields are indicated with an asterisk (*). In addition to adding their first and last name be sure to include their e-mail address, which is required if the provider will be a system user.

If the individual you are adding does not require access to your RealTime-CTMS be sure the 'System User' check box is not checked and click 'Add User'.

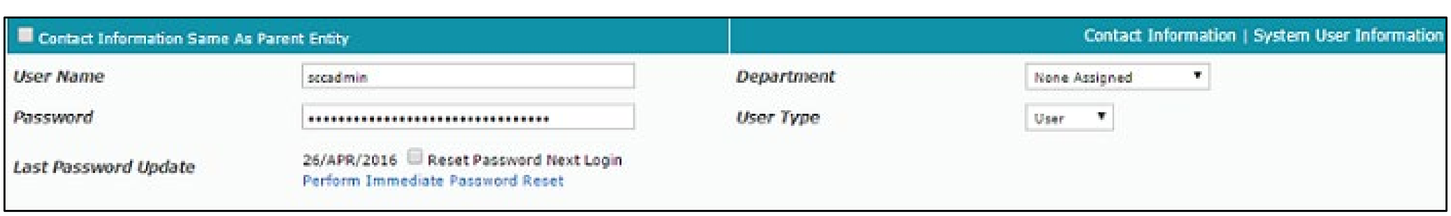
If the individual you are adding will be a system user, meaning that they will need access to your RealTime-CTMS, then the 'System User' checkbox should be checked, and the System User Information will need to be completed prior to you being allowed to save the user.

If your site is participating in the RealTime-TEXT program, you will see an option to opt-in the user to receive reminder text messages for appointments. Refer to the RealTime-TEXT user manual for additional instructions.

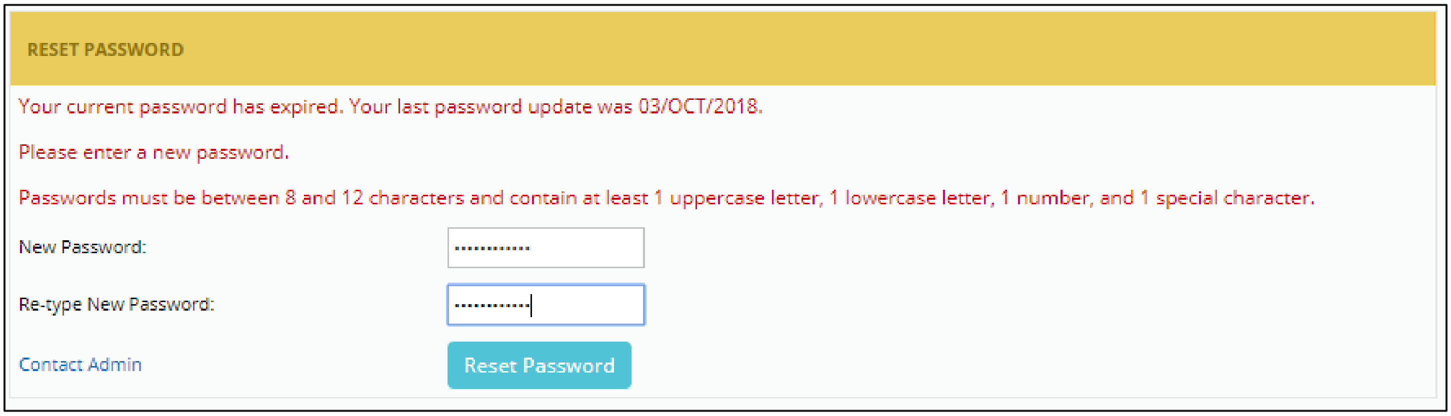
MANAGING ADVERTISERS

In the System User Information section, you can quickly manage the provider's profile, from establishing the provider as a user to assigning/editing the provider's privileges and studies.

When adding a new provider, populate the 'User Name' and 'Password' fields. The username will be the first initial of the provider's first name and their complete last name (for example: jsmith). Please note that usernames are not case sensitive. RealTime-CTMS requires that passwords contain 8-12 characters, an uppercase letter, lowercase letter, symbol, and number.



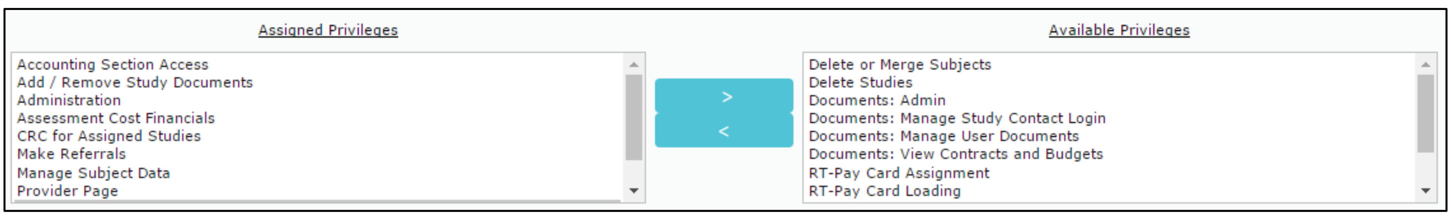
By checking the 'Reset Password Next Login' checkbox you are telling the system to have the provider create a new password at the provider's first or next login. The user will be sent an email with a temporary password to enter upon logging in. After this step RealTime will prompt the user to enter a new password.



ADDING PRIVILEGES TO PROVIDERS

Each provider should be assigned privileges to allow access to specific areas and functions within RealTime-CTMS. Assign or remove privileges for providers by simply moving privileges in and out of the 'Available Privileges' box and 'Assigned Privileges' box by clicking on the directional arrows.

To move multiple privileges, hold down the Ctrl button on your keyboard. Hover your mouse over a desired privilege for a quick description of its controls. To save changes to a user profile, the 'Add User' button must be pressed.



Detailed descriptions of provider privileges are defined below:

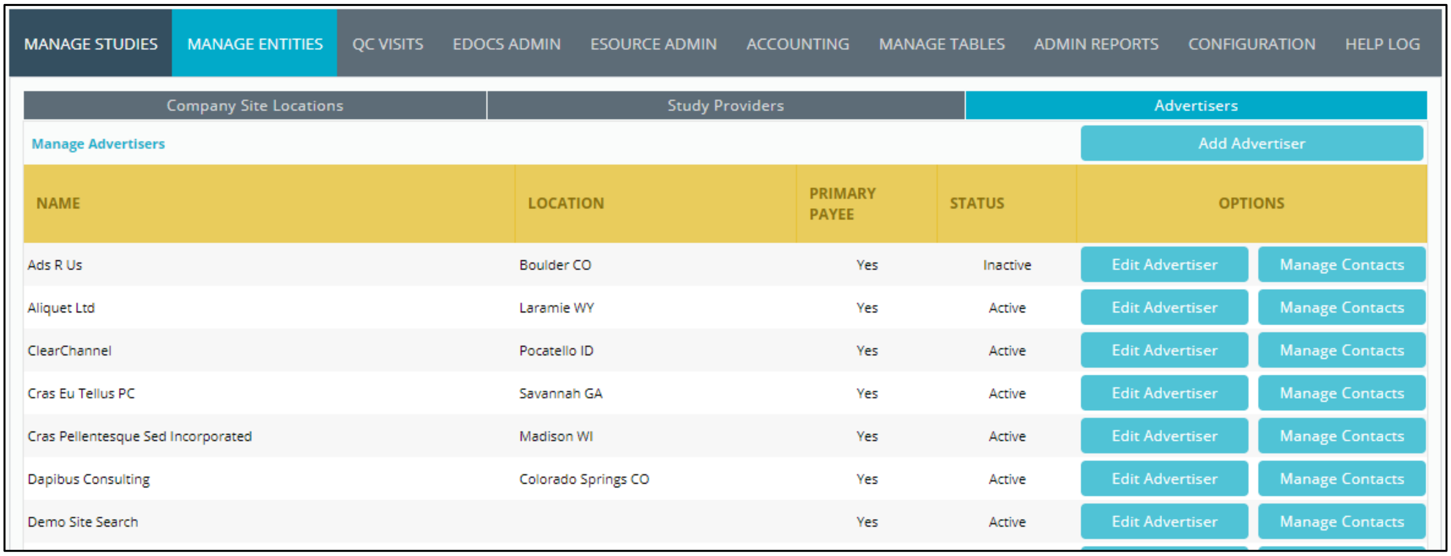
- **Site Manager**: Allows a provider to view financial data for the company entity which they are associated. This allows the doctors access to their company's financial data, not access to the entire research site.

ASSIGNING STUDIES TO PROVIDERS

Selecting studies for Providers is as simple as moving studies from the 'Available Studies' box to the 'Assigned Studies' box using the arrows. When setting up a new provider it is required that the provider is assigned to at least one study. If no studies are created in RealTime-CTMS that apply to a user, then the study labeled 'RealTime-CTMS – Future Candidates' can be used. This is a "dummy" study set up in RealTime-CTMS to allow for this situation. To save changes to a user profile, the 'Add User' button must be pressed.

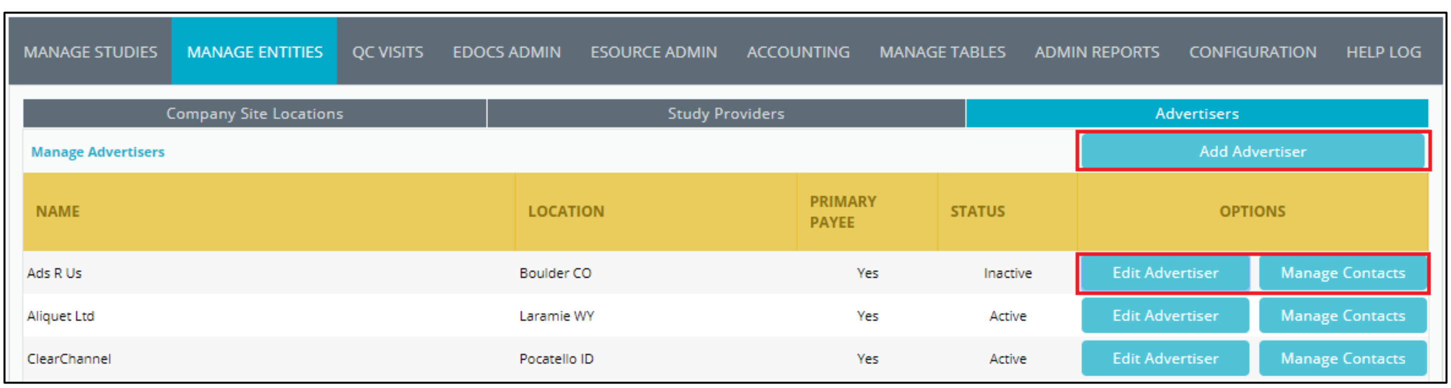
ADVERTISERS

This section will manage all of your site's contracted advertising companies. Central recruitment campaigns/companies should not be entered into this section. This section is solely reserved for the entities you will contract for recruitment purposes. Advertisers that are listed in this section will become available vendors to select when using the Recruitment Campaign Manager section in the Manage Studies tab. Note: To add additional advertisers to the list of vendors in the Recruitment Campaign Manager section, you will need to add the advertiser as a provider in the Manage Entities tab, Advertiser section.



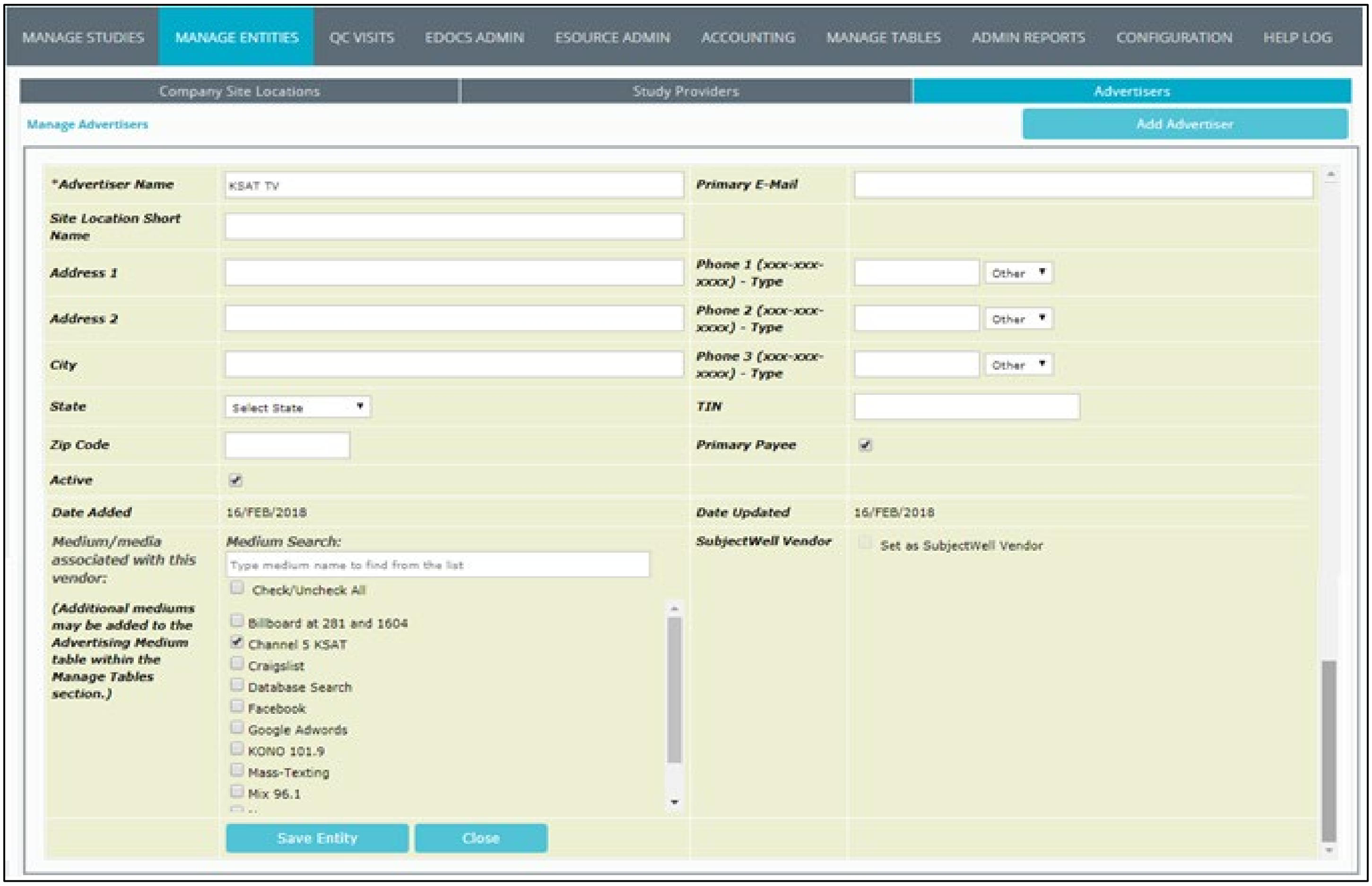
MANAGING ADVERTISERS

Entered advertisers will appear on the screen identified by their name, location, whether they are the "primary payee," and their status 'Active' or 'Inactive'.



ADDING ADVERTISERS

To add a new advertiser, click the ‘Add Advertiser’ button. An entry box will appear on the screen.



Populate the information as necessary. The ‘Active’ checkbox will determine whether an advertiser is active or inactive. If you are currently conducting business with or will conduct business with the advertiser in the future be sure the ‘Active’ checkbox is checked. Once created, the advertiser cannot be deleted from RealTime-CTMS due to the corresponding data that advertiser is associated with in the system.

When utilizing contracted entities there is always a ‘Primary Payee,’ which is determined by how you are to pay for the contracted services. If you are paying the company for the contracted services, the ‘Primary Payee’ checkbox should be checked. If you are paying individual providers for their contracted services, the ‘Primary Payee’ checkbox in the contracted entity profile should be unchecked. When working with advertising companies the advertising company tends to always be the “primary payee,” however, the system does allow for a study contact to be the “primary payee”.

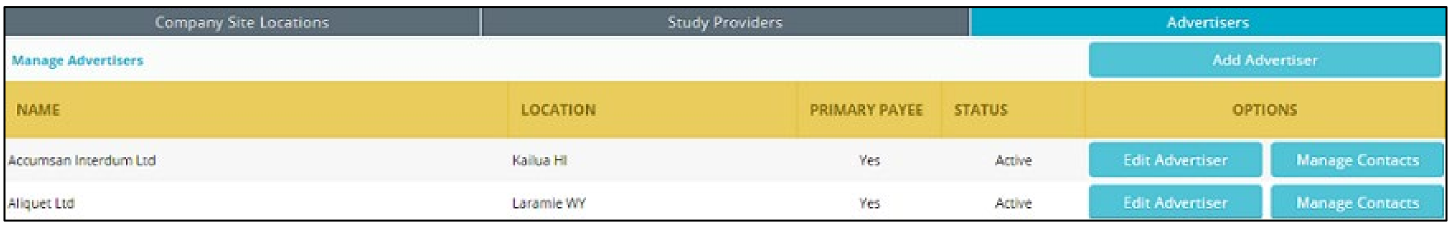
Once all of the required information (*) is populated, click ‘Save Entity’.

EDITING ADVERTISERS

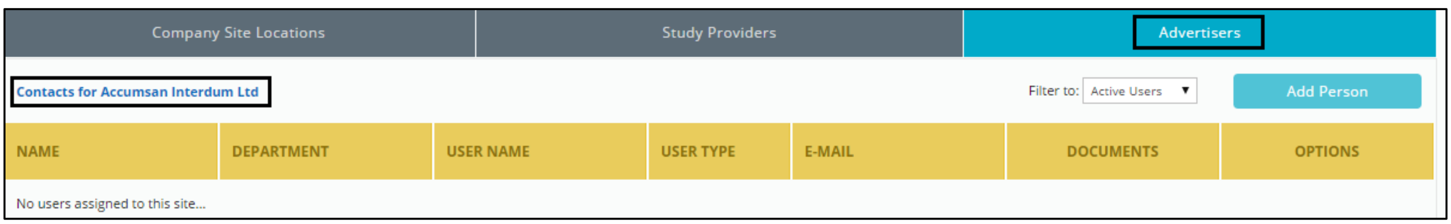
To edit or view any previously entered information for an advertiser that is listed on the Manage Advertisers page, click on the 'Edit Advertiser' button. If an update is required, make the desired change and click 'Update Entity' to save your changes. To close the window without making any changes, click the 'Close' button.

MANAGING PERSONNEL WITHIN ADVERTISERS

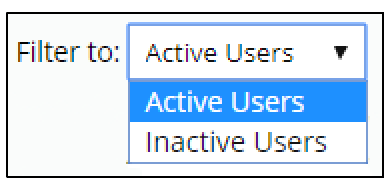
To add an advertiser contact, click the 'Manage Contacts' button located on the study provider management page.



You will be directed to the contact management page for that specific advertiser. To go back to the Manage Advertiser page click the 'Contacts for 'Advertiser' or the 'Advertisers' links.



Visible contacts can be filtered by 'Active Users' and 'Inactive Users'. Once created, advertiser contact accounts cannot be deleted from RealTime-CTMS due to system data associated with that contact.



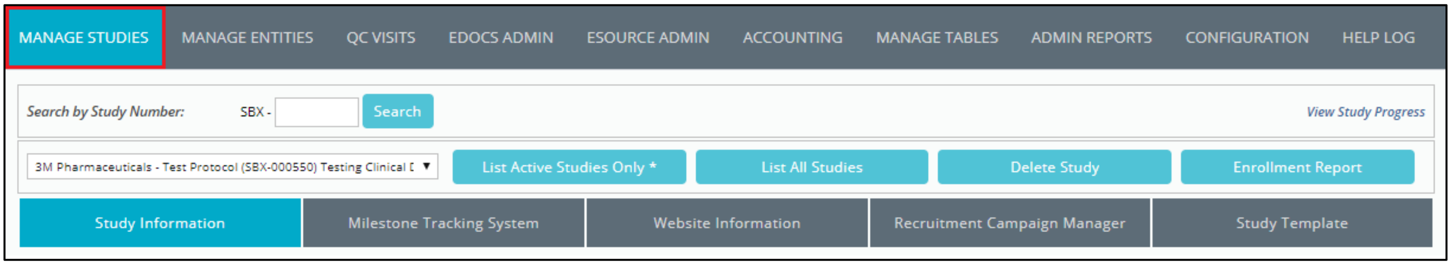
ADDING A CONTACT TO AN ADVERTISER

To add a contact to an advertiser, click the ‘Add Person’ button.   An entry box will appear on your screen.

If the contact’s information is the same as the parent entity a quick check of the ‘Contact Information Same as Parent Entity’ box will pull in the same mailing address and phone numbers as the parent site.   All required fields are indicated with an asterisk (*).

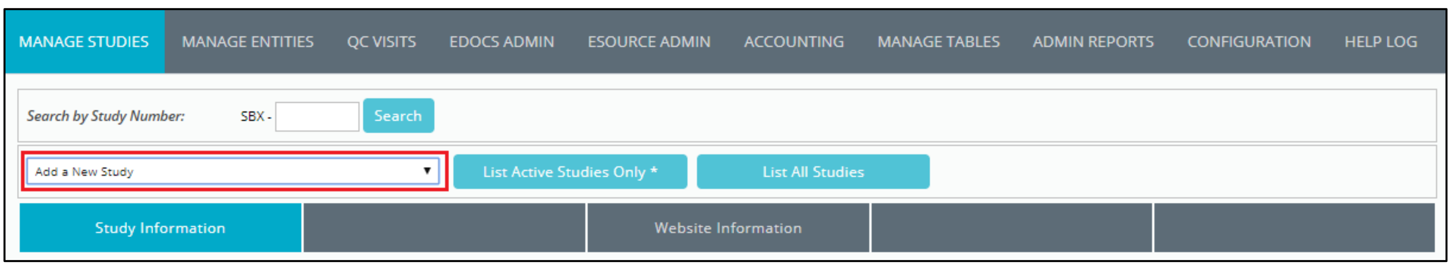
MANAGING A STUDY

To add, edit or delete a study access the Administration section, onto the Manage Studies tab. There are five sections appended to each study: Study Information, Milestone Tracking System, Website Information, Recruitment Campaign Manager, and Study Template.



ADDING A NEW STUDY

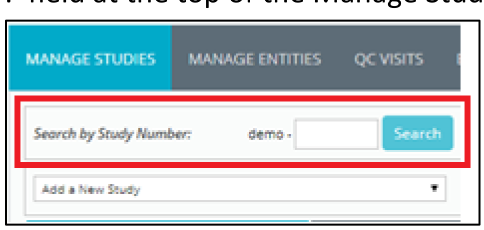
To add a new study, begin by selecting Add a New Study from the dropdown, then enter the general information onto the Study Information tab.



STUDY INFORMATION

The study information section allows administrators to enter general study information.

- **Site Number** – Enter the sponsor provided site number. This number will be generated on study reports, invoices and in the General Info tab for the selected study.
- **Study Number** – The is a system generated number that will allow a study to be identified without disclosing a particular sponsor, protocol or drug name. This generic number can be utilized on curricula vitae (CVs) and/or other public documents; for example, as shipping reference numbers to help associate pass through costs to a particular study. A study can be searched using this system generated number in the 'Search by Study Number:' field at the top of the Manage Studies tab screen.



- **Therapeutic Area** – The therapeutic area is a general description of the study field and is not limited to a particular indication. If you do not see the desired therapeutic area listed, please refer to the Manage Tables section of this manual. If your site is utilizing website integration capabilities, RealTime-CTMS will use the assigned therapeutic areas to categorize your studies on your website.

- **Indication** – Select the appropriate study indication for the study. If you do not see the desired indication listed, please refer to the Manage Tables section of this manual. It is important to enter the appropriate study indication in order to utilize the Study Indication Matching Report, which will assist in business development and filling out feasibility questionnaires.

- **Text Indication**- This field can be utilized for sites who sign up for the RealTime-TEXT feature. Please see the RealTime-TEXT manual for more information.

- **Sponsor** – If you do not find the study's sponsor listed on the dropdown menu, please refer to the Manage Tables section of this manual.

- **Status** – Select the appropriate study status. Special attention should be given to the 'Status' of the study. Below is a description of each study status.

  Enrolling – Web: The study is active and will appear on user study rosters and will be posted to the website (if applicable). If you have study listings integrated into your website, then setting the status to 'Active – Posted to Website' means that the study will be posted to your website.
  New subjects may add themselves through the website posting. Administrators should only switch to this status once all information in the Website Information section has been added.
  Enrolling: The study is active and will appear on user study rosters. New subjects may be added when logged into RealTime-CTMS.
  Enrollment Closed: The study is active. Subjects may not be added.
  Upcoming: This status will allow you to enter the study into the system, but will not allow you to enroll subjects. This status does not count toward you monthly license fees.
  Upcoming - Web: This status will allow you to enter the study into the system, will be posted to the website (if applicable), but will not allow you to enroll subjects. This status does not count toward you monthly license fees.
  New subjects may add themselves through the website posting. Administrators should only switch to this status once all information in the Website Information section has been added.
  Study Not Conducted: If negotiations fail between your site and the Sponsor/CRO, you can change the status to Study Not Conducted to keep the study information for historical tracking purposes.
  Inactive: Study is Inactive. The study will be removed from user's active study home page.

- **Protocol** – Indicate the study protocol number into the provided field.

- **Phase** – Select the study phase as described in the study protocol. If the desired phase is not available, please refer to the Manage Tables section of this manual.

- **Complete Protocol Title** – The entered the complete study title as read on the study protocol. Do not include unnecessary spacing to help alleviate any formatting issues on reports, web pages, etc.

- **Clinical Description** – Enter a brief description of the stud, typically the indication or study nickname. This information is visible on the home page of users assigned to the study.

SPONSOR	CLINICAL DESCRIPTION
Abbott	Acne - Mild to Mod
Abbott	Endometriosis
Abbott	Endometriosis

- **Principal Investigator** – Select the applicable PI for the study using the provided dropdown box. If the desired PI is not listed, the investigator will need to be added to RealTime-CTMS. Please refer to the Manage Entities and Users section of this manual. The principal investigator must be selected in order to save the page.

- **Sub Investigators** – Select all applicable Sub Investigators from the 'Available Site Investigators' list to the 'Assigned Sub Investigators' using the arrow keys. If the desired sub investigator is not listed, the investigator will need to be added to RealTime-CTMS. Please refer to the Manage Entities and Users section of this manual.

- **IRB** – Select the reviewing institutional review board (IRB) for the study. If you do not see the desired IRB listed, please refer to the Manage Tables section of this manual.

- **IRB Study Number** – Enter the IRB reference number provided for the study. The entered information will be made available to the study team on the study's General Information tab.

- **CRO** – If applicable, please select the appropriate CRO. If they study you are entering is not using a CRO to help manage the study, please leave the CRO dropdown box on 'No CRO Assigned'. If the desired CRO is not listed, please refer to the Manage Tables section of this manual.

- **Recruitment Goal** – Your site's recruitment goal for the study should be entered. The number provided will display on users' home page, helping to calculate goal percentages, and be made available on each study's General Information tab.

- **Recruitment Notes** – Use the provided field to include any recruitment notes that will help the study team. For example, any provided timelines, overall study recruitment goals, total number of sites, notes regarding approval of increase recruitment caps at your site, etc. Entered information will be made available to the study team on the study's General Information tab.

- **Expected Enrollment Rate (Per Month)** – The number enter should be the expected number to enroll into the study each month. Take into account if there is a high screen fail ratio. The number entered will help you project anticipated revenues using the Revenue Forecast report found in the Administration section, Admin Reports tab.

- **Sponsor Payment Withholding Percentage** – If applicable, enter the disclosed withholding percentage, which will be used to auto-calculate sponsor payments and invoice amounts during the study.

- **Sponsor Payment Overhead Percentage** – Indicate the overhead percentage approved by the sponsor. This percentage may be applied to the procedures within the study template.

- **PO Number** – If you are required to list a PO number to reference when submitting invoices enter that number here. This number will pull into invoices created in the Accounting tab.

- **Screen Fails** – Notes regarding screen fail limitations such as "maximum allowable" or "ratios" can be added to the Screen Fails comment box. Screen fail notes will be available for all system users in the General Info tab. Note: It is not recommended that you list any financial information in this field.

- **Authorized Users** – Select which RealTime-CTMS users will have access to the study by moving users from the 'Available Users by Site and Name' box to the 'Authorized Users by Site Name' box using the directional arrows.

- **Lead Coordinator** – Select the primary coordinator for the study.

- **Projected Study Dates** – Anticipated study dates may be inserted at the bottom of your screen. Fields can be left as 'UNK' if month or day is unknown. The date entered will be useful for timeline reporting in the reports section of RealTime-CTMS.
  Note: These are projected study dates as provided by the sponsor at the start of a study, more accurate dates should be captured in the Study Progress tab which is described in detail in the User Manual.

Once all study information is entered, click the 'Update This Study' button at the bottom of the page.

MILESTONES

Designed mainly for the automated adjustment of Screen Fail visits, the section also provides the ability to notify users of other study related milestones. Users are able to determine what Triggers and Actions are taken by a Milestone. For example, what visits are adjusted (revenue and/or costs) before a Screen Fail Max is reached, and what visits are adjusted (same or different revenues and/or costs) after the Screen Fail Max is reached.

OVERVIEW

The Milestones functionality provides the ability to create rules and actions based on triggers, thresholds, or cases. Some actions can notify users in a variety of ways or adjust costs and/or revenues for specified visits. Milestones are broken down into Types, Rules, Conditions (Triggers / Thresholds /Cases), and Actions. The Assessment/Cost Financials privilege is required to view or edit Milestones.

TYPES

Currently RealTime offers a variety of Milestones, typed or grouped as Screen Fail and Revenue Payment. The Screen Fail type of milestone has rules for **Max Number of Screen Fails** or **Screen Fail Ratio**. Revenue Payment currently has one rule for **Gross Earnings**.

RULES

When creating a Milestone, the selection of the rule determines what conditions, action(s), and options are displayed for selection while creating the Milestone. While each rule is different and has a different set of conditions and options, some share actions across all rules, and some share actions across similar rules. Possible Rules are:

- **Gross Earnings** – multiple triggers and actions can be created in a Milestone
- **Max Number of Screen Fails** – actions can be defined for subjects that DO NOT Exceed the Threshold, and a different set of actions can be defined for subjects that Do Exceed.
- **Screen Fail Ratio** – actions can be defined for subjects that are INSIDE the ratio Case, and a different set of actions can be defined for subjects that are OUTSIDE the ratio Case.

CONDITION (TRIGGER / THRESHOLD / CASE)

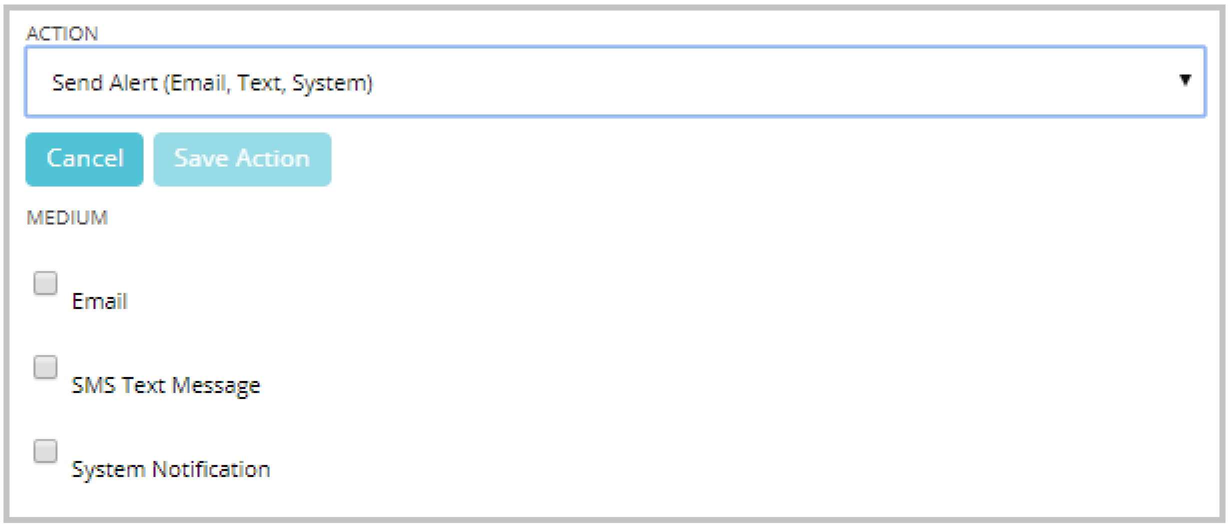
The Condition (Trigger, Threshold, or Case) is a value, that for a Milestone rule, determines when an action will occur, or determines when ongoing action(s) (if any) will stop and other action(s) will occur. Triggers are values that are reached once, Thresholds are values where different actions occur before and after the value is reached, and Cases are a set of values that can be achieved multiple times.

ACTIONS

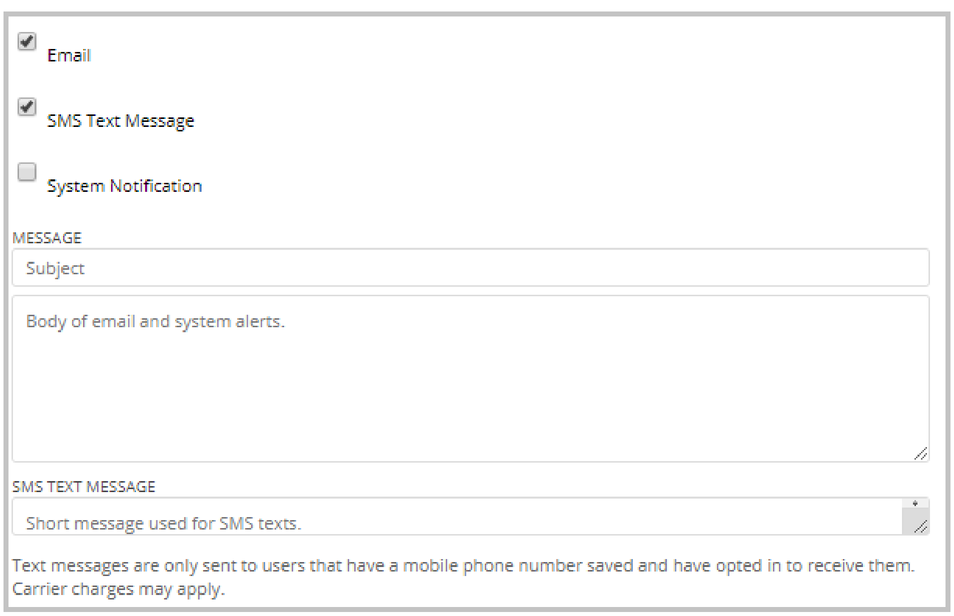
Depending on Types and Rules selected, and Condition entered, a set of possible actions can be added to a Milestone during creation or later during editing. Possible actions are:

- Send Alert (Email, Text, System)
- Reduced Fixed Visit Revenue
- Reduce Procedure Cost
- Reduce Procedure Revenue

Send Alert (Email, Text, System) is an action available for all Rules and can be initiated by a Trigger, Threshold, or Case. This action communicates via email, text (if TEXT is enabled for the site), or system notification. When this action is selected, check boxes for the different medium are displayed.

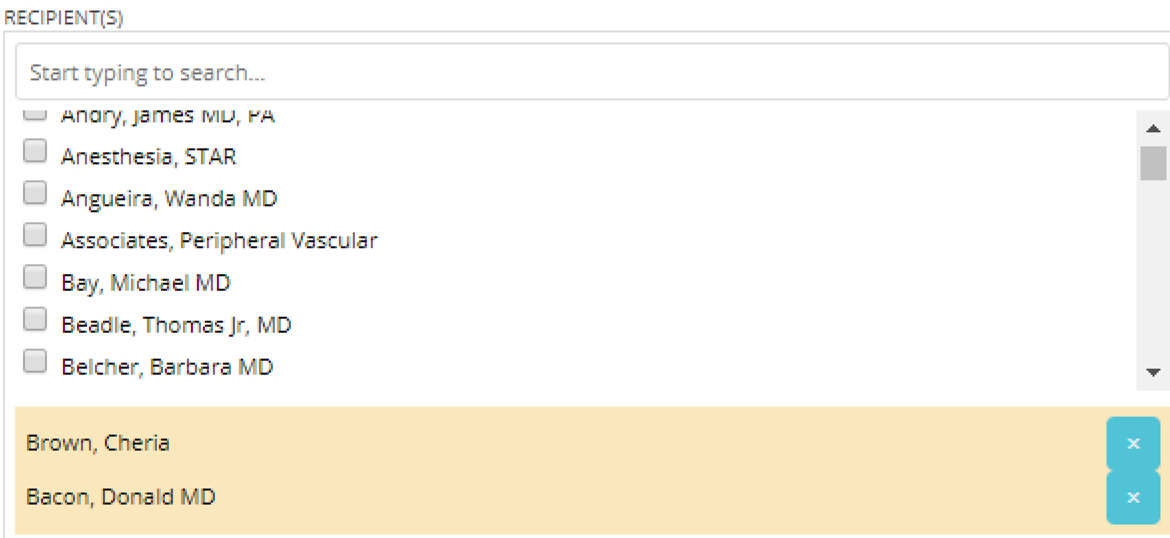


- When Email is selected fields for Subject and the Body (the message) are displayed.
- When SMS Text Message is selected a field for the message is displayed. Text messages are only sent to users that have a phone number typed as Mobile saved and have opted in to receive SMS texts.

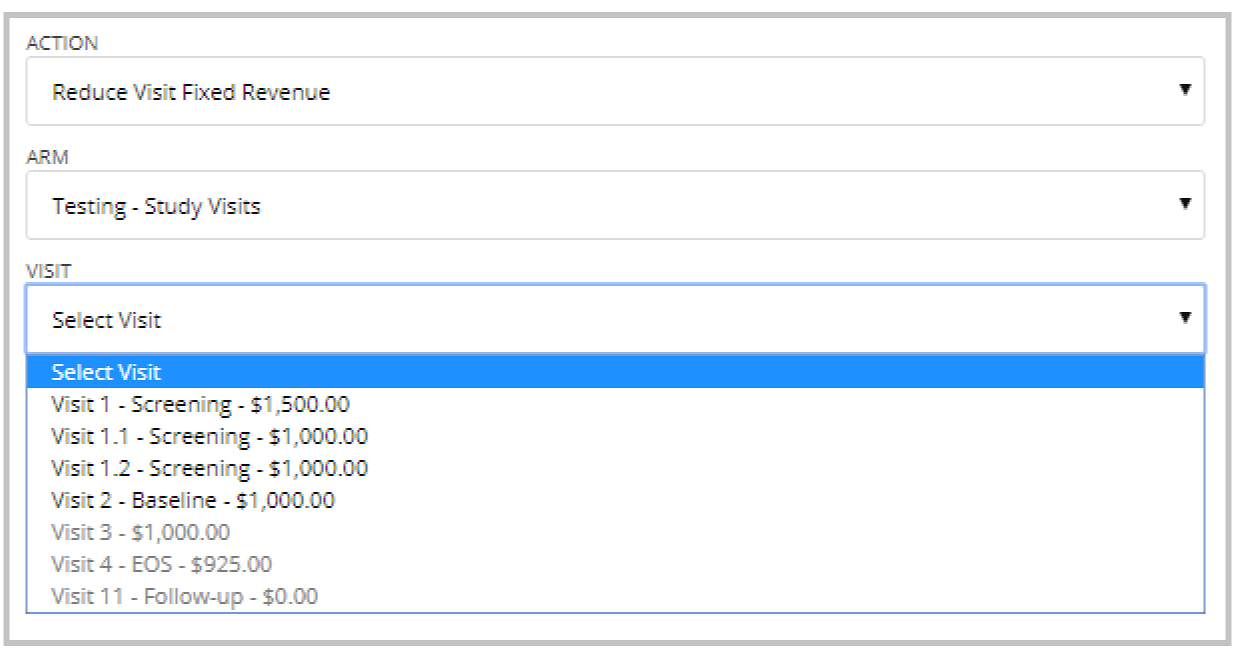


- When System Notification is selected the same fields for Email are displayed. Messages are displayed in the My Tasks>NOTIFICATIONS area.

A list of all users and providers in the system is presented to choose from for recipients. Each individual selected is listed at the bottom of the window and can be removed by selecting the “x” on the right by their name. A Search window is available to quickly find a user or provider.

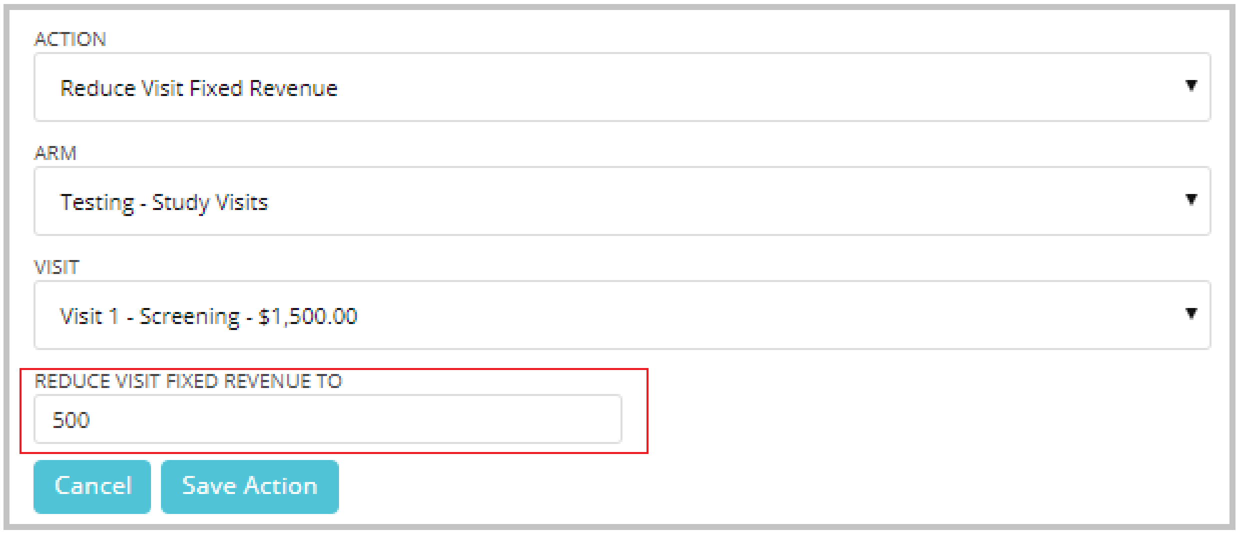


Reduced Fixed Visit Revenue is an action that will reduce the selected visits Fixed Revenue amount to a specific value, is available for all Screen Fail Rules, and can be initiated by a Threshold or Case. This action can occur before a Threshold (DO NOT Exceed) or after a Threshold (DO Exceed). This action can also occur when the Case is not met (INSIDE the ratio) or when the Case is met (OUTSIDE the ratio).



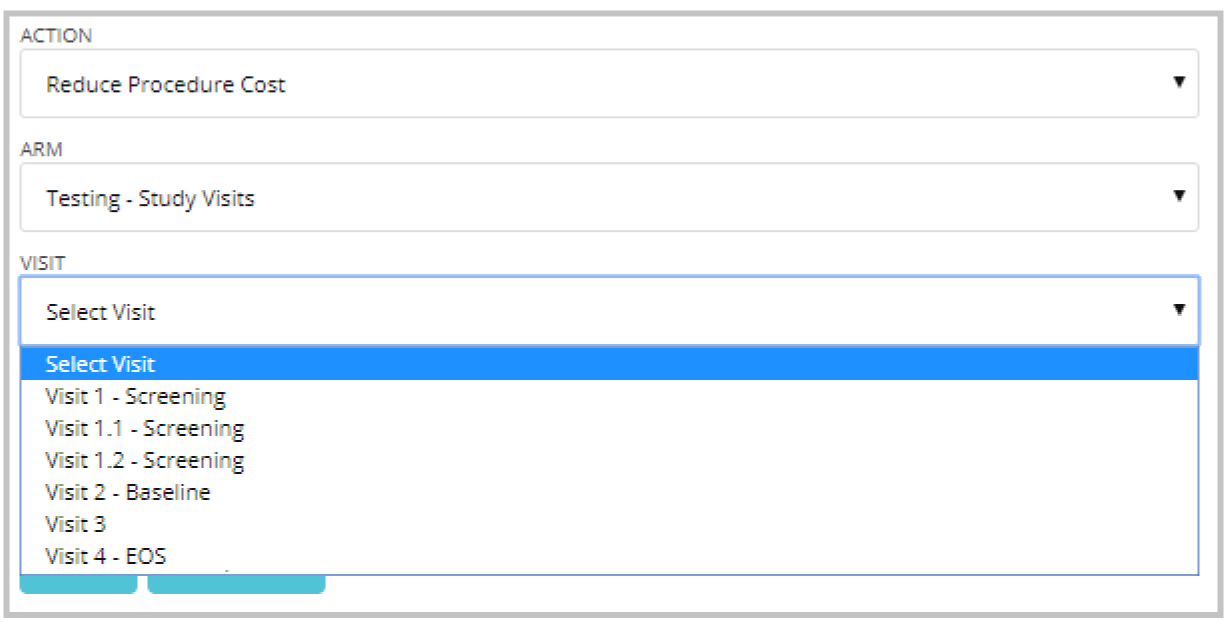
When selected, prompts for ARM selection and Visit selection are displayed. All visits in the selected ARM are listed. Visits that have a Fixed Amount Revenue Method are active, and visits that have a Line Item Total Revenue Method are greyed out and unavailable for selection.

A field labeled REDUCE VISIT FIXED REVENUE TO is also displayed. The value entered in this field is the amount the selected visit will be changed to when the Action for the Rule occurs.



Reduce Procedure Cost is an action that will reduce the selected procedure cost amount to a specific value, is available for all Screen Fail Rules, and can be initiated by a Threshold or Case. This action can occur before a Threshold (DO NOT Exceed) or after a Threshold (DO Exceed). This action can also occur when the Case is not met (INSIDE the ratio) or when the Case is met (OUTSIDE the ratio).

When selected prompts for ARM selection and Visit selection are displayed. All visits in the selected ARM are listed. Visits that have a Line Item Total Revenue Method as well as Fixed Amount Revenue Method are available for selection. The Fixed Amount Revenue Method visits are listed because they may have procedures that can be / need to be modified.



A field for Procedure selection is displayed, listing all the procedures in the selected visit and the Cost assigned to each procedure.

A field labeled REDUCE PROCEDURE COST TO is displayed. The value entered in this field is the amount the selected procedure will be changed to when the Action for the Rule occurs.

Reduce Procedure Revenue is an action that will reduce the selected procedure revenue to a specific value, is available for all Screen Fail Rules, and can be initiated by a Threshold or Case. This action can occur before a Threshold (DO NOT Exceed) or after a Threshold (DO Exceed). This action can also occur when the Case is not met (INSIDE the ratio) or when the Case is met (OUTSIDE the ratio).

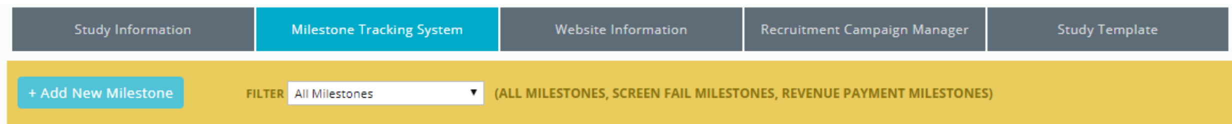
When selected, prompts for ARM selection and Visit selection are displayed. All visits in the selected ARM are listed. Visits that have a Line Item Total Revenue Method as well as Fixed Amount Revenue Method are available for selection. The Fixed Amount Revenue Method visits are listed because they may have procedures that can be / need to be modified.

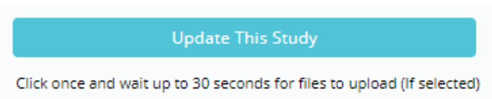
A field for Procedure selection is displayed, listing all the procedures in the selected visit and the Revenue assigned to each procedure.

A field labeled REDUCE PROCEDURE REVENUE TO is displayed. The value entered in this field is the amount the selected procedure will be changed to when the Action for the Rule occurs.

CREATING A NEW MILESTONE

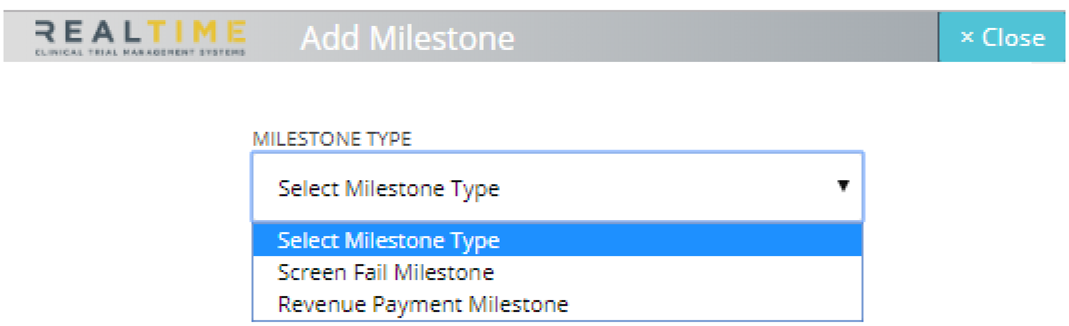
Under MANAGE STUDIES is an existing tab titled Milestone Tracking System. This section is blank until one or more Milestones are created.



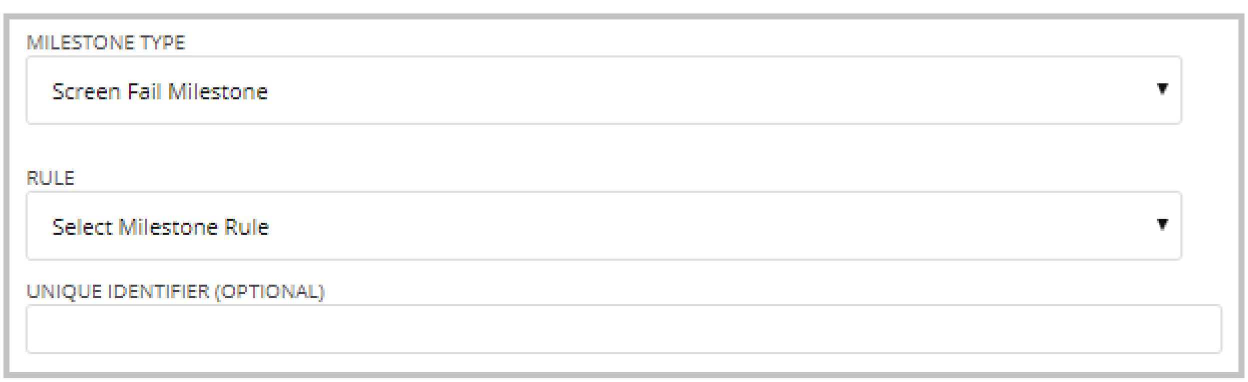


Selecting the Add New Milestone button displays a full page with only a Milestone Type selection box.

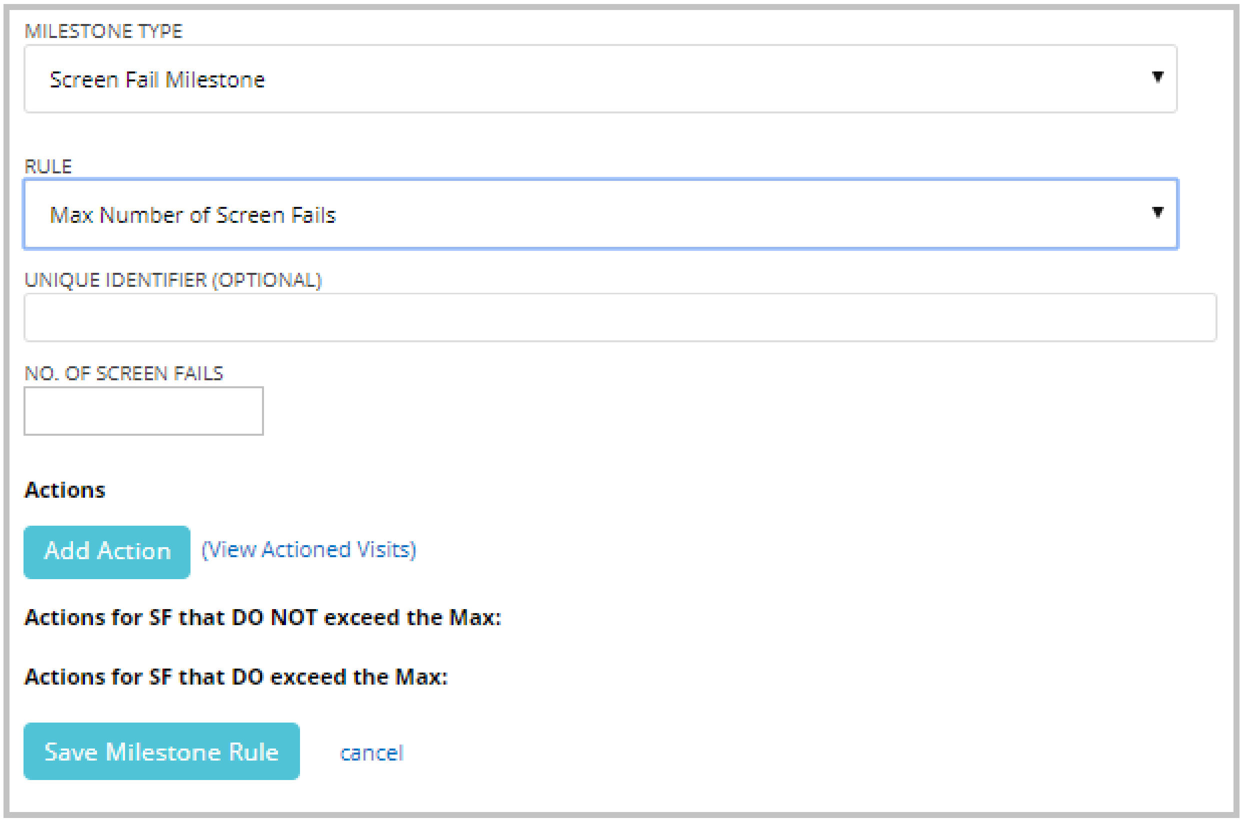
In the upper right corner is a “x Close" button that when selected will close the Add Milestone window.



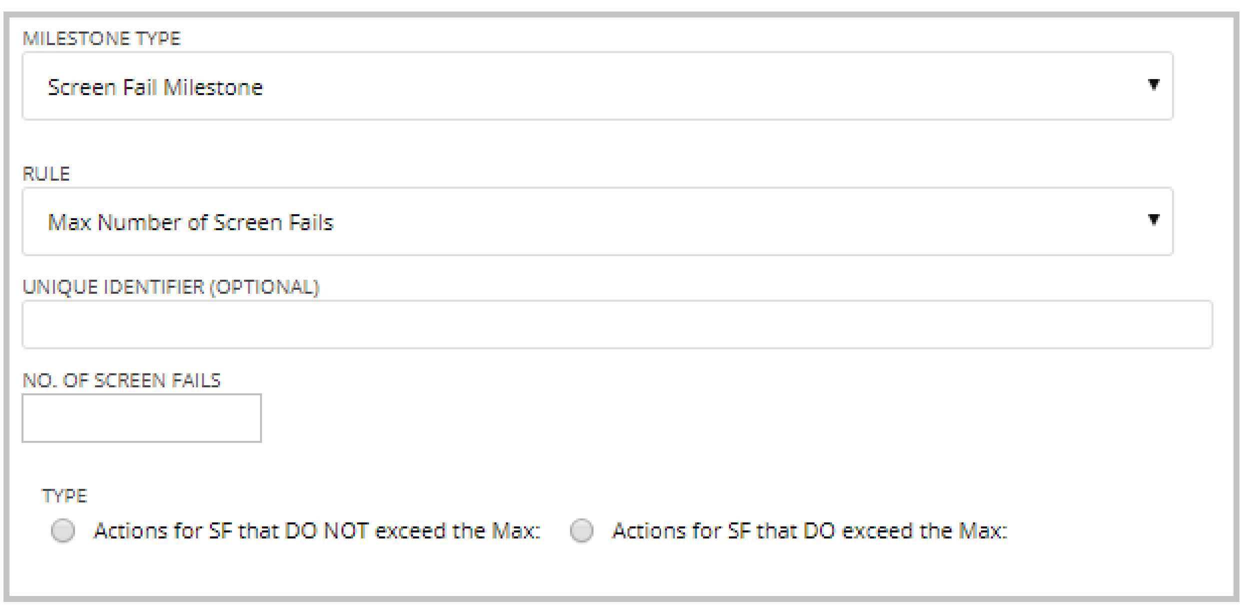
When a Milestone Type is selected, two fields are displayed. One is the Rule selection drop down field, that will have values listed based on the Milestone Type selected. The other field is an optional UNIQUE IDENTIFIER field. This field can be used to name or indicate the purpose of the milestone.



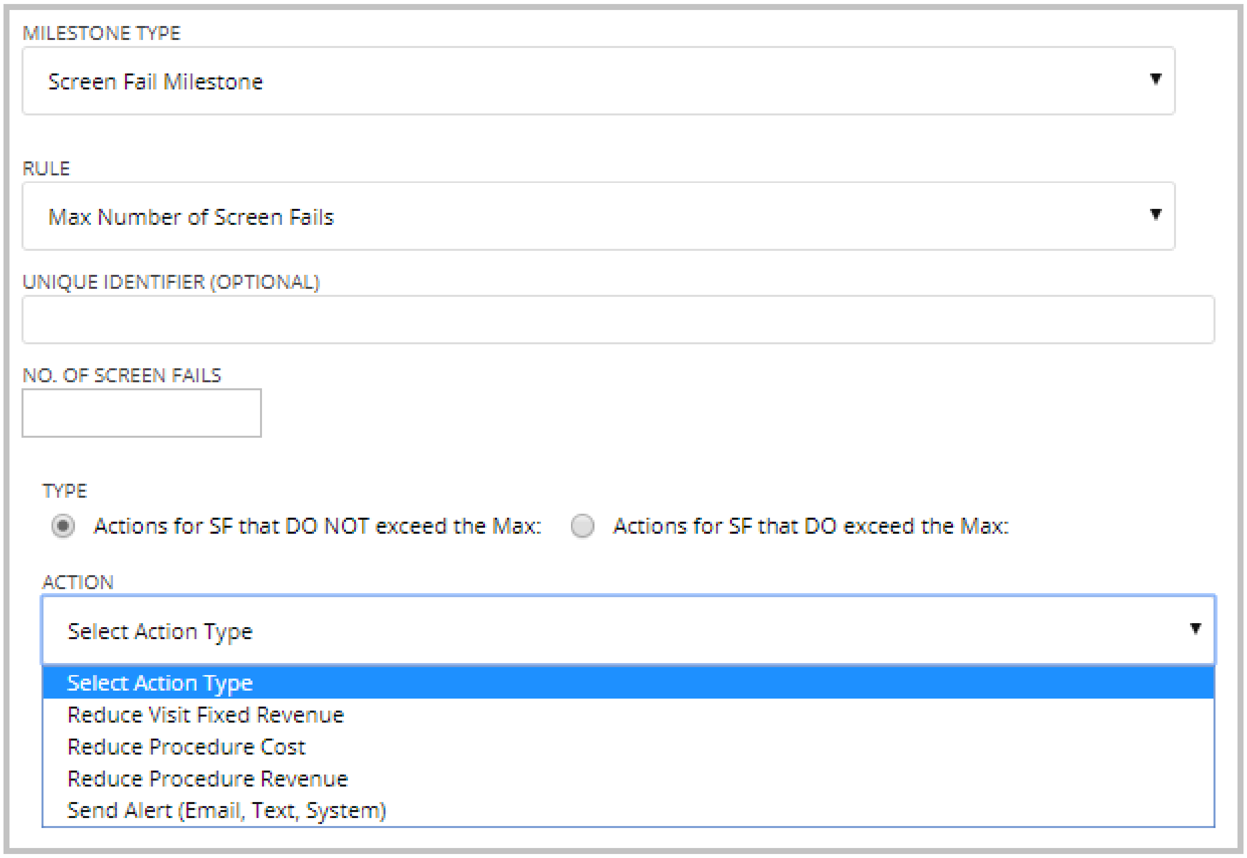
When the Rule is selected, a field or fields for the value of the Trigger, Threshold, or Case are displayed, depending on the Rule selected. Also displayed are the Add Action button, the Actions that have been created, the Save Milestone Rule button, and the cancel button. Also displayed is a link to (View Actioned Visits). The Actioned Visits Report is discussed here.



When the Add Action button is selected radio buttons for the type of Action are displayed, depending on the Rule.



When an action type radio button is selected, a drop down for Action selection is displayed.



Reduced Fixed Visit Revenue – displayed are selections for ARM, Visit, and amount of the reduced Visit Fixed Revenue.

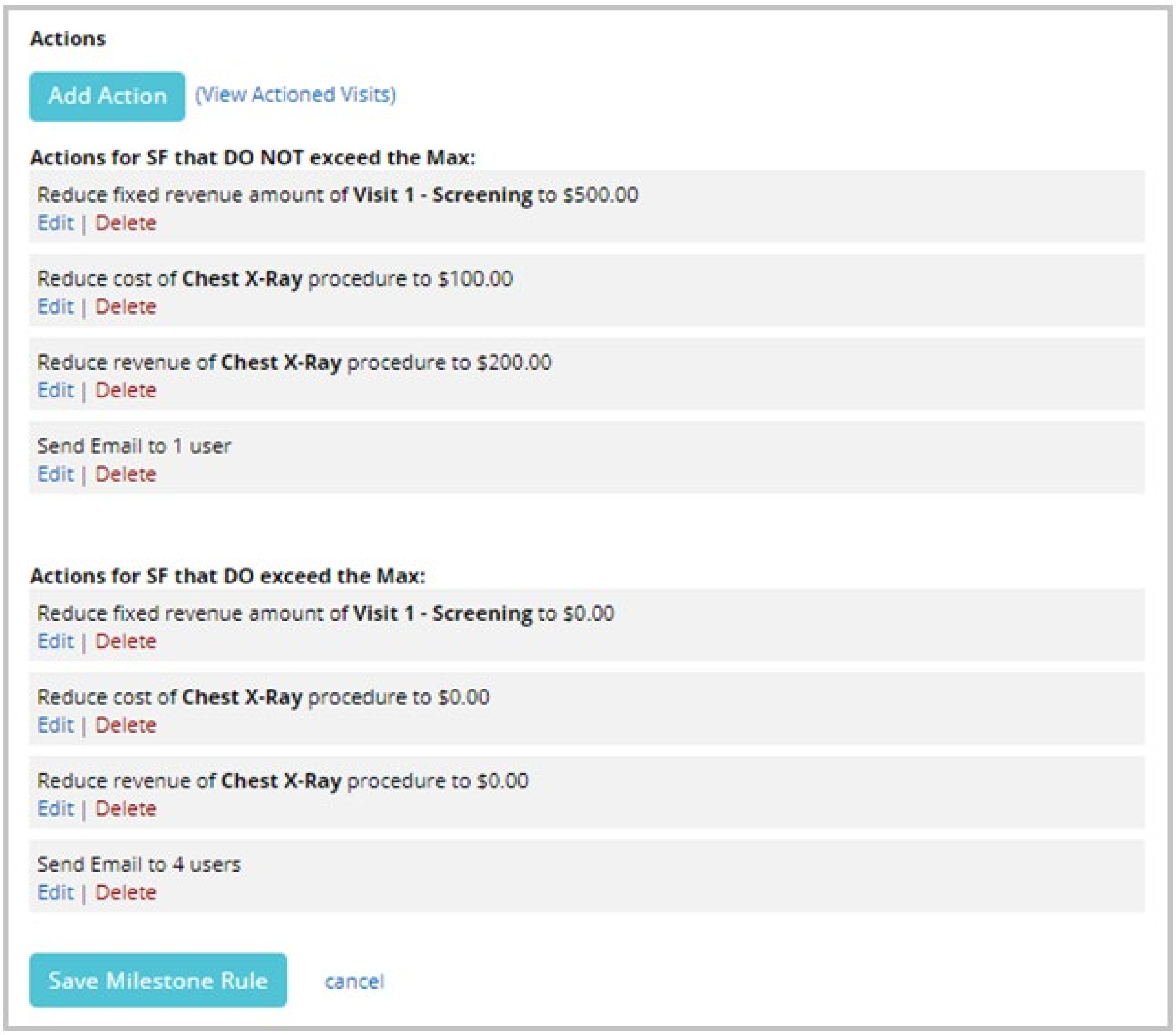
Reduce Procedure Cost – displayed are selections for ARM, Visit, procedure, and the amount of the reduced procedure cost.

Reduce Procedure Revenue – displayed are selections for ARM, Visit, procedure, and the amount of the reduced procedure cost.

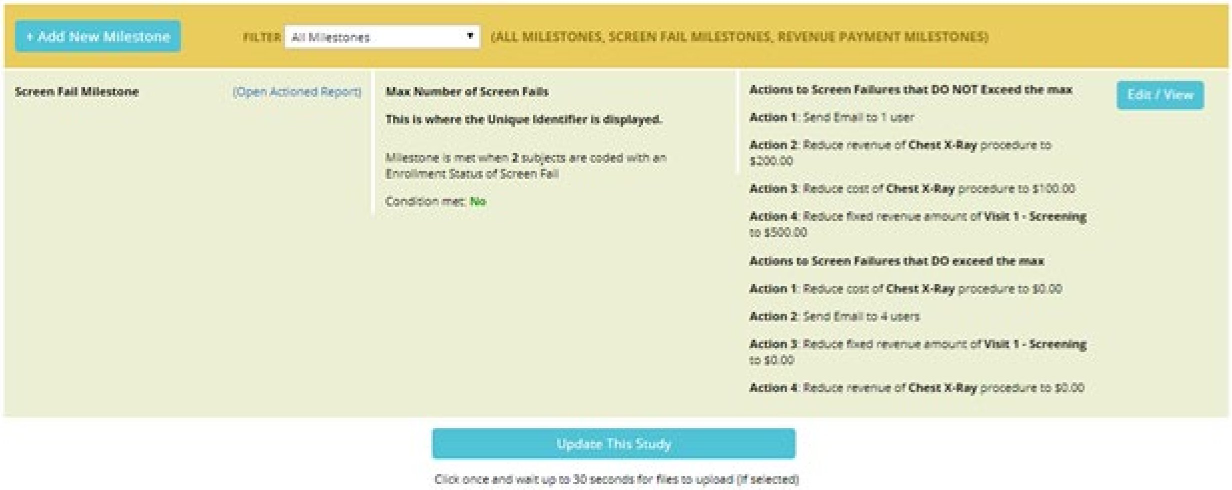
Send Alert (Email, Text, System) – displayed are selections for medium, recipients, and message (depending on medium selected)

When an Action is configured and saved, the action is listed under the Action Type where the action was configured. A description of the Action, with specifics, is displayed. Links to Edit or Delete the Action are displayed under the Action.

Multiple actions can be added to the Milestone Rule. The Actions can be for the same visit or procedure but have different configurations or action parameters.



When the Milestone is saved, the Milestone details are displayed on the Milestone Tracking System tab.

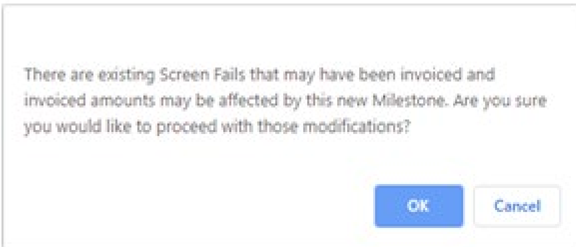


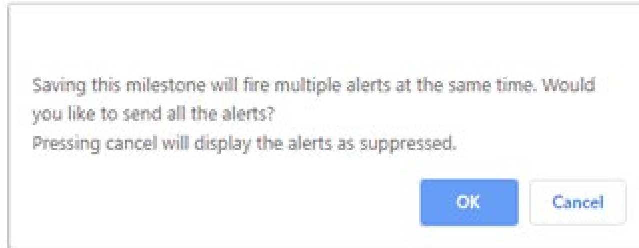
Multiple Milestones can be created, except for Screen Fail, which is limited to one Milestone per study. A single Screen Fail Milestone can have multiple Actions for different ARMs on the study.

When Milestones have been created, the Filter can be used to display a type of Milestone, Screen Fail or Revenue Payments.

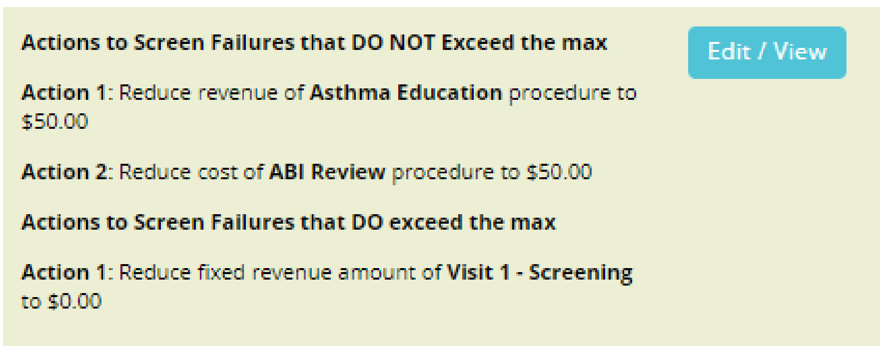
EDITING AN EXISTING MILESTONE

A Milestone can be edited at any time. Changes made to an Action or a Condition may cause changes to visits or repeat notifications to be sent. Warning messages regarding these changes will be displayed.

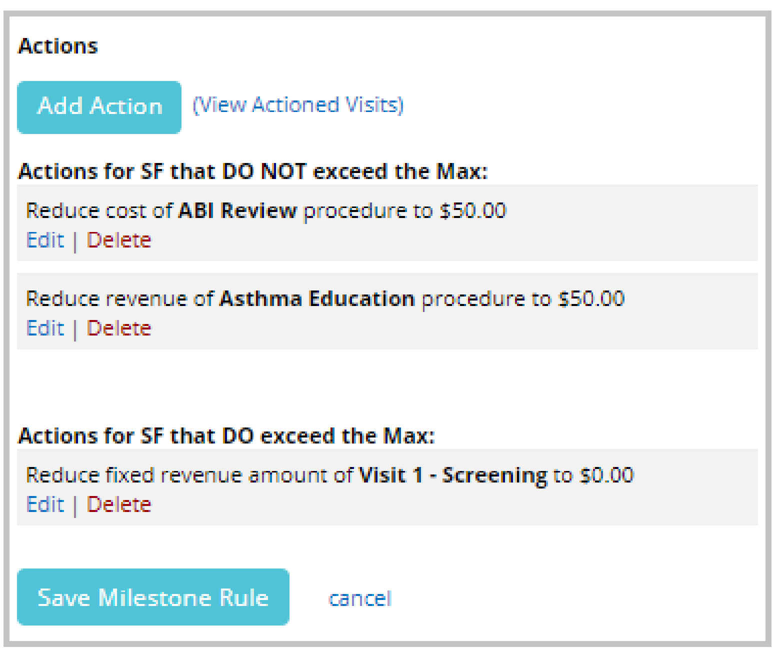




Selecting the Edit/View button for a Milestone displays all the fields and Actions for the Milestone.



Actions have a selection available to Edit or Delete for each Action.

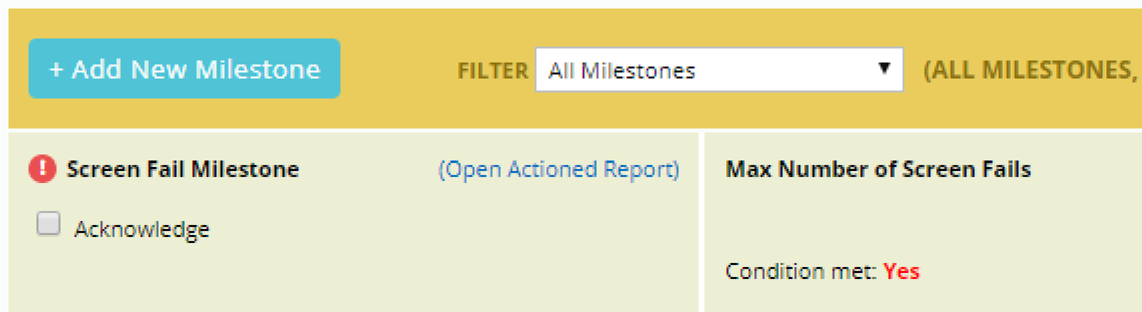


Edits to Actions must be saved, then the Milestone Rule must be saved.

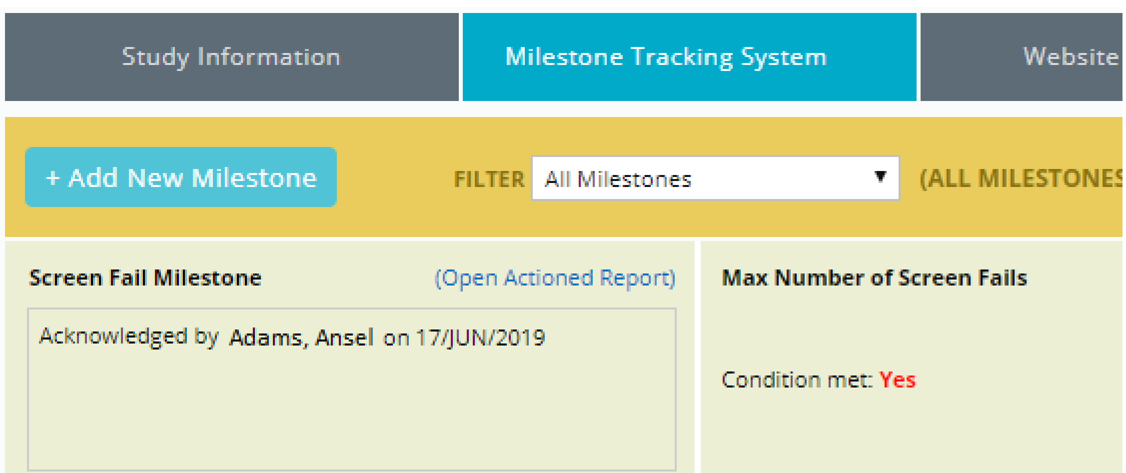
WHEN A CONDITION IS MET

When a Condition is met the defined Actions occur, and an alert icon is displayed on the Milestone Tracking System tab.

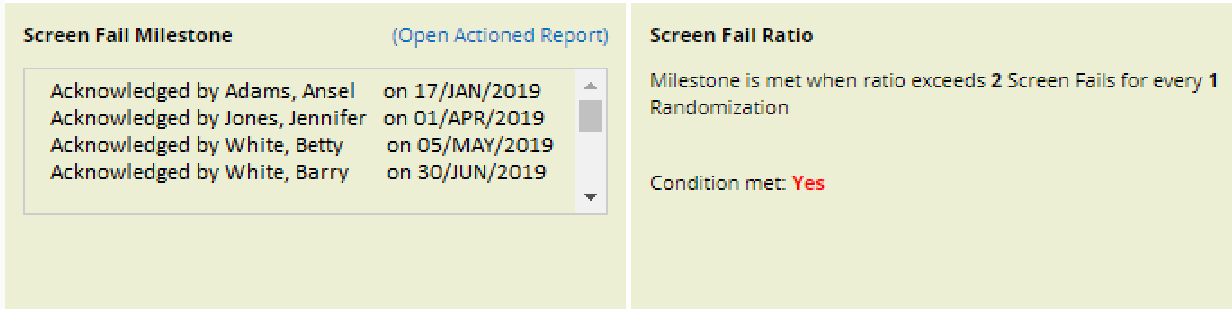
The same alert icon is displayed next to the specific Milestone, an Acknowledge checkbox is displayed, and the **Condition met:** status is displayed as Yes.



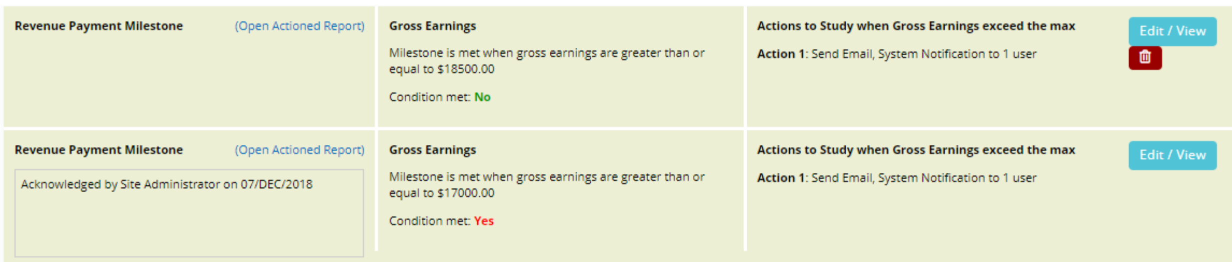
The Acknowledge checkbox provides the ability to recognize that the Condition has been met. When the Acknowledged checkbox is selected the alert icons are no longer displayed, and the date, time, and logged in user that selected the checkbox are recorded and displayed. The **Condition met:** is still displayed as Yes.



Milestones that are based on a Case, for example a ratio of 2 Screen Fail to 1 Randomized, may have the **Condition met:** change from No to Yes and back to No several times. The Acknowledge checkbox will be available for selection every time the Condition is Yes, and the alert icons will be displayed. Each time the Acknowledge checkbox is selected the date, time, and logged in user that selected the checkbox are recorded and displayed.



A Milestone can be deleted by selecting the trash icon. Milestones that have the **Condition met:** Yes are not available to be deleted and the icon is not displayed.

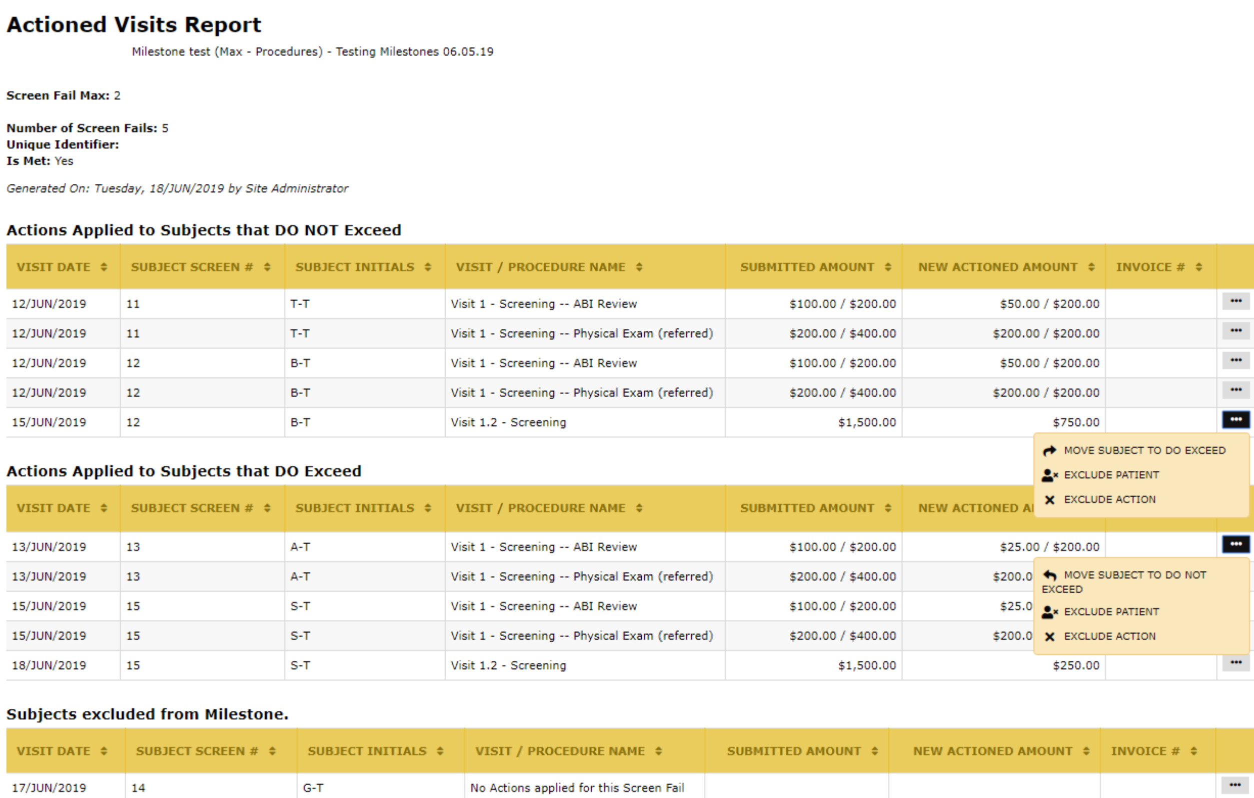


ACTIONED REPORT

The Actioned Report is a report that shows all the actions taken by the Milestone. Depending on the type of Milestone, the report may also provide management of the Actions, what set of Actions should be or should not be applied to a subject, or if there are exceptions to the Milestone. Selecting the (Open Actioned Report) or the (View Actioned Visits) link opens a new tab for the Actioned Report.

Specifics for the Milestone are provided in the upper left corner of the report.

Depending on the type of Milestone the option to manage Actions will be made available via the ••• icon at the right end of each line item reported.


Actioned Visits Report

Milestone test (Max - Procedures) - Testing Milestones 06.05.19

Screen Fail Max: 2

Number of Screen Fails: 5
Unique Identifier:
Is Met: Yes

Generated On: Tuesday, 18/JUN/2019 by Site Administrator

Actions Applied to Subjects that DO NOT Exceed

VISIT DATE	SUBJECT SCREEN #	SUBJECT INITIALS	VISIT / PROCEDURE NAME	SUBMITTED AMOUNT	NEW ACTIONED AMOUNT	INVOICE #	
12/JUN/2019	11	T-T	Visit 1 - Screening -- ABI Review	$100.00 / $200.00	$50.00 / $200.00		•••
12/JUN/2019	11	T-T	Visit 1 - Screening -- Physical Exam (referred)	$200.00 / $400.00	$200.00 / $200.00		•••
12/JUN/2019	12	B-T	Visit 1 - Screening -- ABI Review	$100.00 / $200.00	$50.00 / $200.00		•••
12/JUN/2019	12	B-T	Visit 1 - Screening -- Physical Exam (referred)	$200.00 / $400.00	$200.00 / $200.00		•••
15/JUN/2019	12	B-T	Visit 1.2 - Screening	$1,500.00	$750.00		•••

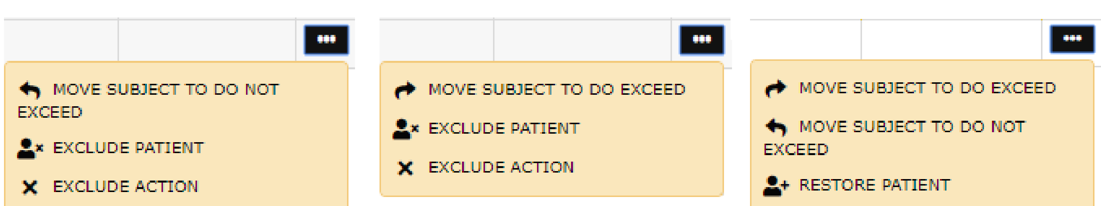
Actions Applied to Subjects that DO Exceed

VISIT DATE	SUBJECT SCREEN #	SUBJECT INITIALS	VISIT / PROCEDURE NAME	SUBMITTED AMOUNT	NEW ACTIONED A		
13/JUN/2019	13	A-T	Visit 1 - Screening -- ABI Review	$100.00 / $200.00	$25.00 / $200.00		•••
13/JUN/2019	13	A-T	Visit 1 - Screening -- Physical Exam (referred)	$200.00 / $400.00	$200.0		
15/JUN/2019	15	S-T	Visit 1 - Screening -- ABI Review	$100.00 / $200.00	$25.0		
15/JUN/2019	15	S-T	Visit 1 - Screening -- Physical Exam (referred)	$200.00 / $400.00	$200.0		
18/JUN/2019	15	S-T	Visit 1.2 - Screening	$1,500.00	$250.00		•••

Subjects excluded from Milestone.

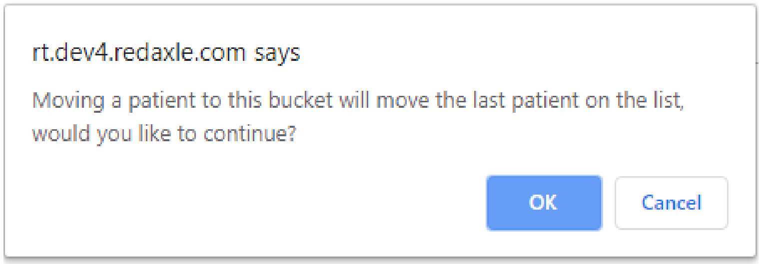
VISIT DATE	SUBJECT SCREEN #	SUBJECT INITIALS	VISIT / PROCEDURE NAME	SUBMITTED AMOUNT	NEW ACTIONED AMOUNT	INVOICE #	
17/JUN/2019	14	G-T	No Actions applied for this Screen Fail				•••

If a Milestone is based on a subject (i.e. the subject status), the report provides the ability to move the subject into or out of Action groups. Specific Actions can be moved to the Excluded group and as a result will not be applied. Excluded subjects or actions can be Restored or moved to Action groups.



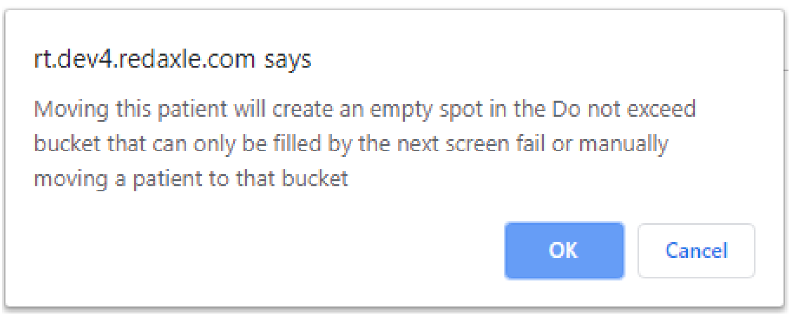
The subjects are listed and considered based on the most recent visit date first. Even though the DO NOT Exceed group may be fully populated, a subject that Screen Fails and has a first visit date older than an existing subject in the group will be placed in the group and the subject with the most recent first visit date will be moved to the DO Exceed group.

If a subject is manually selected to be moved to the DO NOT Exceed group, the last patient on the list in the group will be moved out of the group to make room.



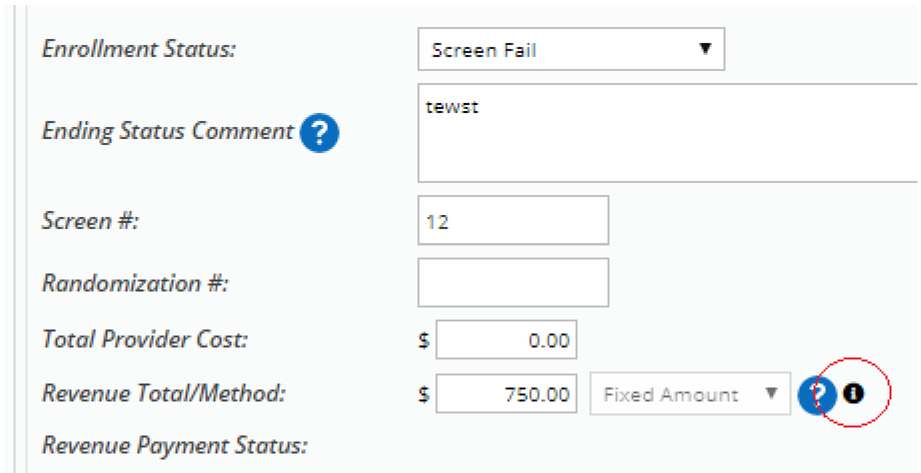
Attempting to move a subject into the DO NOT Exceed group with a first visit date more recent than the other subjects in the group will result in nothing happening.

Moving a subject out of the DO NOT Exceed group will create an empty spot that can only be filled by the next screen fail or manually moving a patient to the group.



VISITS THAT ARE ACTIONED

When a Milestone has an Action that changes a Cost or Revenue amount on a visit, the fields that are changed cannot be changed at the visit level and have an iDOT next to them.



If the Action is reversed for any reason, the original amounts are restored and the iDOTs are removed.

If the Action is changed to a different Action, the amounts are changed based on the new applicable Action, impacted fields are locked and iDOTs displayed.

Visits or Procedures that are invoiced can be changed by a Milestone. The change(s) to the amount(s) will be reflected on the invoice.

Procedure Revenue or Visits Totals that are changed by Milestones are not changed by Overhead selections. The amount determined by the Milestone is the amount earned or reported for the Procedure or Visit.

VISITS THAT ARE NOT ACTIONED

If a visit has a full or partial payment(s) applied to the visit or an associated invoice, or a payment has been made to a visit cost, the visit will be considered locked and will not be changed by a Milestone Action.

Visits that are considered locked due to payment(s) will be reported on the Actioned Report as

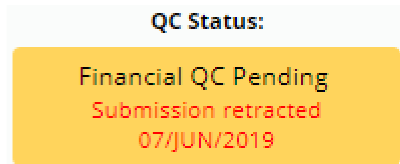
“No Actions applied for this Screen Fail”

FINANCIAL QC SUBMISSION RETRACTION

Visits that have been financially reviewed and then the Financial QC Submitted can have financial values (costs and/or revenues) for the visit changed by Milestone Actions.

When a Milestone Action changes a financial value on a visit that has the Financial QC Submitted, the submission will be automatically retracted. When the Financial QC Submission is retracted in this manner:

- At the visit level, the Financial QC button will indicate the submission was retracted and when



- The visit will be listed on the QC VISITS tab under the Financial Assessment QC tab. Retracted visits will have a red icon and only be listed on the Financial Assessment QC tab.
- An email will be sent to the individual that submitted the Financial QC, providing details about the sponsor, study, subject/screen#, visit name, what was changed, and changes From/To.

Visits that have had the Financial QC Submission retracted can be submitted again in the normal manner at the visit level but will be subject to retraction by any future Milestone Action.

Edits made to a Milestone may cause an Action to occur on a visit. If the visit has the Financial QC Submitted, the submission will be automatically retracted.

QC VISITS – FINANCIAL QC SUBMISSION RETRACTION

Visits that have the Financial QC Submission retracted due to a Milestone Action will be listed under QC VISITS>Financial Assessment QC. Retracted visits will have a red icon and only be listed on the Financial Assessment QC tab.

The Financial Assessment QC tab also has a checkbox to "Show only visits that have been Retracted". Selecting this checkbox and applying the Filter will results in a list of visits that have had the Financial QC Submission retracted due to a Milestone Action.

Visits that have had the Financial QC Submission retracted can be submitted again at the visit level or via the Batch QC function but will be subject to retraction by any future Milestone Action.

VISIT TRACKING – FINANCIAL QC SUBMISSION RETRACTION

Visits that have the Financial QC Submission retracted due to a Milestone Action are indicated as such on VISIT TRACKING by the Visit Completion Date being displayed as red. 01/JUL/2019

CREATING MILESTONES FOR A NEW VS AN EXISTING STUDY

There should be no issue for new studies. The Milestone related activity is all new, a clean slate.

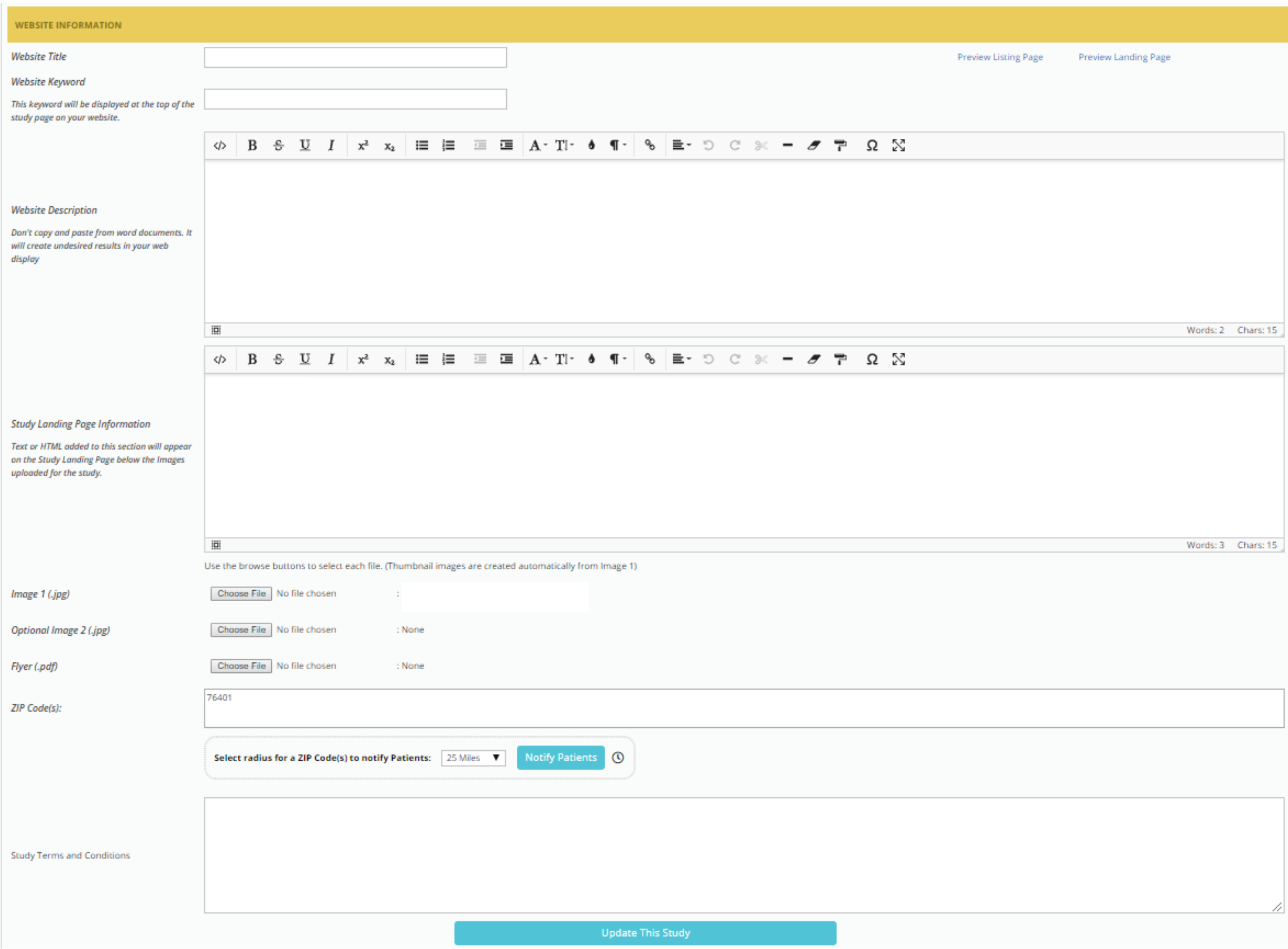
Existing studies could have several actions performed by a new milestone, notifications sent and/or visit amounts changed. Even if the visit amounts have been manually changed, the Milestone may “change” the amount and report the change. Visits that are reverted, or have the Milestone action removed, will return to the original value (the manually changed value).

KEY FACTS ABOUT MILESTONES

- Can be created to produce desired automated actions
- Only one Screen Fail Milestone per study
- Multiple Revenue Payment Milestones per study
- Milestone Rules available for Screen Fail Max, Screen Fail Ratio, Gross Earnings notification
- Can change visit revenue for multiple visits on different ARMs
- Can change multiple procedure cost and/or revenue on different ARMs
- Can manage (move) subjects, visits or procedures to different Action groups
- Visits Financial QC Submitted can have the submission retracted
- Milestones created for existing studies or changes to a Milestone may cause Action(s) for all Conditions
- Changes to invoiced visits will be reflected on the invoice(s)
- Visits that have payments made to visits/procedures or costs are not changed by Milestones

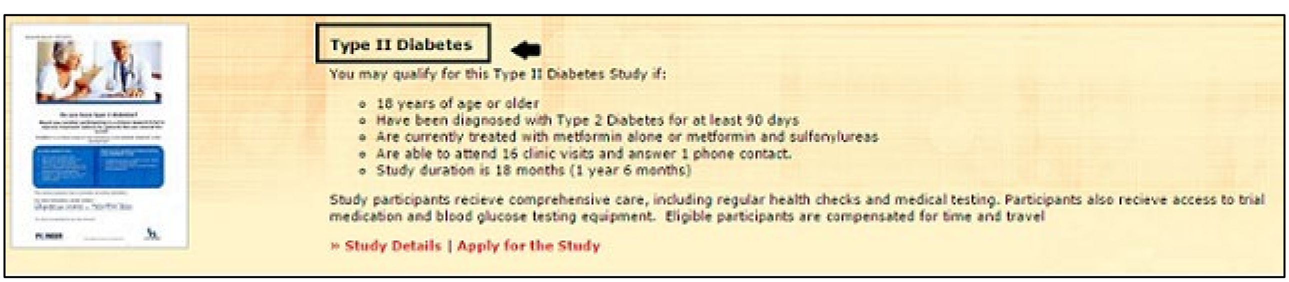
WEBSITE INFORMATION (IF APPLICABLE)

If you have RealTime-CTMS integrated with your website for study postings, the section for Website Information will be available.   If not, it will display 'Section Not Used'.



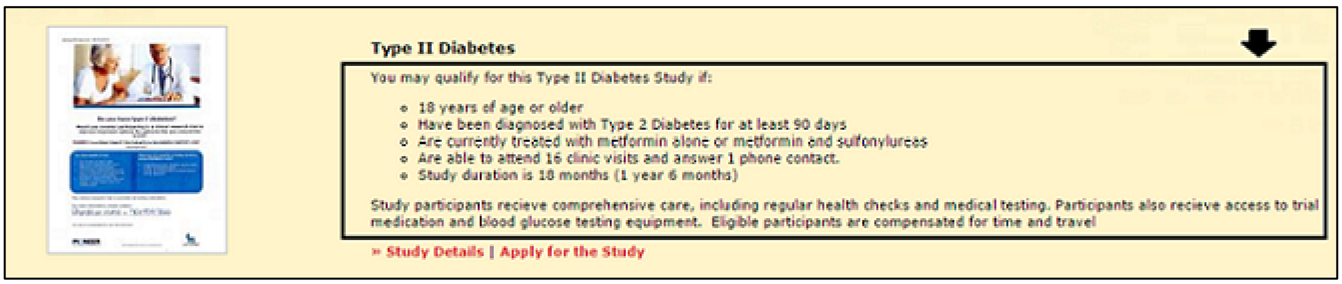
Below is a detailed explanation of each field and its related function(s):

- **Website Title** – The text that is entered into this field will display as the header for the study's web listing.



- **Website Keyword** – The entered keyword will appear as a link on the top of the iFrame and help potential patients quickly navigate to the study's web listing.

- **Website Description** – Entered text will appear on your studies' page and provide potential subjects with a narrative introduction to the study or basic entry criteria. Note: Do not copy and paste from word documents. It will create undesired results in your web display. The Preview Listing Page link can be selected to preview the information entered. Note: The web address or URL for the Studies Listing Page must be entered on the WEB INTEGRATION section of the CONFIGURATION page.



- **Study Landing Page Information** – Use this section to insert a relevant news story or medical report related to the study indication. This will improve your listing in search engine results. The entered information will appear next to the study flyer and be an added source of information to potential subjects regarding the study indication. The Preview Listing Page link can be selected to preview the information entered. Note: Don't forget to credit your source.
- **Images** - Two images may be uploaded for the posting as well as a .pdf file. Typically, a study flyer in .jpeg format should be loaded for 'Image 1 (.jpeg)' and an Adobe Acrobat .pdf version of the flyer for 'Flyer (.pdf)'. 'Optional Image 2 (.jpeg)' may be used in cases where a second image is necessary. Use the browse buttons to select each file.

  Note: Thumbnail images are created automatically from Image 1.
- **ZIP Code(s)**: - For sites utilizing the web site integration there is an additional marketing function available, sending a onetime study informational email (a notification) to subjects based on provided ZIP Code(s). Enter the desired ZIP Code(s) and select the Update This Study button (at the bottom of the page). Multiple radius selections are available, up to 500 miles.
- **Study Terms and Conditions** – Terms and Conditions can be entered for each study in this field. If no text is preset in this field the default message will be displayed. "BY SUBMITTING THIS FORM YOU AGREE TO RECEIVE EMAIL AND TEXT NOTIFICATIONS ABOUT THIS AND OTHER ENROLLING STUDIES. YOU CAN UNSUBSCRIBE AT ANY TIME. TEXT MESSAGE DATA RATES MAY APPLY. REFER TO PRIVACY POLICY."

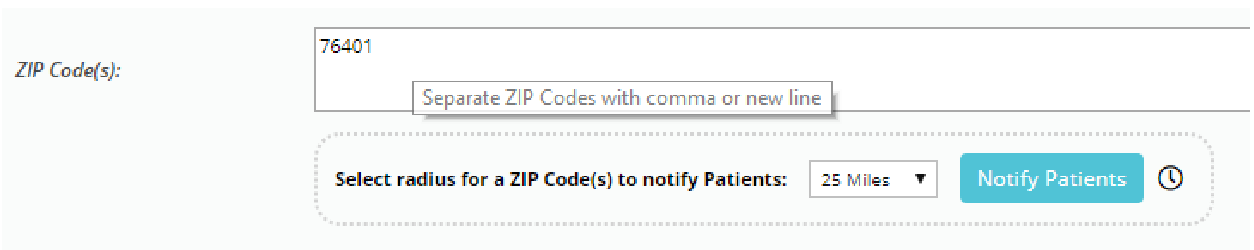
Once all study information is entered, click the 'Add This Study' button. In order for the study to display on your website, you will then need to navigate back to the General Information tab and switch the study status to Enrolling-Web. Be sure and check your website posting for content and to ensure that all images are displaying properly.

NOTIFY SUBJECTS WITHIN A RADIUS OF PROVIDED ZIP CODE(S) OF STUDY INFORMATION VIA EMAIL

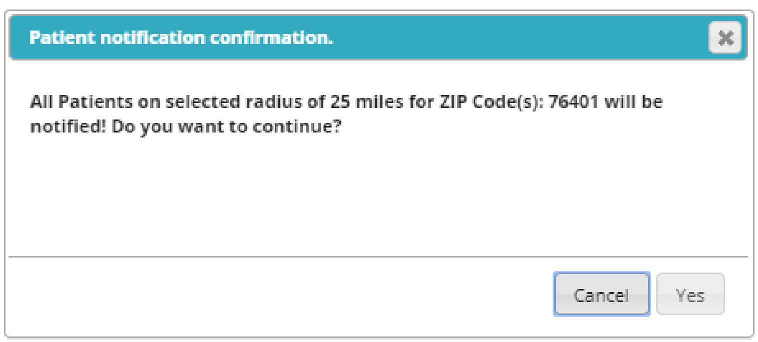
For sites utilizing the web site integration there is an additional marketing function available, sending a onetime study informational email (a notification) to subjects based on provided ZIP Code(s).

Under MANAGE STUDIES>Website Information is a section for ZIP Code(s). Multiple ZIP Codes are separated with a comma or a new line.

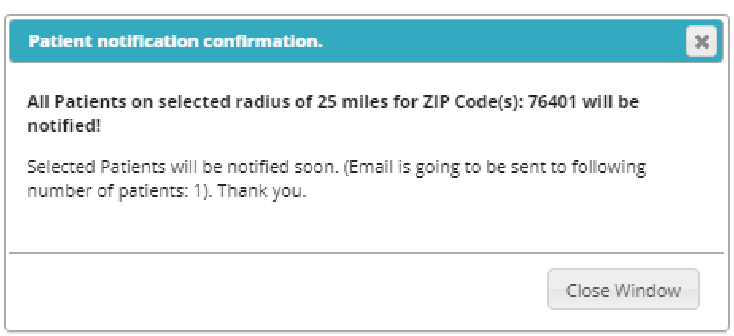
Enter the desired ZIP Code(s) and select the Update This Study button (at the bottom of the page). Multiple radius selections are available, up to 500 miles.



When the Notify Patients button is selected, a prompt will display the radius and ZIP Code(s) that will be notified. Cancel and Yes are the options.

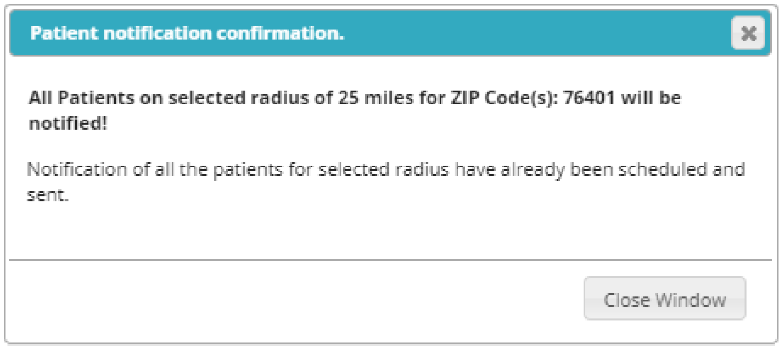


If Yes is selected an updated window is displayed, indicating the number of patients that will be sent the email.



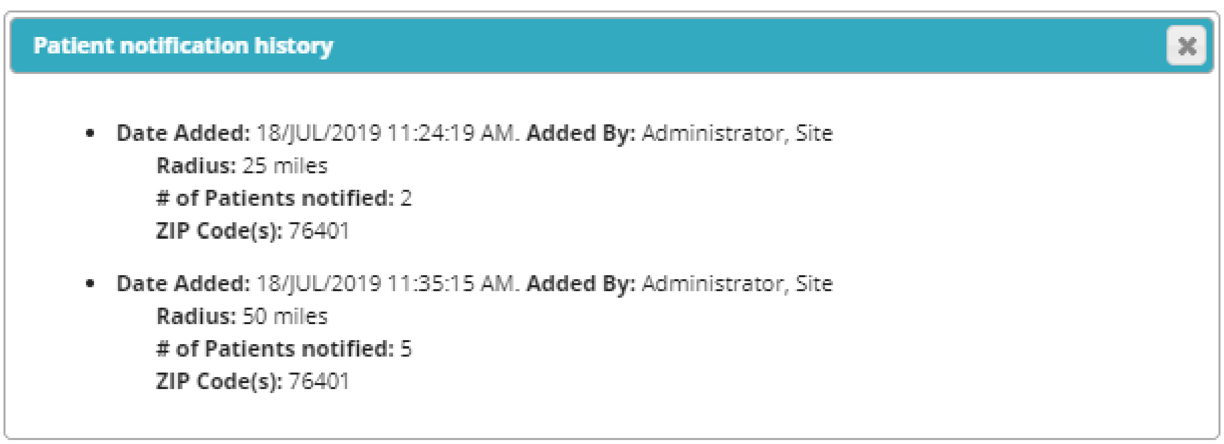
Notification History

A history is maintained of study notifications sent to subjects. If an attempt is made to send the same study informational email to subjects that have previously been sent the email, those subjects will not be included in repeat efforts. If all the subjects within the selected radius of a ZIP Code have been sent the study informational email the following message is displayed.



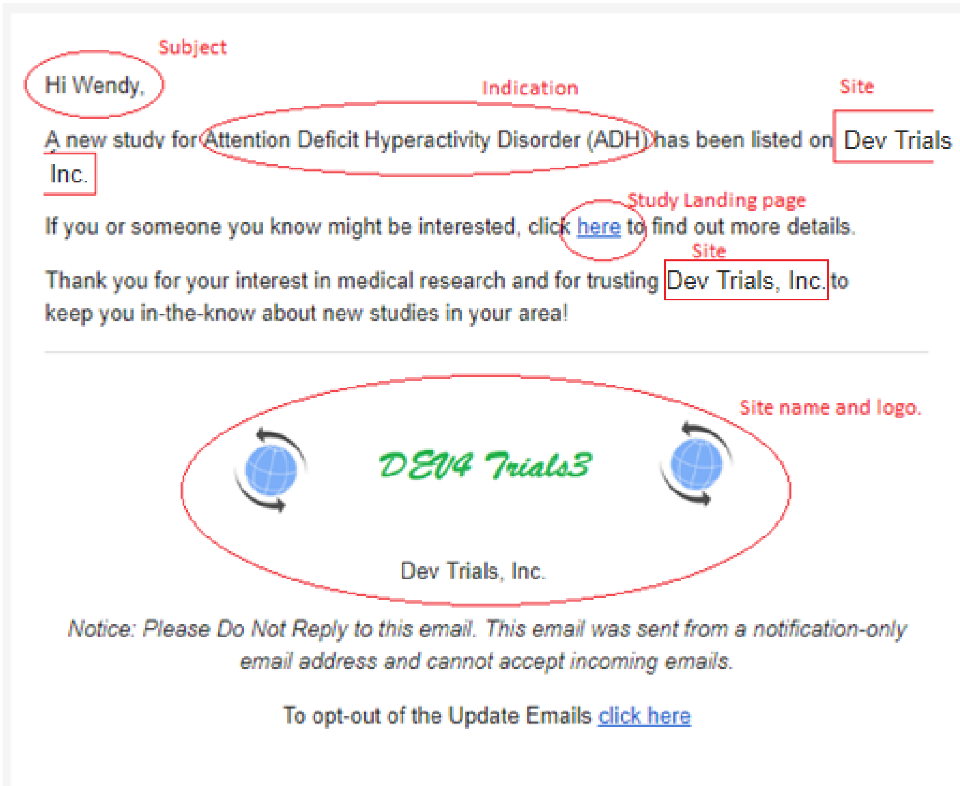
To view the history of notifications sent, select the icon next to the Notify Patients button.

A Patient notification history window will be displayed.



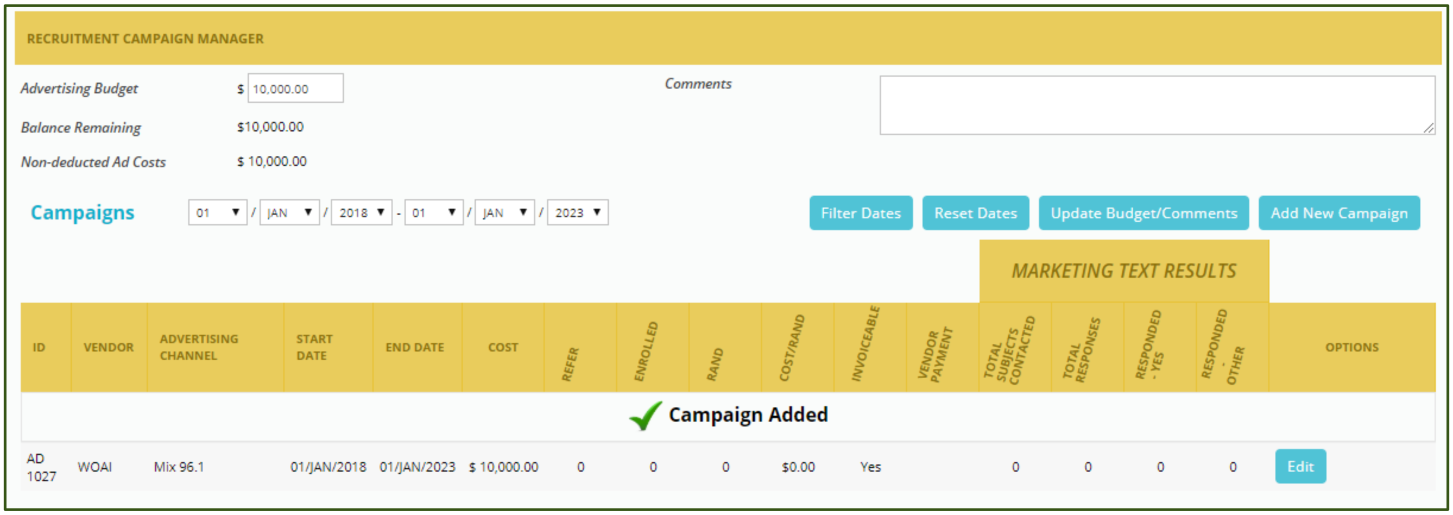
Email Message

The email is personalized to the recipient, announces that a new study for the Indication (selected on the Study Information page) has been listed on site's web site, offers a link for more details, and displays the site's Company Name and if available the site logo from the CONFIGURATION page.



RECRUITMENT CAMPAIGN MANAGER

Tracking advertising and recruitment methods for your study can provide valuable metrics to your site as well as to the sponsor. By using the Recruitment Campaign Manager section located in the study specific administration section, sites will be able to track the study advertising budget in RealTime.

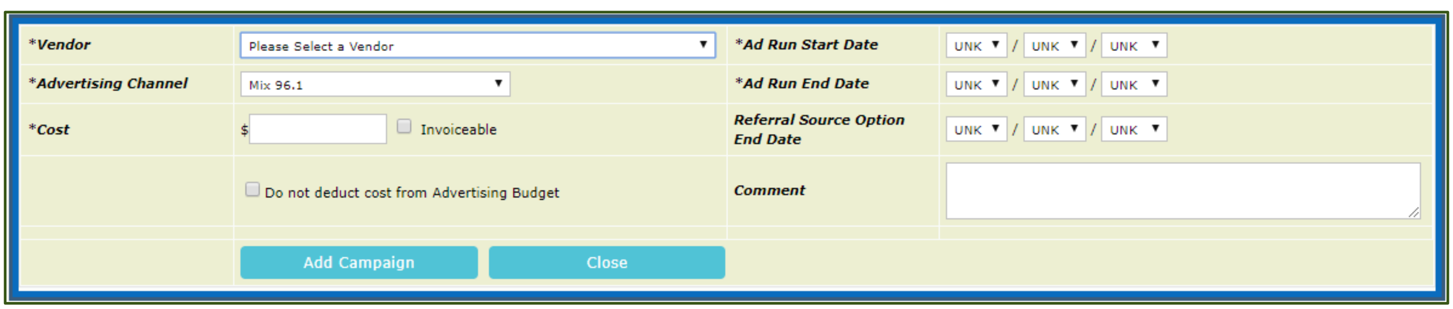


Simply enter the contracted advertising budget in the top cell as well as any notes in the 'Comments' section *(Example: Must get sponsor approval before utilizing advertising budget.)*

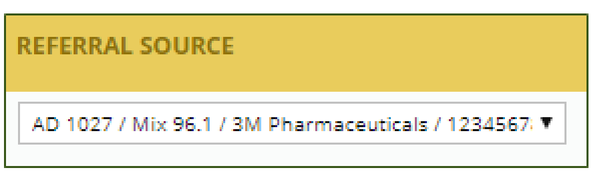
To add a new advertising campaign, hit the 'Add New Campaign'. An entry box will appear on your screen. All required fields are indicated with an asterisk (*).

Select the advertising vendor from the 'Vendor' dropdown menu. If the desired advertising vender is not available, please refer to the Advertisers section of this manual.

Enter the 'Advertising Channel,' 'Cost,' 'Ad Run Start Date', 'Ad Run End Date', and 'Referral Source Option End Date' for the campaign. By checking the 'Invoiceable' checkbox, this entry will be flagged by the system as a billable item to the sponsor. After all available information has been entered click the 'Add Campaign' button.



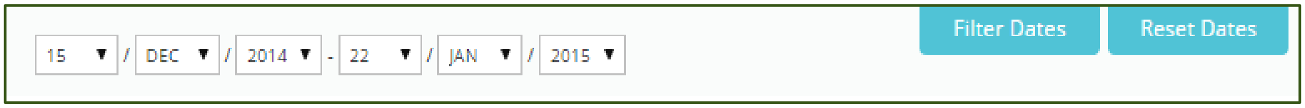
Once a campaign is entered into RealTime-CTMS, it will now appear as a 'Referral Source' option for new subjects.



The campaign will only be displayed as a 'Referral Source' during its specified start/end dates. As you assign subjects to this referral source, the total number of referrals, screened, and randomized subjects will be tracked within the Recruitment Campaign Manager section.

You can also use this section to track study specific recruitment methods that are free of cost. For example, if your site participated in a Diabetes Expo in order to attract leads for a specific diabetes research study, you could enter this Expo as a campaign with a cost of $0.00. This will allow you to assign the Diabetes Expo as a referral source for patients and track the effectiveness.

Visible information can be filtered by date range. By default, it will display all campaigns ever run for that particular study.

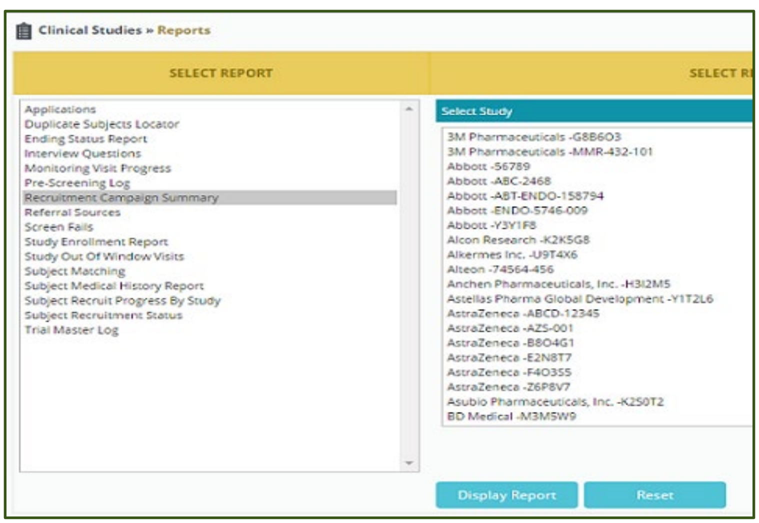


Each individual campaign is selectable and by clicking, an Excel spreadsheet will display all subjects that were referred by the campaign.

ID	VENDOR	STATION/MEDIUM	START DATE	END DATE	COST	REFER	ENROLLED	RAND	COST/RAND	INVOICEABLE
AD 887	Express News	Local Newspaper	12/JAN/2015	22/JAN/2015	$ 976.25	12	3	2	$488.13	Invoiced: #11798
AD 795	ClearChannel	Television	15/DEC/2014	05/JAN/2015	$ 3,500.00	38	7	4	$875.00	Invoiced: #11551

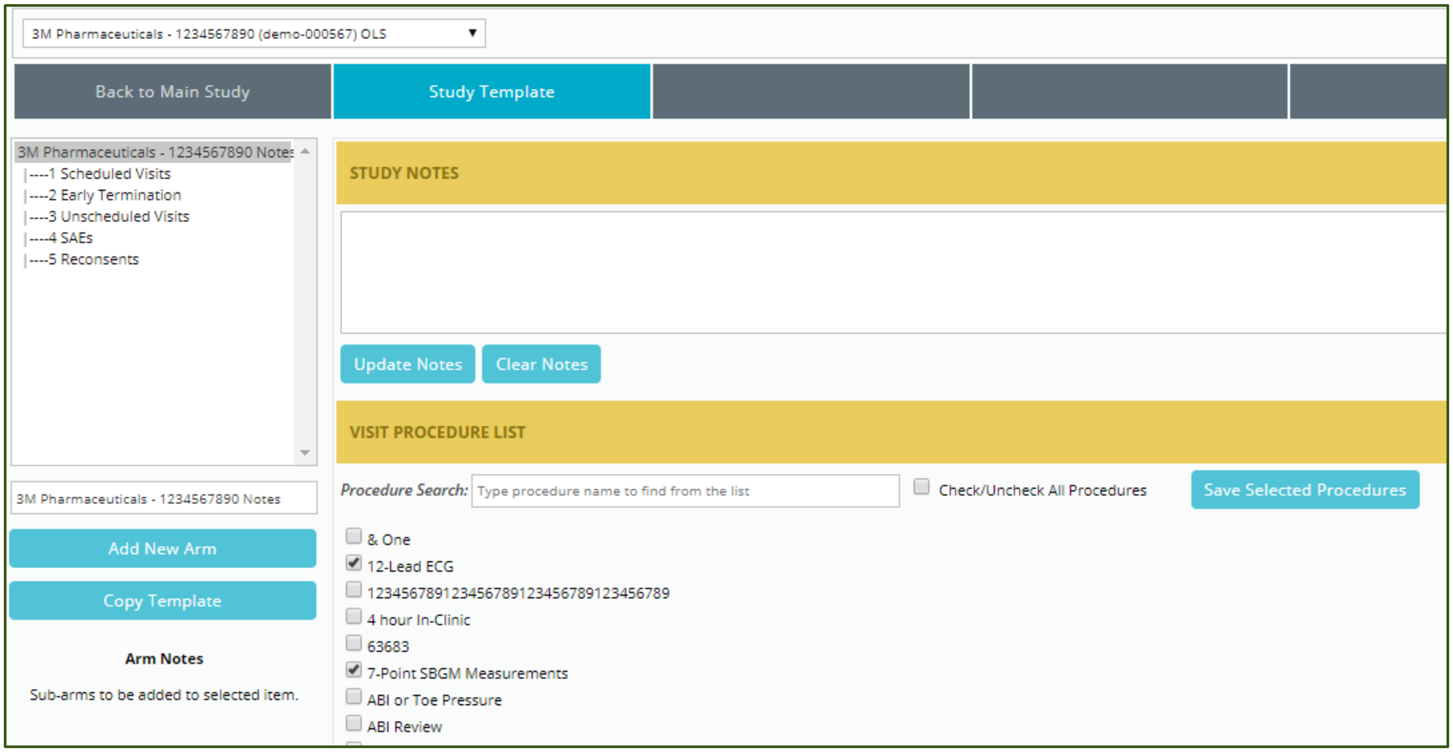
REFER	ENROLLED	RAND	COST/RAND
12	3	2	$488.13

The entire campaign can be exported into a printable format by using the Recruitment Campaign Summary report in the User section.



STUDY TEMPLATE

When accessing the *Study Template* tab, a user will be defaulted into the Study Notes section. A user can add study specific notes that will populate in the *General Info* tab for all users to view. In this section, a user can also view the Visit Procedure List. If a desired procedure is not listed, please refer to the Manage Tables section of this manual. In this section, user will have the ability select which procedures should be listed within this study's visit procedure dropdown list.



RealTime-CTMS makes tracking study financials possible by allowing users to create study templates. Study templates bridge the gap between the financial and clinical branches of your organization.

A study template consists of two elements:

1. ***Study Arms*** facilitate an overview of study specific visits with an overview to include visit timelines/ windows, subject stipend payments, potential revenue earned for each visit and provider costs.
2. ***Study Visits*** facilitate the tracking of visit timelines/windows, durations, coordinators, subject enrollment statuses, visit payment type, procedure revenue/ costs, and subject stipend payments.

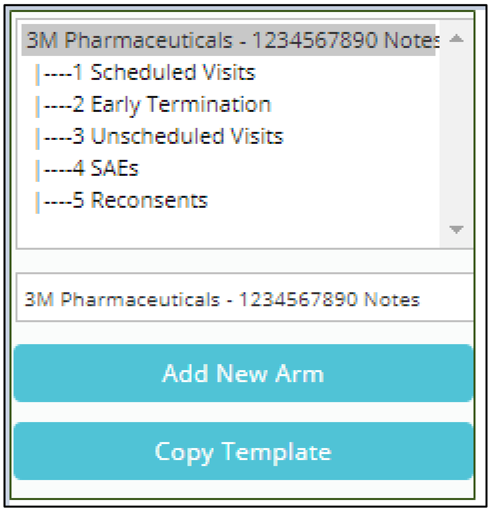
PREPARATION AND INFORMATION GATHERING

The following information must be readily available when creating a study template:

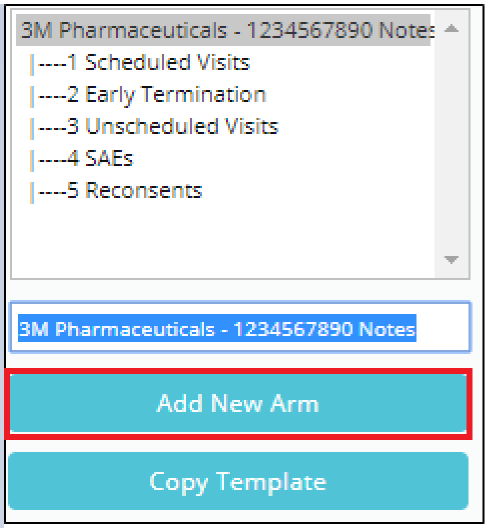
- **Protocol** detailing visit timelines, procedures, and footnotes.
- Sponsor/CRO Budget detailing amounts earned per visit or procedure.
- **Clinical Trial Agreement** detailing the payment terms, visit/procedure payment amounts, screen fail information, study revenue items, invoiceables/ conditional procedures.
- **Costs** associated with a procedure. *Example: paying an entity to complete a specific procedure (i.e. colonoscopy).*
- **ICF** detailing subject stipend information

CREATING A STUDY ARM

To create a study arm, a user must always select the first line item indicated in the box on the left-hand side.



Once selected, highlight the text in the text field and rename to the desired arm name and click "Add New Arm". Arms will be listed in alphabetical order *(Tip: Use a number to sort the arms in chronological order).*

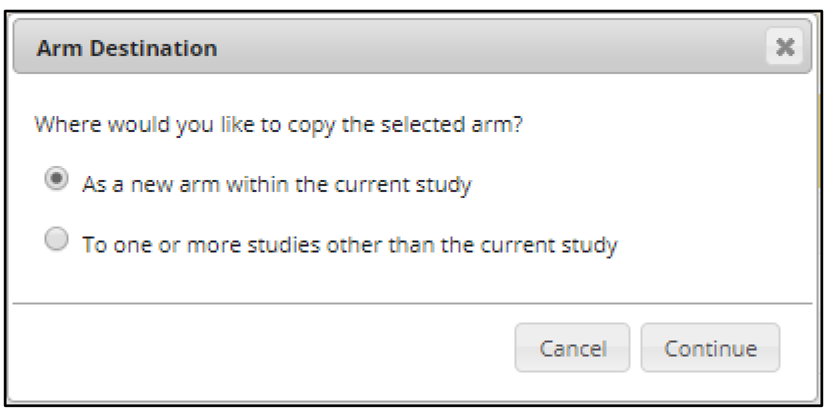


Updating a Study Arm Name

To update the arm name, select the desired arm, then edit the text field and click "Update Selected Arm Name"

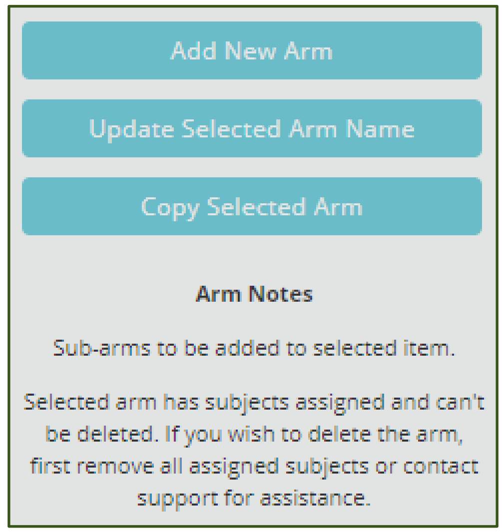
Copying a Study Arm

An arm can be copied within the current study or into a different study. Select the desire arm to be copied, then click the "Copy Selected Arm" button. A pop up will prompt the user to select the destination of the copied arm.



Deleting a Study Arm

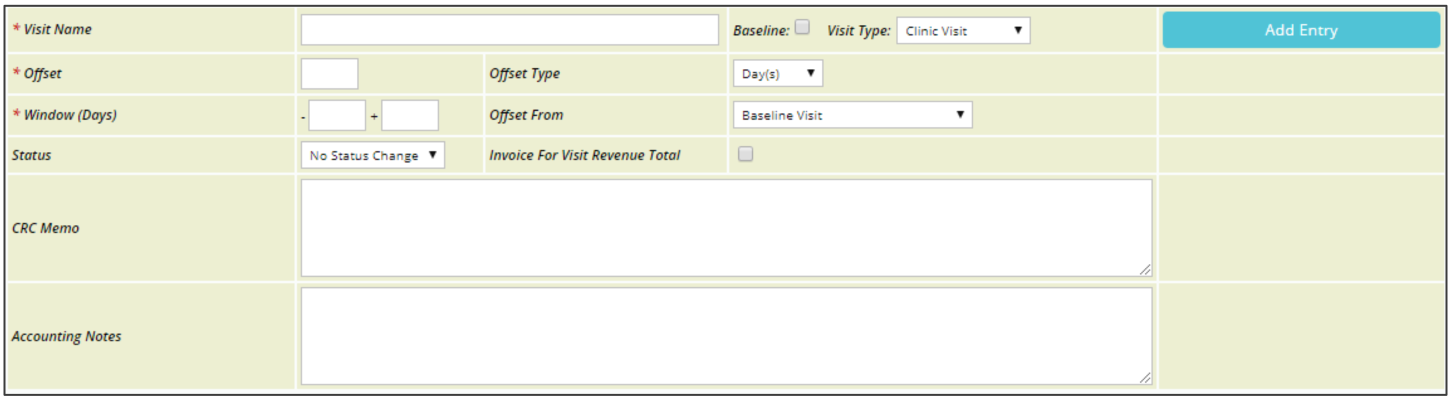
A study arm can be deleted provided there are no subjects assigned to it. If any subjects are assigned to the arm the Delete button will no longer display, and an arm note will be indicated.



Creating a Study Template Visit

Once a template arm has been created, study visits can be created.

To create a visit, highlight the arm and click the Add New Visit button at the top right.



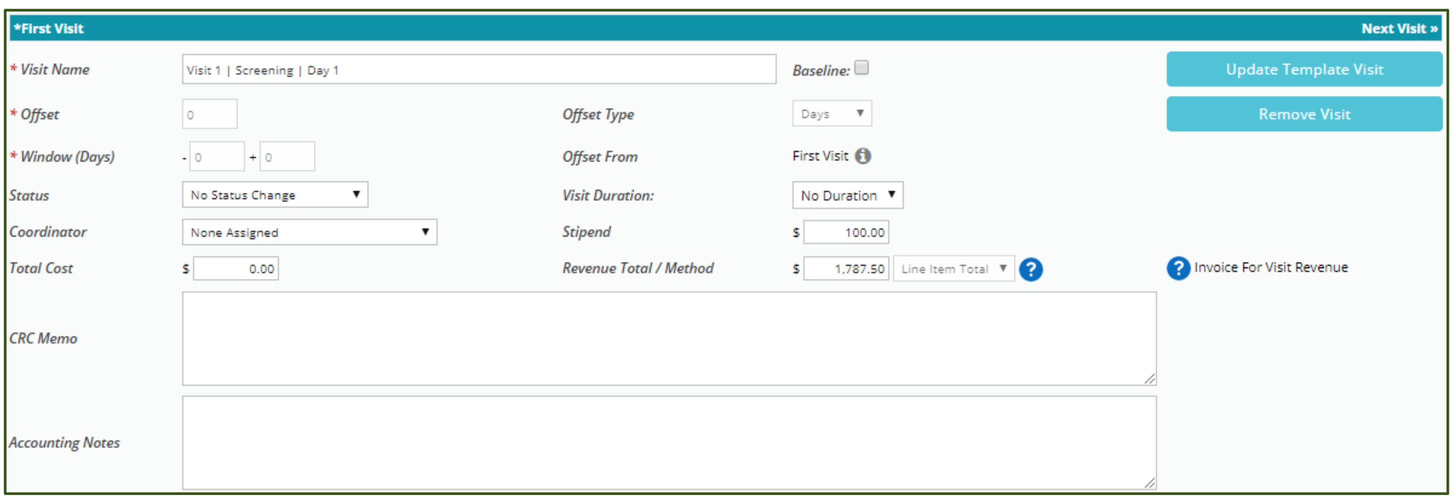
Below is a detailed explanation of each field and its related function(s):

- **Visit Name**: Enter the name of the visit. In order to make it easier for front-end users to identify the visit, name the visit using the protocol and/or budget description.
- **Baseline Checkbox**: Check this box if the visit that a user is creating is a Baseline visit by which other visits are calculated from.
- **Visit Type**: Select the type of visit that that applies which will allow for reporting of visit types. "Other" should be used to capture other trackable procedures or occurrences not considered to be a clinic visit or phone visit (e.g. x-ray, CT scans, SAEs).
- **Offset**: The Offset refers to the days/weeks/months to offset from the Baseline Visit (Day 0), Previous Visit, or another visit in the protocol. Type the Offset of the visit into the Offset textbox. Make sure to enter the negative sign if the visit is occurring prior to Day 0. The First Visit does not require a value for offset/windows.
- **Offset Type**: Choose from days, weeks or months.
- **Window (Days):** Enter the visit window in this field. Note that it is always in days. If a protocol has a window of +/- 1 week, then you will need to convert it to days (i.e. 7 days). Note: With the exception of the first Visit. The first visit cannot have a window
- **Offset From**: A user can select from the dropdown to offset a visit from the baseline, a previous, or a visit that is listed prior to the selected visit.
- **Status**: Enter what the patient's enrollment status will become if they were to complete this visit. Example: if this is a screening visit, you would want to select In Screening. If it is a Early Terminating visit, select Dropped.

- **Invoiceable Checkbox**: Check this box if you are planning to invoice the sponsor for the visit as a whole. If you are going to invoice the sponsor for individual procedures, leave this box unchecked.
- **CRC Memo**: Notes to the CRC who is conducting and/or submitting the visit in RealTime-CTMS can be added. These notes may be related to options for marking procedures as done/not done or any other important visit notes. Example: "If a urine pregnancy test is positive, then a serum pregnancy test is required and invoiceable. Pay special attention to make sure to mark the procedure Serum Pregnancy as Done/Not Done so we can invoice appropriately."
- **Accounting Notes**: Use this section to enter any financial notes for the visit. Notes entered into this field can only be viewed by RealTime users with Accounting privileges. Example: Screen fails will be paid at a rate of $900. Make sure to adjust the revenue for this visit if the patient screen fails.

Once all required new visit information is populated, click the Add Entry button to enter the visit. The next screen will allow you to enter the financial data, stipend information, and procedures to the visit.

All of the previous information entered will be translated to this screen. You now have the ability to add the following additional information.



Below is a detailed explanation of the additional fields and their related function(s):

- **Visit Duration**: In an effort to aid with scheduling, enter an estimated timeframe for the visit in the Visit Duration dropdown.
- **Coordinator**: To have the system automatically add a specific coordinator to each visit, select their name from the dropdown. However, it is recommended to leave this field as "None Assigned", to allow each coordinator to select his/her own name from the dropdown.
- **Stipend**: Enter the stipend amount per the Informed Consent to this field. This amount will be used to calculate the money owed to the subject in the *Subject Stipend* section of the Accounting tab.
- **Total Cost**: The amount in this field cannot be entered manually. It auto-calculates based on the procedures entered below. Refer to the Adding Procedures to Visits section for details. Note: Keep in mind that RealTime-CTMS only tracks hard costs of study procedures such as physical exams, diagnostic

tests, and other procedures that a direct cost can be assigned to. Cost allocations based on employee/CRC time are NOT tracked with RealTime-CTMS.

- **Revenue Total/Method**: Depending on your site's contract with the study sponsor/CRO, you may be paid per completed visit or per completed procedures within that visit. To have revenue totals calculated based on completed procedures, select "Line Item Total" using the dropdown. If revenues will not be tracked on a procedural basis, then "Fixed Amount" should be selected and a fixed total can be entered for the visit. You can find more detailed information in the next section of this manual: Adding Procedures to Visits.

ADDING PROCEDURES TO VISITS

Select a procedure from the dropdown list, indicate a cost, provider and revenue. If an overhead percentage must be applied to the procedure revenue, check the "Apply Overhead %" box. If the procedure must be invoiced, check the "Invoiceable" box. Procedures can be added/edited through the manage tables tab. Information on adding procedures can be found under the Manage Tables section of this manual. Once changes are made select Update Visit.

Add New Procedures

PROCEDURE	COST	PROVIDER (CHECK TO LOCK)	REVENUE	APPLY OVERHEAD %	INVOICEABLE	OPTIONS
Select Procedure	$ 0.00	Please select a provider ☐	$ 0.00	☑	☐	Add to List
Select a Procedure, Update the Financial Information, then 'Add to List'. After reviewing your selections, 'Update Visit'.						Update Visit

MANAGING CURRENT PROCEDURES

Below Add New Procedures is Manage Current Procedures which allows procedures in the list to be sorted and the check boxes in the column headers (Provider, Apply Overhead %, Total Revenue Override, Invoiceable and Options) can be checked to 'mass select' and 'mass unselect.'

Manage Current Procedures

LINE ITEM	SORT	PROCEDURE	COST	PROVIDER (CHECK TO LOCK) ☑	REVENUE	APPLY OVERHEAD % ☑	TOTAL REVENUE OVERRIDE ☑	TOTAL REVENUE	INVOICEABLE ☑	OPTIONS ☐
1	↕	Informed Consent	$ 0.00	No Provider ☑	$ 75.00	☑	☑	$ 82.50	☑	☐ 🗑
2	↕	Visit Revenue	$ 0.00	No Provider ☑	$ 1,500.00	☑	☑	$ 1,650.00	☑	☐ 🗑

A cost will need to be entered if you are planning on utilizing RealTime to track your expenses for this study. Enter the associated cost. Example: if you have to pay GI Consultants a sum of $800.00 every time they perform a colonoscopy, you will want to enter $800.00 into the cost field.

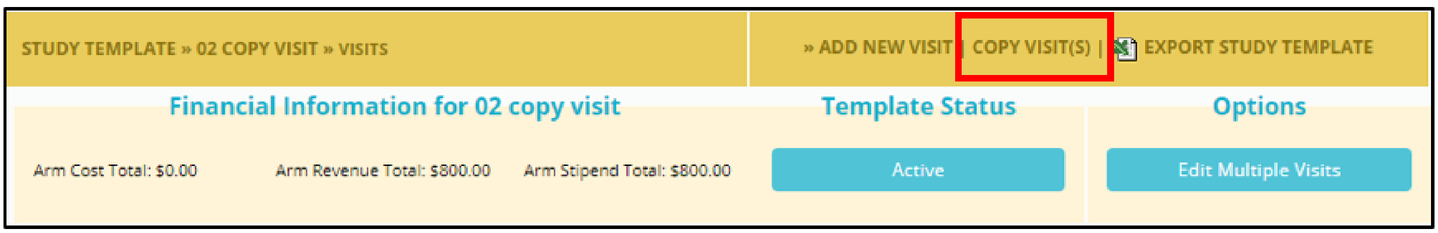
If the procedure requires a specific provider to perform the procedure, select the provider from the dropdown list. In the example above, you would want to select GI Consultants as the provider. If a provider will not change throughout the study, then the provider may be locked for specific procedure(s) by checking the box next to the provider dropdown menu. Locking a procedure means that clinical staff will not be able to change the provider without help from an administrator. In our example, we would want to lock the provider to GI Consultants because we do not want the $800.00 to be expensed to any other provider.

If the sponsor will be paying you per procedure completed, you will want to enter the revenue amount in the revenue field. Make sure that the Revenue Method selected above is set to Line Item Total. If instead the sponsor is going to pay you a fixed amount per visit, then you do not need to enter a revenue amount into this section. You just need to enter it once in the Revenue Total/Method field above.

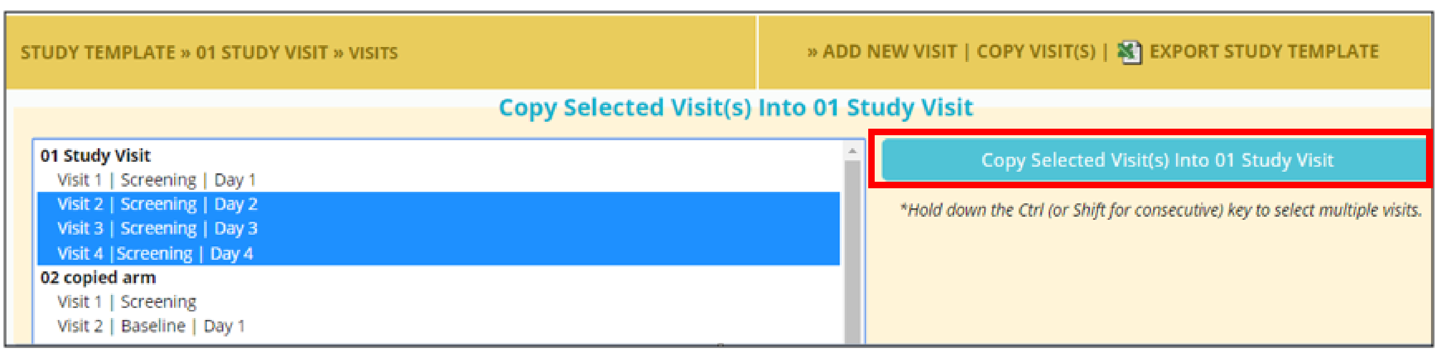
If you have chosen “Line Item Total” as the revenue method, then the individual template procedures can be marked as “Invoiceable”. Marking a procedure as Invoiceable will allow the procedure to be added to an invoice once the visit is submitted/completed.

COPYING VISITS

Visits can be copied using the *Copy Visit(s)* feature at the top right within the arm.



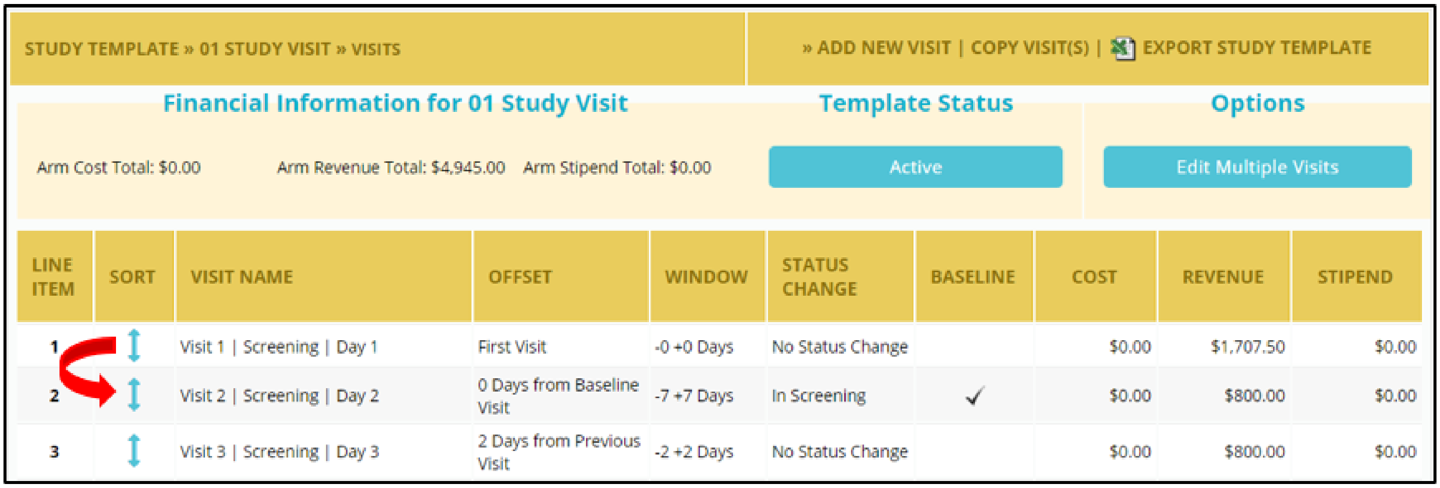
Select the visits you wish to copy by highlighting them and clicking *Copy Selected Visit(s)* Button. The selected visits will be copied into the referenced arm. Example shown: Visits 2,3 and 4 are copied into ’01 Study Visit’ arm.



Next, simply click into the newly copied visits and make the necessary changes to the visit name, offset dates, visit window and add/delete any procedures.

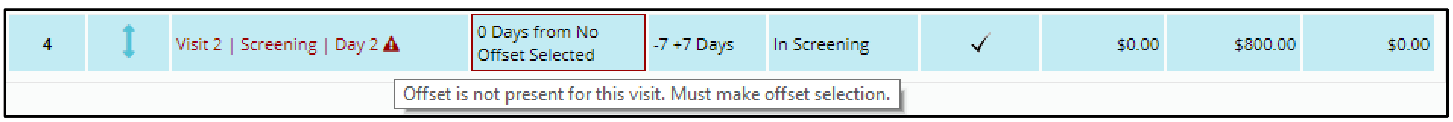
UPDATING STUDY VISITS

To update, a user can click into the visit and make updates or by selecting *Edit Multiple Visits.* If the visits do not appear in the desired order, simply drag (click and hold) and sort using the icon.



STUDY TEMPLATE » 01 STUDY VISIT » VISITS					» ADD NEW VISIT | COPY VISIT(S) | EXPORT STUDY TEMPLATE				
Financial Information for 01 Study Visit					Template Status		Options		
Arm Cost Total: $0.00		Arm Revenue Total: $4,945.00	Arm Stipend Total: $0.00		Active		Edit Multiple Visits		
LINE ITEM	SORT	VISIT NAME	OFFSET	WINDOW	STATUS CHANGE	BASELINE	COST	REVENUE	STIPEND
1		Visit 1 | Screening | Day 1	First Visit	-0 +0 Days	No Status Change		$0.00	$1,707.50	$0.00
2		Visit 2 | Screening | Day 2	0 Days from Baseline Visit	-7 +7 Days	In Screening	✓	$0.00	$800.00	$0.00
3		Visit 3 | Screening | Day 3	2 Days from Previous Visit	-2 +2 Days	No Status Change		$0.00	$800.00	$0.00

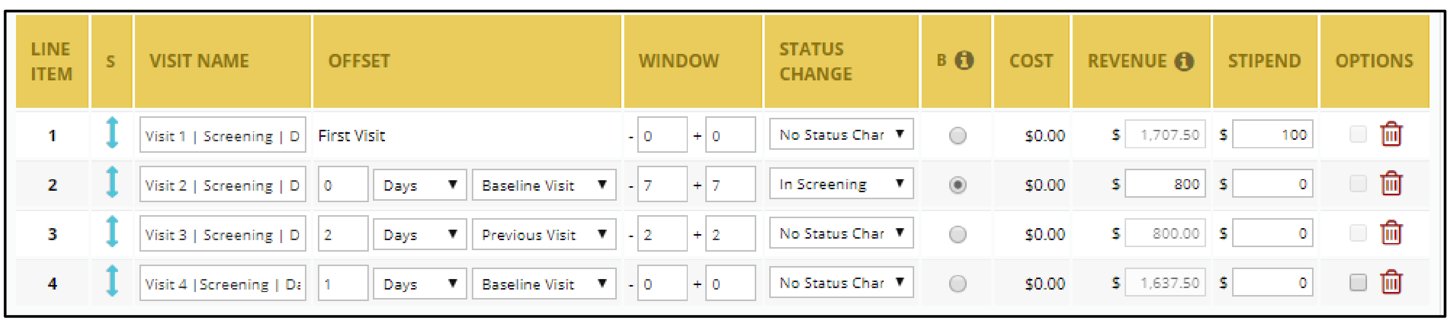
When sorting, an offset may be removed prompting an alert to change the offset -"*Offset is not present for this visit. Must make offset selection".*



4		Visit 2 | Screening | Day 2	0 Days from No Offset Selected	-7 +7 Days	In Screening	✓	$0.00	$800.00	$0.00

Offset is not present for this visit. Must make offset selection.

When editing multiple visits, a user will have the ability to make mass selection to each visit.



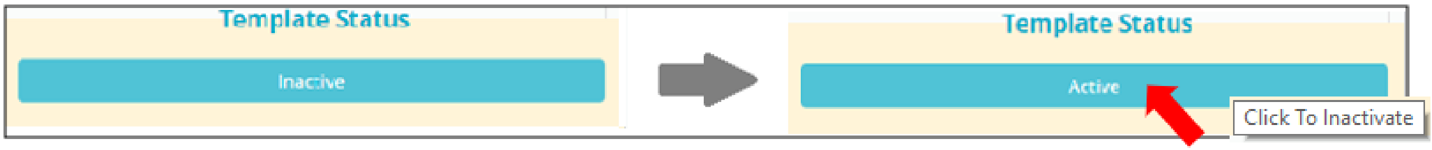
LINE ITEM	S	VISIT NAME	OFFSET	WINDOW	STATUS CHANGE	B	COST	REVENUE	STIPEND	OPTIONS
1		Visit 1 | Screening | D	First Visit	- 0 + 0	No Status Char		$0.00	$ 1,707.50	$ 100	
2		Visit 2 | Screening | D	0 Days Baseline Visit	- 7 + 7	In Screening		$0.00	$ 800	$ 0	
3		Visit 3 | Screening | D	2 Days Previous Visit	- 2 + 2	No Status Char		$0.00	$ 800.00	$ 0	
4		Visit 4 |Screening | Da	1 Days Baseline Visit	- 0 + 0	No Status Char		$0.00	$ 1,637.50	$ 0	

Please note that the *Sort* and *Baseline* column have abbreviated column titles. Select *Update All* once changes are made.

For more information on adding items such as Study Start-Up Fees, Record Storage and other items, refer to the [Accounting section] of this manual.

ACTIVATING A STUDY ARM

After an arm is complete, it must be activated to allow users to assign subjects and assess visits. An arm is activated by selecting the Template Status button within each template arm.



MANAGING ENROLLED SUBJECTS

Once a subject has signed the informed consent document for a study, the subject will need to be added to the *Enrollment Roster* tab. There are two ways to accomplish this: 1) the subject's recruitment status should be changed to *'Enrolled'* on the subject's *Contact Attempts* tab. This action will automatically add the subject to the *Enrollment Roster* for the study and will change the *Not on Study* tab in the subject's profile to *On Study*. 2) If you had scheduled the screening appointment using RealTime's *Calendar,* you can click into the event and follow the instructions on the screen to convert the appointment to a 'Study 1 Visit'. The subject will automatically be added to the *On Study* tab. The *On Study* tab is where subjects can be assigned to study template arms for visit tracking purposes. It is within this *On Study* section that subject enrollment statuses are updated and visit assessments are completed.

STUDY VISIT SUBMISSIONS AND QC FUNCTIONS

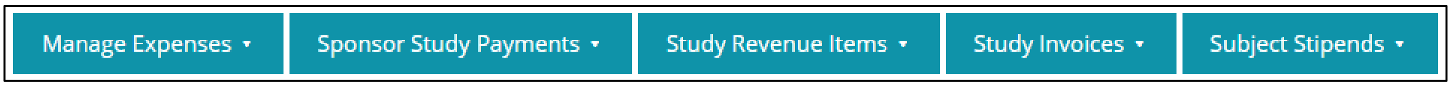
ASSESSING VISITS AS AN ADMINISTRATOR

As an administrator, you have complete control to modify visit information as needed, but assessment control as a standard user/coordinator is limited. Once a study subject has been assigned to a study template arm, all visits will become available for assessment by the study coordinator as they occur. Additionally, unforeseen or unscheduled visits can also be created as needed. Once a visit has been completed for a subject, it should then be assessed in RealTime-CTMS to show the completion as well as allocate costs and revenues as applicable for the visit. Once a visit has been assessed, it will be shown as completed on the study Visit Tracking page as well as on the subject's "On Study" page.

Although each study visit is pre-populated with information derived from the study template arm, all information is editable to accommodate any scenarios that may present themselves during the visit. Scenarios may present themselves such as over-riding a revenue amount if a subject is a screen failure. As an administrator, you can adjust the revenue amount.

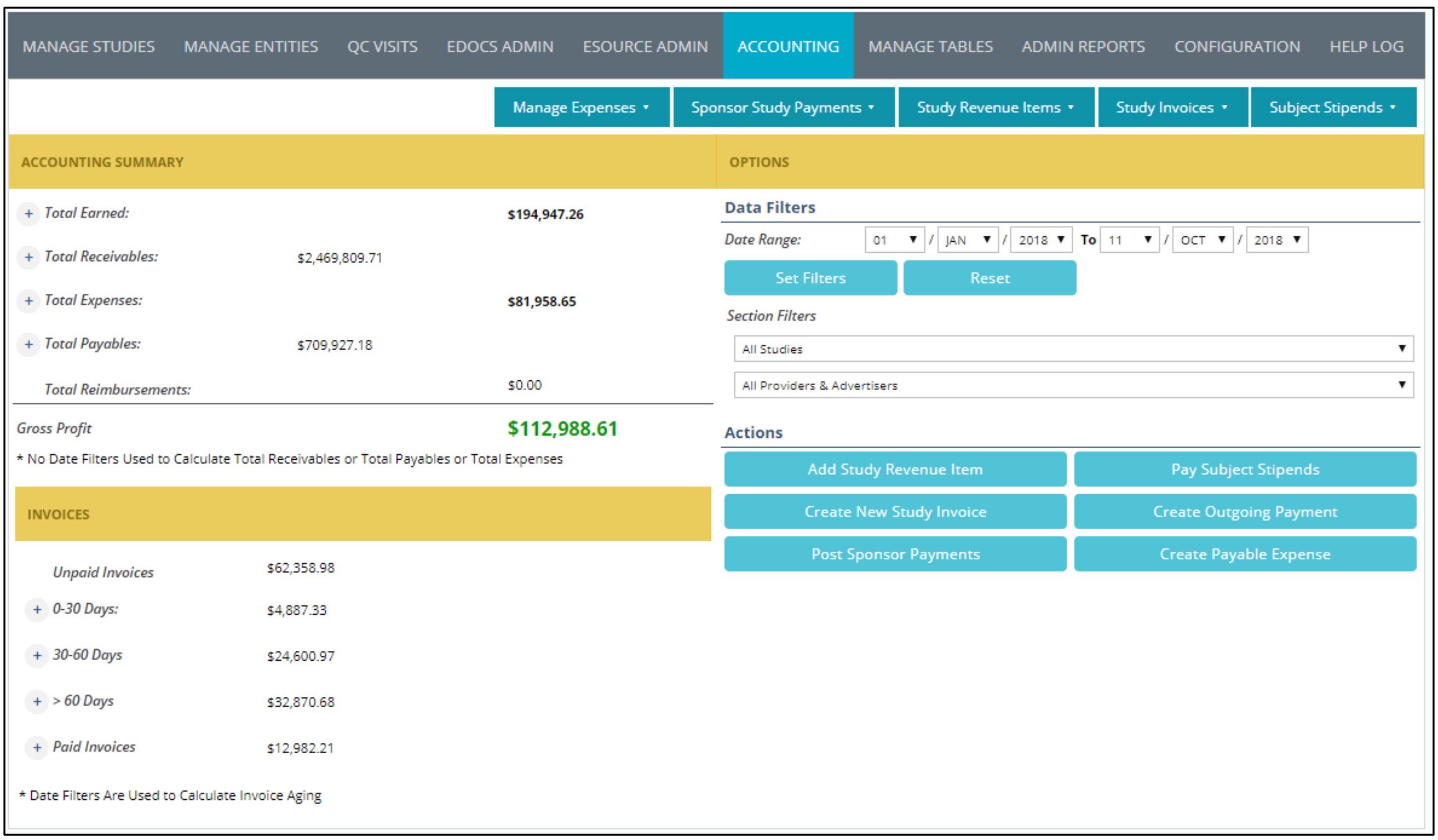
ACCOUNTING

The accounting section of RealTime-CTMS has numerous valuable functions. It is designed to provide real time financial data to managers, manage subject stipend payments, track study revenues and costs, and create payments for providers. Access to the Accounting tab is located within the administration section. There are five sections within the *Accounting* tab: Manage Expenses, Sponsor Study Payments, Study Revenue Items, Study Invoices, and Subject Stipends.



ACCOUNTING TAB

The main page of RealTime-CTMS's Accounting tab provides an overall site view of study finances. Listed on the main page are Total Earnings, Total Receivables, and Total Payables as well as an invoice aging section. By default the values listed will be for all studies and all providers.



Total Earnings is limited to the Date Range listed in the top right corner of the Main Page. By default the Date Range starts from the beginning of the current year to today's date; however, this range can be modified to view data for a different time period. Also, modifications can be made to the displayed data by setting a filter. Selections can be made to view financial data for a single study, or a single provider.

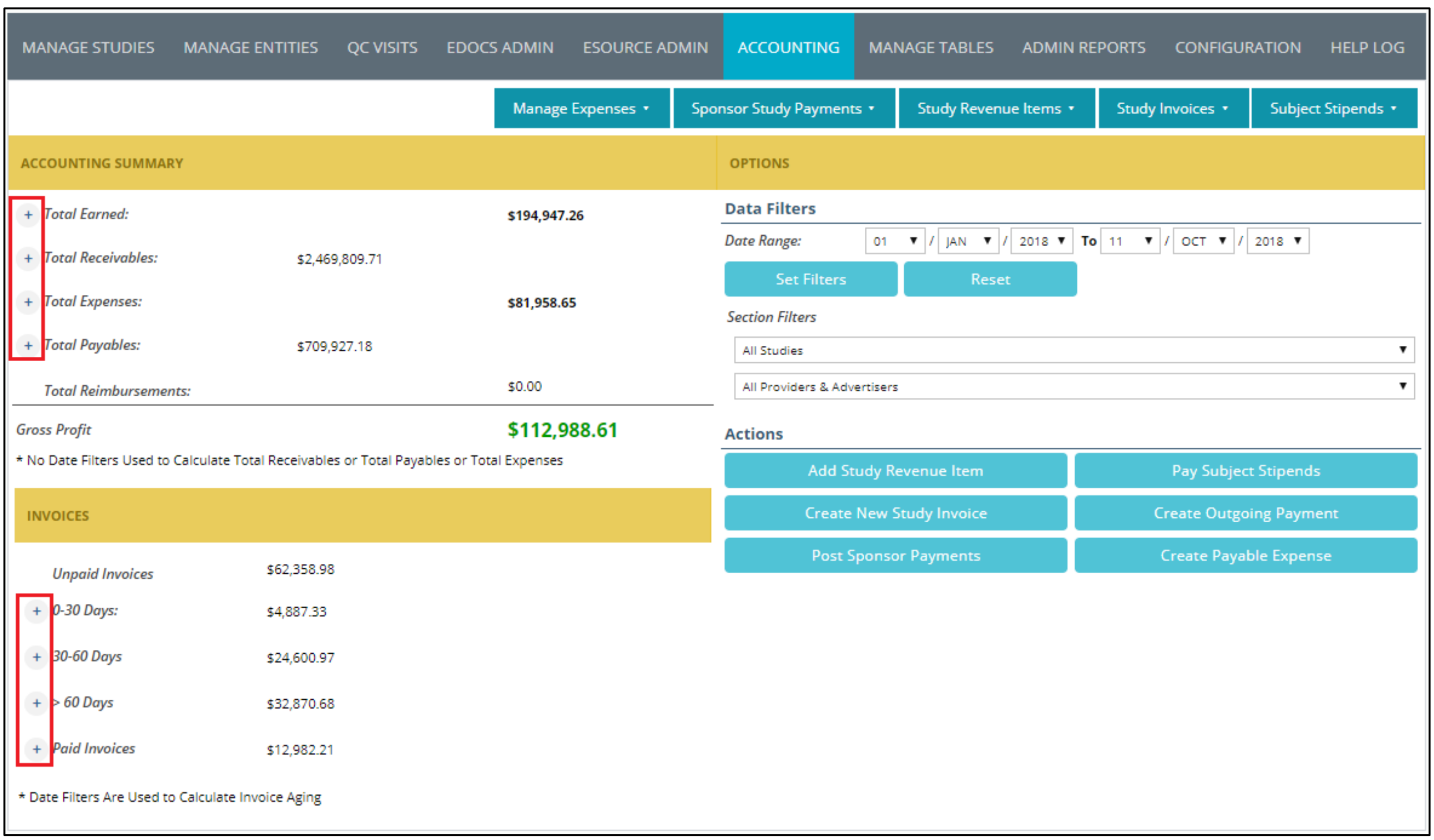
To the left of each main accounting summary heading is a plus (+) sign. Clicking on the plus sign will expand the data for that section. Expanding Total Earnings will provide a list of earnings for each study within the specified date range. Expanding the Total Receivables will provide a receivable amount for each study (not filtered by the Date Range). Lastly, expanding the Payables Section will provide a list of providers and the amounts owed to each (not filtered by Date Range). Clicking on a study or provider listed under each respective heading will automatically show detailed financial information for that provider.

At the bottom-right portion of the Accounting Main Page under the Actions section are six quick links to navigate directly to some of the most common accounting tasks performed in RealTime-CTMS.

STUDY ACCOUNTING

To view financial data for a single study, select that study in the Section Filter on the main accounting page.

The summary accounting page for that study will be shown, and the date range will automatically be set to include all known transactions for the study.



All study-specific financial summary information for the selected study will be displayed to include: Study Earnings, Study Costs, and Invoice Aging. To the left of each main summary heading is a plus (+) sign. Clicking on the plus sign will expand the data for that section. Expanding Total Earned will provide a list of enrolled subjects for the study and the total earned for each subject. Additional expansion of each subject will provide a total earning for each visit. Expanding the Progress Payments section will provide a list of payments received for the selected study. Expanding the Total Provider Costs section will provide a list of all providers who have earned monies in the study, and further expansion will provide a list of patients and applicable visits. Clicking on a visit will access that visit's assessment screen.

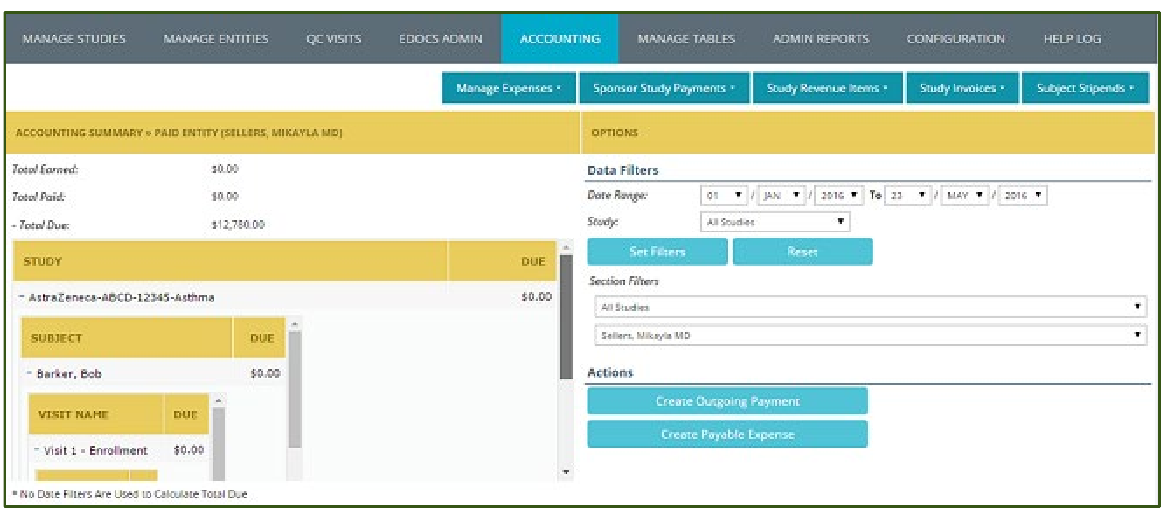
Lastly, expanding the Current Payables section will provide a list of providers and the amounts owed to each. At the bottom of the Study Summary page is an invoicing aging section to track invoice payments. At the bottom-right portion of the Study Accounting page under the Action section are five quick links to navigate directly to some of the most common tasks performed for study accounting management.

PROVIDER ACCOUNTING

To view financial data for a single provider or advertiser, select that provider in the Section Filter on the main accounting page.

The summary accounting page for that provider/advertiser will be shown with a default date range including all transactions in the current year.

Primary summary information for the provider will be displayed to include: Total Earned, Total Paid and Total Due. To the left of each main summary heading is a plus (+) sign. Clicking on the plus sign will expand the data for that section. Expanding Total Earned will provide a list of studies that the provider has performed services on. Further expansion of a study will show a list of subjects and specific visits that the provider has performed procedures for.



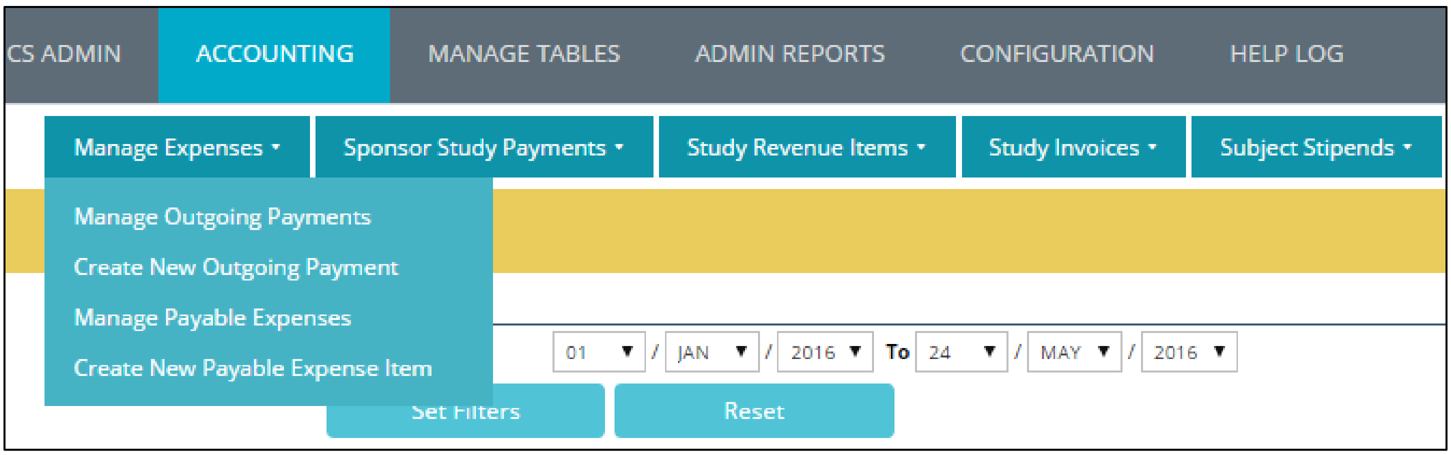
Expanding the Total Paid section will show what monies have been paid for each applicable study and the corresponding payment IDs.

Lastly, expanding the Total Due will show amounts due to the provider for each study. Additional, filter options are available on the right side of the provider summary page to allow for date range selection and specific study filtering.

At the bottom-right portion of the Provider Accounting page under the Actions section is one quick link that can navigate directly to the most common task performed for provider/advertiser accounting management.

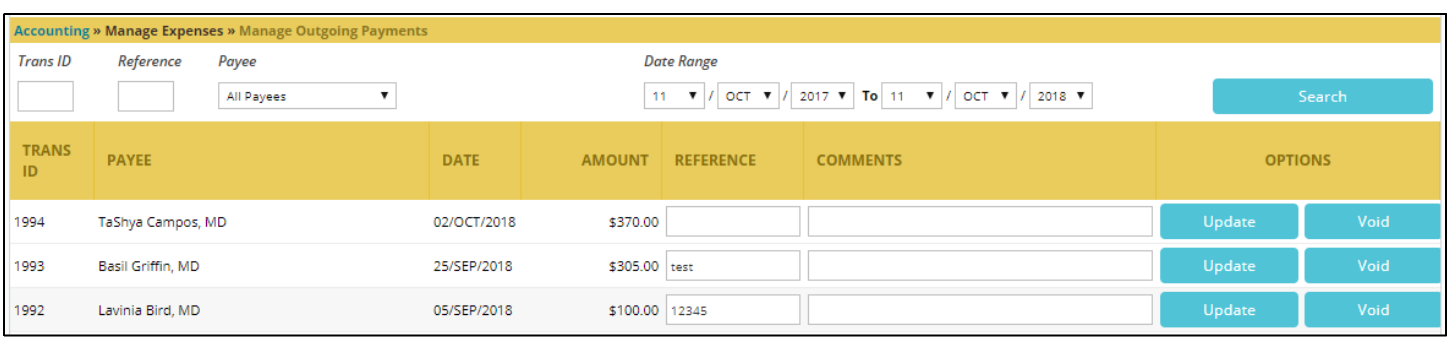
MANAGING EXPENSES

In the Manage Expenses area, provider/vendor expenses can be viewed, created and paid. There are the following choices at the top right of the screen: Manage Outgoing Payments, Create New Outgoing Payment, Manage Payable Expenses, and Create New Payable Expense Item.



MANAGE OUTGOING PAYMENTS

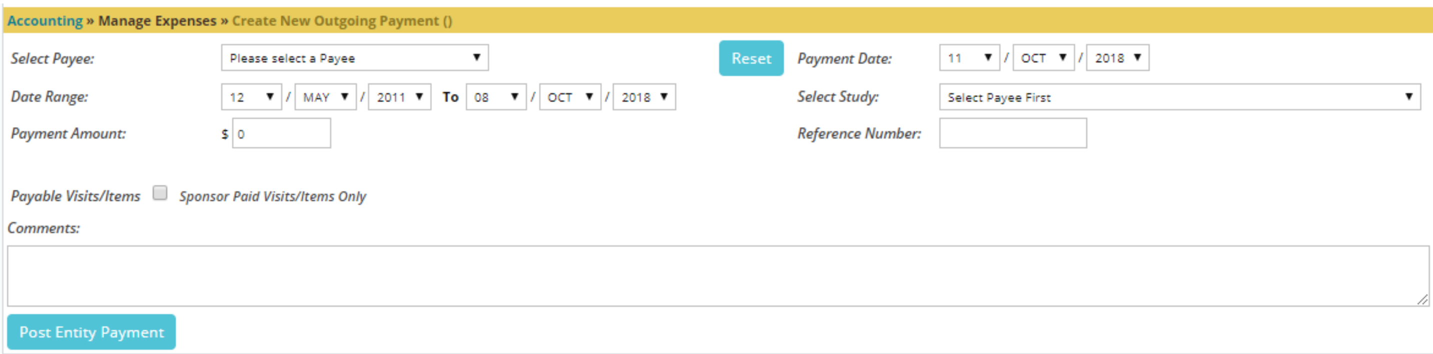
On the Manage Outgoing Payments page a list of payments is shown with a default date range including the past twelve months. The search criteria at the top of the page including, Trans ID, Reference, Payee Selection and Date Range can be utilized to locate a specific payment transaction. Payment details such as a reference number and comments can be updated, and transactions can be voided, if necessary. Clicking on a transaction will evoke the Provider Payment Transaction Detail report for the selected Trans ID.



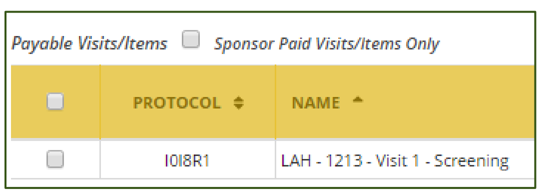
CREATE NEW OUTGOING PAYMENT

Outgoing payments can be created that include both visit-level procedure expenses as well as study-level expenses. To create an outgoing payment, click on the Create New Outgoing Payment link in the Manage Expenses accounting section.

Select the Payee from the dropdown. You may also select a study if you wish to filter the payable transactions to a specific study.



A list of Payable Visits/Items will be shown in the left-hand selection box. The date range, by default, will be set to include all available transactions; however, the range can be altered to narrow the available transactions for payment. If you would like to only pay the provider for Visits/Items that have received payment from the study sponsor, then the "Sponsor Paid Visits/Items" checkbox should be checked to exclude non-paid items. Additional Visits/Items can be excluded from the payment by moving those Visits/Items to the right-hand exclusion box. The total payment amount will update as Items are added or removed from the Payable Selection box.



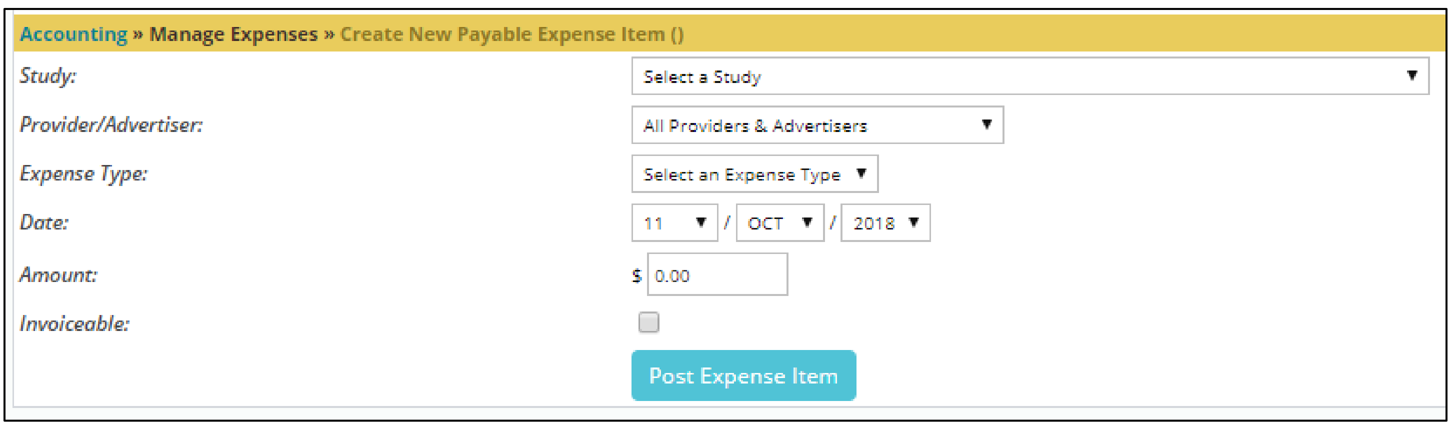
Once all desired payable Visits/Items are shown in the Payable box, add a payment date, reference number, and any desired comments to the transaction and click the *Post Provider Payment* button. The payment will be created, and a Trans ID will be assigned to the payment. Once the payment is posted, the [Provider Payment Transaction Detail] will be available and can be printed for record-keeping.

MANAGE PAYABLE EXPENSES

Once provider expenses are added, they will appear in the Manage Payable Expenses section of the Manage Expenses section. Open expenses can be marked as Invoiceable or deleted by checking the “Remove” checkbox. Expenses that are marked as Invoiceable will become selectable on a Sponsor/CRO invoice.

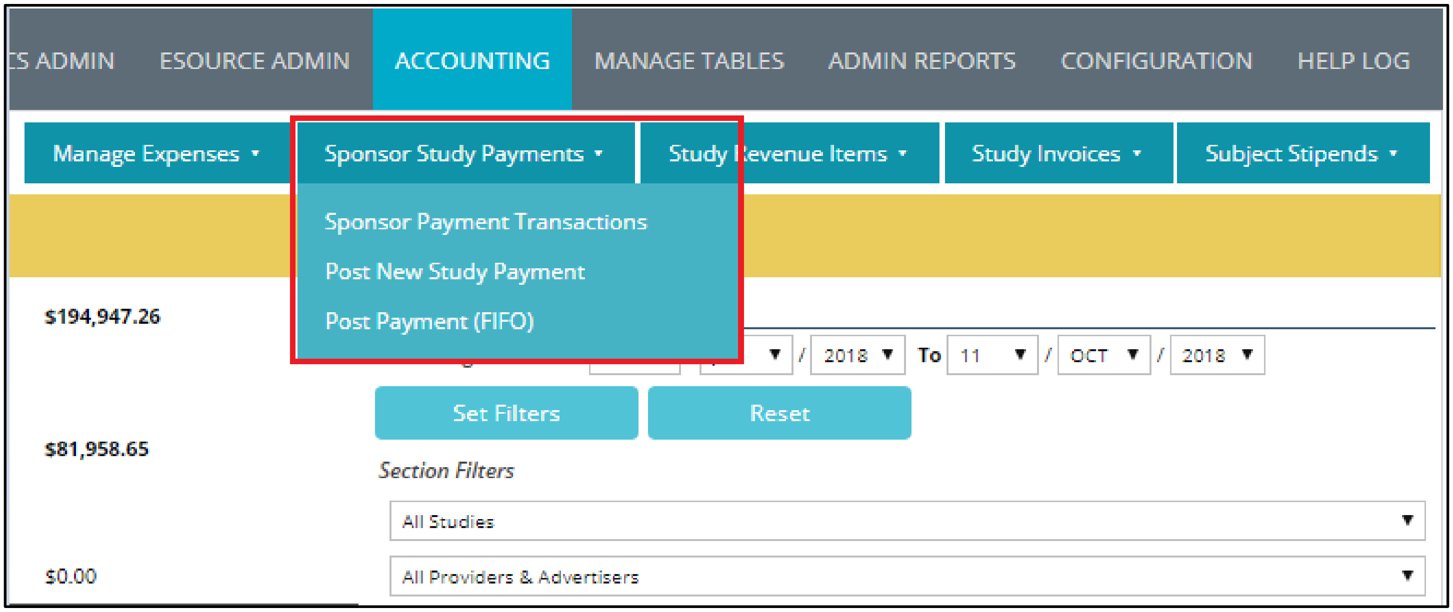
CREATE NEW PAYABLE EXPENSE ITEM

Most provider expenses are generated through procedures within completed study visits; however, additional study-level provider expenses can be created for non-visit-specific activities. These study-level expenses may include Training, Meeting Attendance, etc. Enter the specific provider expense details. Provider Expense Types can be added in the [Managing Tables](#) section.



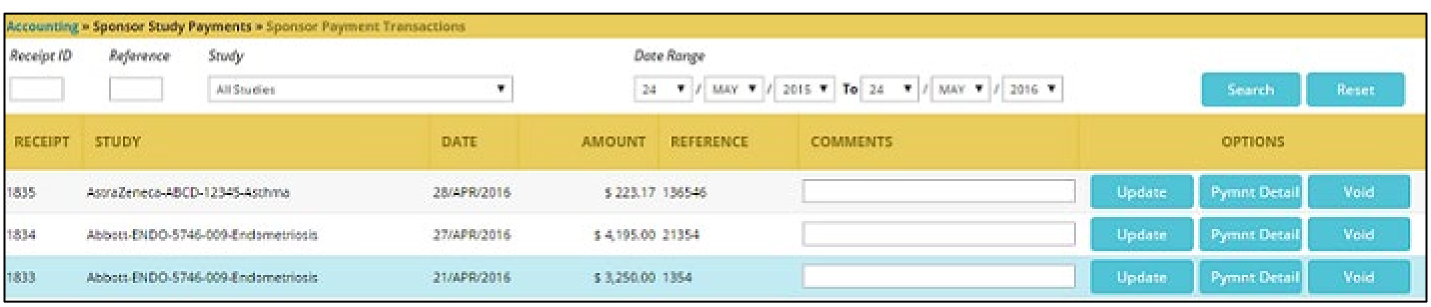
SPONSOR STUDY PAYMENTS

In the Sponsor Study Payments area, there are the following choices at the top right of the screen: Sponsor Payment Transactions, Post New Study Payment, and Post Payment (FIFO). RealTime-CTMS provides two options for applying sponsor payments to studies; FIFO and Standard with visit selection. The most accurate and recommended way to track your sponsor payments is utilizing the standard posting method (not FIFO) that tracks payments based on paid visits. Using this standard method has numerous benefits including, more accurate payment tracking, more detailed invoicing, and also allows provider/vendor payments to be created based on which procedures have been paid by the sponsor.



SPONSOR PAYMENTS TRANSACTIONS

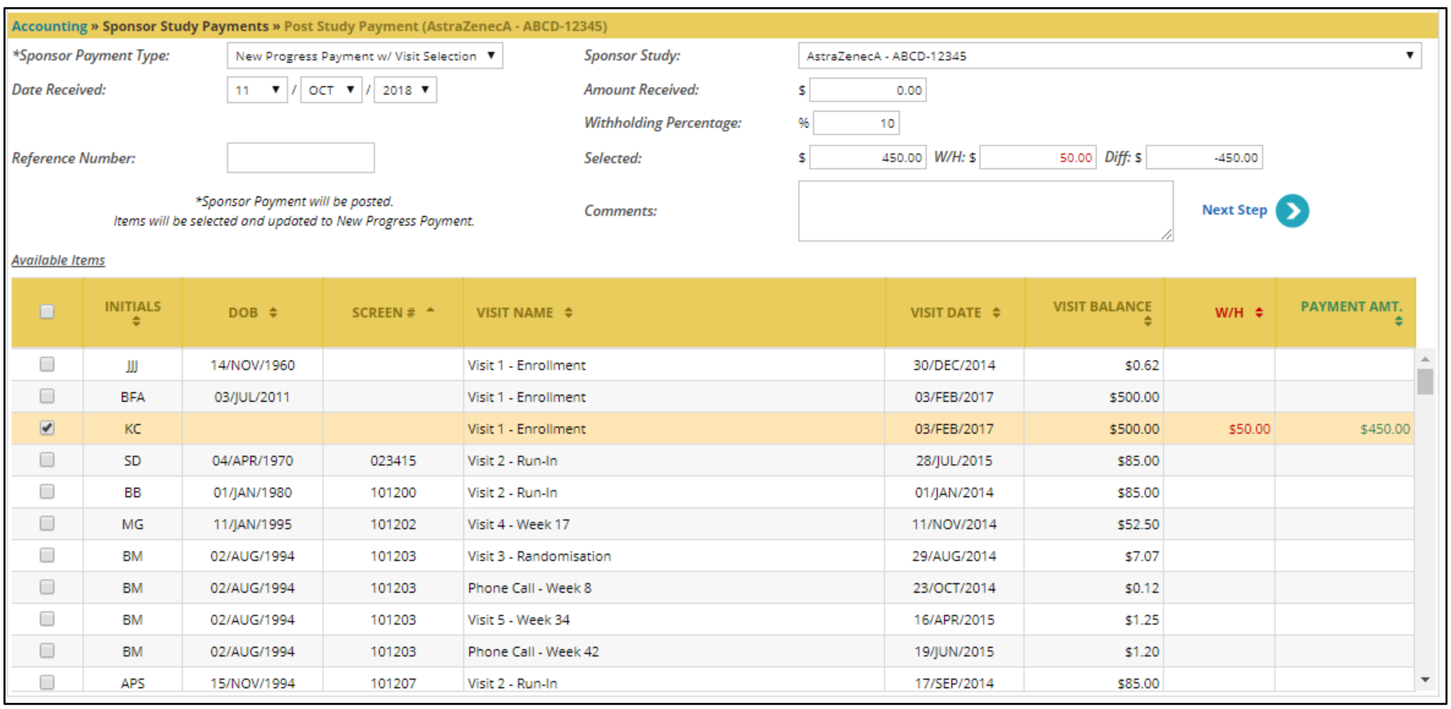
This screen shows a list of sponsor payments over the past 12 months. To locate a specific sponsor payment, type the desired Receipt ID, an automatic number assigned by RealTime-CTMS, and click the Search button. Results can be filtered by Receipt ID, Reference, Study or any date range desired. Lastly, transactions can be sorted by their attributes by clicking on the column headings.



POST NEW STUDY PAYMENT

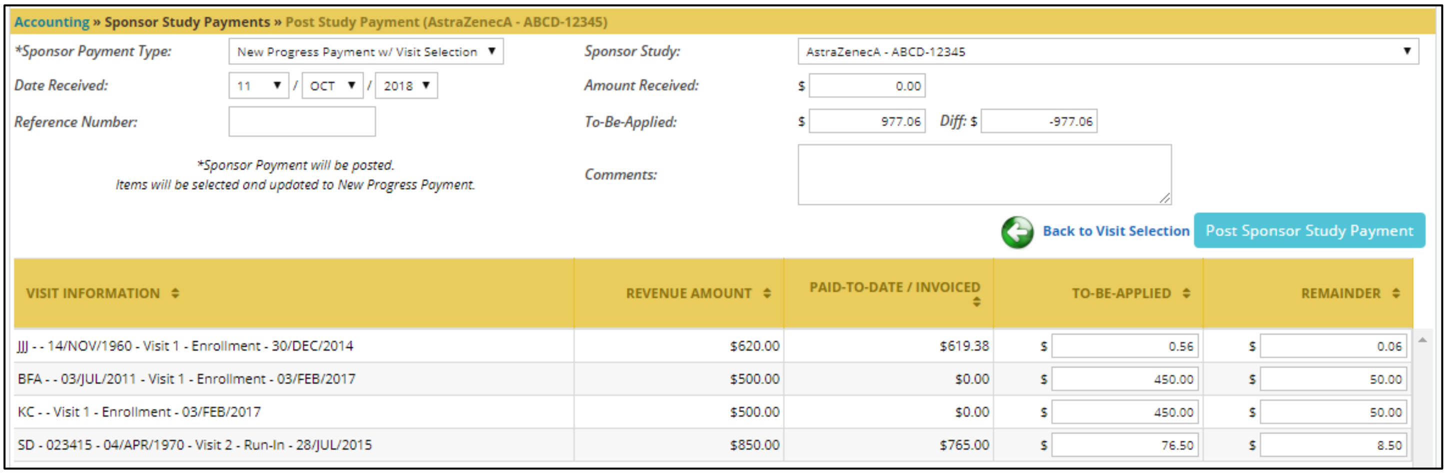
Applying payments using the standard method is recommended as it will provide more accurate tracking of sponsor payments on a per-visit basis. Using this method allows for provider/vendor payments to be tracked based on which visits or procedures have been paid by the sponsor. To apply a sponsor payment using this method, a Payment Detail from the sponsor showing which visits are being paid will be required.

1. Choose "New Progress Payment w/ Visit Selection" in the Sponsor Payment Type drop-down.
2. Select the correct study.
3. Once selected, a list of all visits that are not paid in full will be shown for selection in the "Available Visits" box.
4. Enter the date received, check/reference number, applicable comments, and the total amount of the sponsor payment received.
5. If the sponsor is withholding a percentage of visit payments, this can be indicated in the Withholding Percentage section prior to completing step six. (The correct percentage may already be populated if it has been selected in the study management section.)
6. Based on the sponsor payment detail (provided to you from the sponsor), move visits that are being paid to the "Selected Visits" box. Once all paid visits have been selected, click the "Next Step" button.



	INITIALS	DOB	SCREEN #	VISIT NAME	VISIT DATE	VISIT BALANCE	W/H	PAYMENT AMT.
☐	JJJ	14/NOV/1960		Visit 1 - Enrollment	30/DEC/2014	$0.62		
☐	BFA	03/JUL/2011		Visit 1 - Enrollment	03/FEB/2017	$500.00		
☑	KC			Visit 1 - Enrollment	03/FEB/2017	$500.00	$50.00	$450.00
☐	SD	04/APR/1970	023415	Visit 2 - Run-In	28/JUL/2015	$85.00		
☐	BB	01/JAN/1980	101200	Visit 2 - Run-In	01/JAN/2014	$85.00		
☐	MG	11/JAN/1995	101202	Visit 4 - Week 17	11/NOV/2014	$52.50		
☐	BM	02/AUG/1994	101203	Visit 3 - Randomisation	29/AUG/2014	$7.07		
☐	BM	02/AUG/1994	101203	Phone Call - Week 8	23/OCT/2014	$0.12		
☐	BM	02/AUG/1994	101203	Visit 5 - Week 34	16/APR/2015	$1.25		
☐	BM	02/AUG/1994	101203	Phone Call - Week 42	19/JUN/2015	$1.20		
☐	APS	15/NOV/1994	101207	Visit 2 - Run-In	17/SEP/2014	$85.00		

The following screen will show the outstanding balance of each visit and the amount to be applied to each visit. Adjustments can be made to any or all visits based on the actual amount that is being paid by the sponsor. RealTime-CTMS will not allow the payment to be posted unless the amount applied equals the amount of the payment.



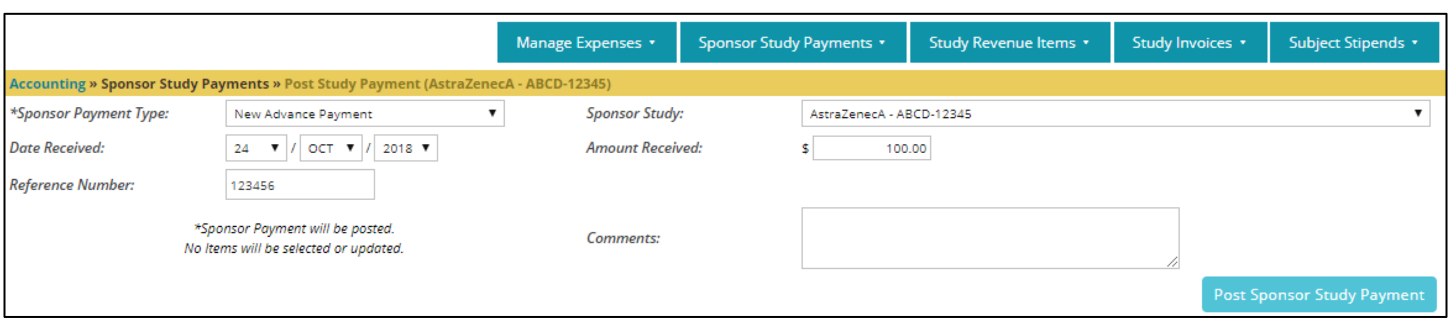
Once the applied amount is in balance with the payment amount, click the "Post Sponsor Study Payment" button to post the payment. The payment will now appear in the Sponsor Payment Transactions list, and the monies will be applied to the applicable study and visits. Once the payment is posted, the Sponsor Payments By Transaction report will be available and can be printed for record-keeping.

NEW ADVANCE PAYMENT

You can use the New Advance Payment selection in two ways:

1. If the Sponsor/CRO provides you with an Advance of funds to be applied to future patient visits.
2. If you are unable to allocate the payment to the visits but still want to enter the payment amount.

Simply enter the Study, Date Received, Amount Received, Reference Number and any Comments. Click Post Sponsor Study Payment.

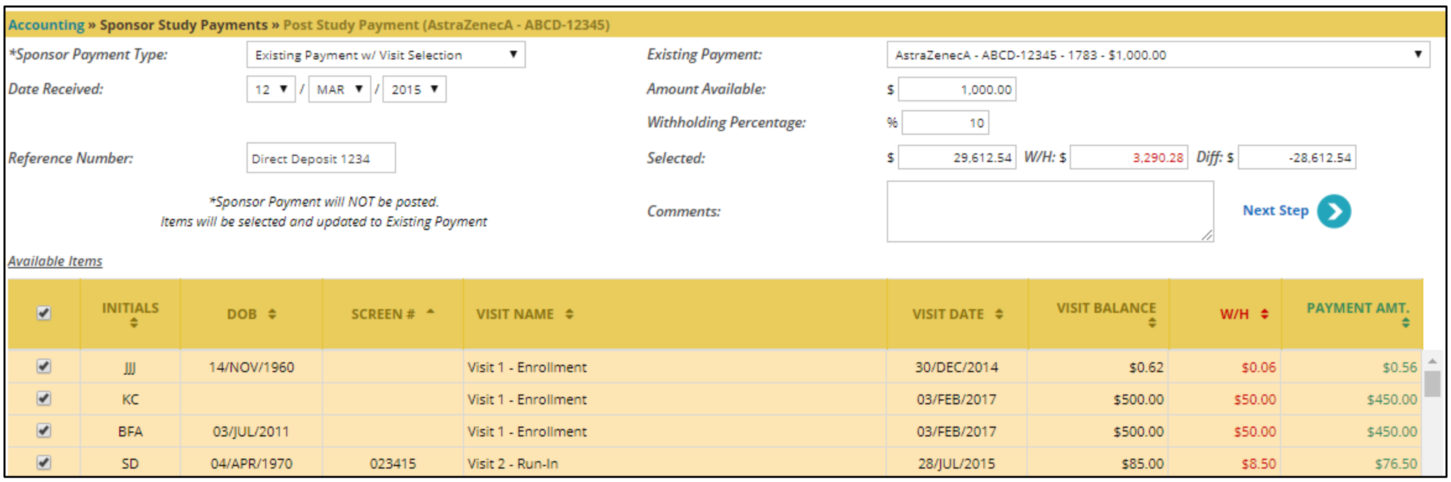


When you are ready to allocate the payment to visits and other items, select Existing Payment with Visit Selection from the Sponsor Payment Type dropdown.

EXISTING PAYMENT WITH VISIT SELECTION

Once you are ready to allocate the payment details of an advance:

1. Choose “Existing Payment with Visit Selection” in the Sponsor Payment Type drop down.
2. Locate the Existing Payment from the dropdown.
3. Once selected, a list of all visits that are not paid in full will be shown for selection in the “Available Visits” box.
4. The date received, check/reference number, applicable comments, and the total amount of the sponsor payment received will auto-populate.
5. If the sponsor is withholding a percentage of visit payments, this can be indicated in the Withholding Percentage section prior to completing step six. (The correct percentage may already be populated if it has been selected in the study management section.)
6. Based on the sponsor payment detail (provided to you from the sponsor), move visits that are being paid to the “Selected Visits” box. Once all paid visits have been selected, click the “Next Step” button.



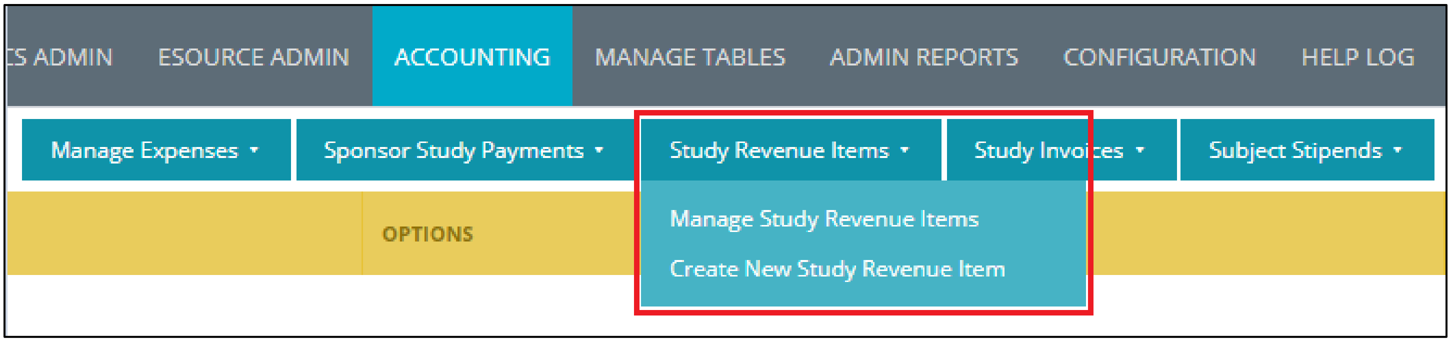
POST PAYMENTS – FIFO (FIRST IN FIRST OUT)

A simpler, faster, but less detailed method is available to post sponsor payments. This method utilizes a simple First-In-First-Out (FIFO) rule that post payments to the oldest transactions first. Using this method makes it possible to see a total of how much has been paid versus how much has been earned as grand totals for each study but does not allow detailed tracking of specific visit payments or detailed payment reconciliation.

Sites that are not concerned with accounting for every penny of study financials may find this method to be quicker, easier and adequate for study payment tracking. To apply sponsor payments using the FIFO method, choose “Post Payment (FIFO)” from the options listed in the Post New Study Payment section. Insert the payment information and click “Post Study Payment”.

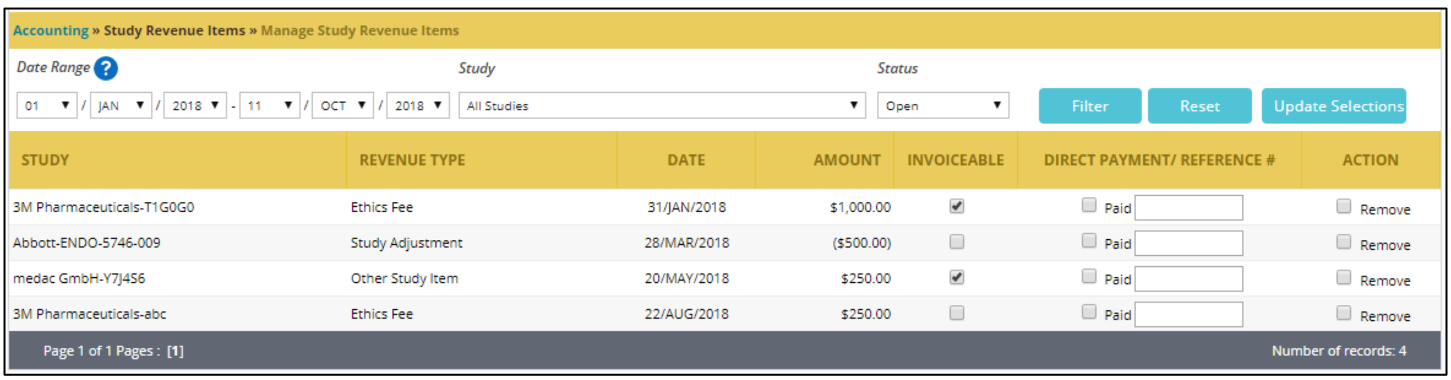
STUDY REVENUE ITEMS

Study Revenue Items are any revenues earned in a study that are not earned through study-specific visits. These items may include Study Start-up Fees, Record Storage Fees, Training Fees, etc.



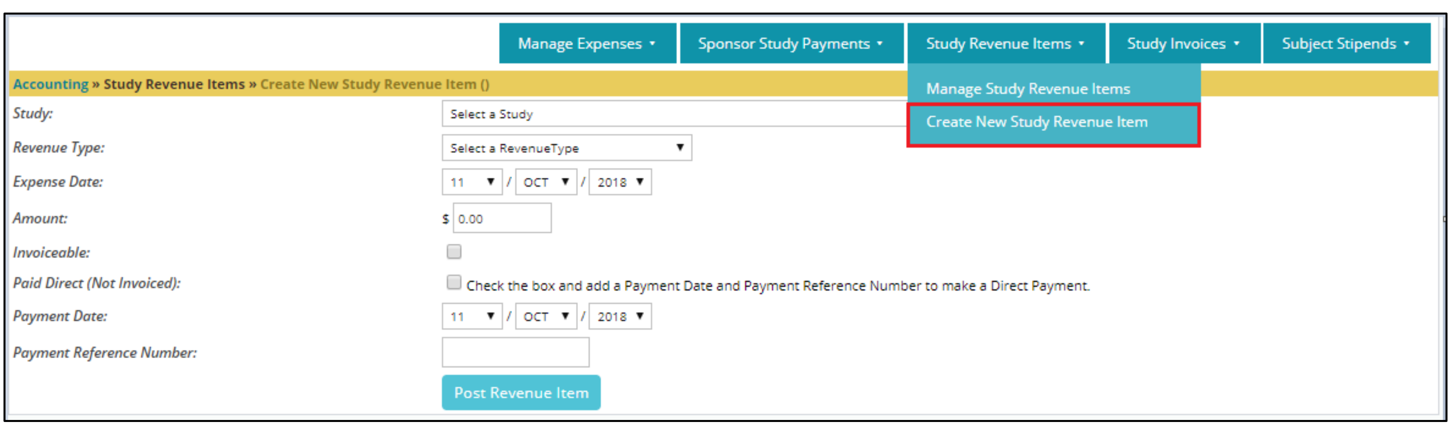
MANAGE STUDY REVENUE ITEMS

When accessing the Manage Study Revenue Items section, you will be directed to a page showing all 'Open' Study Revenue Items.



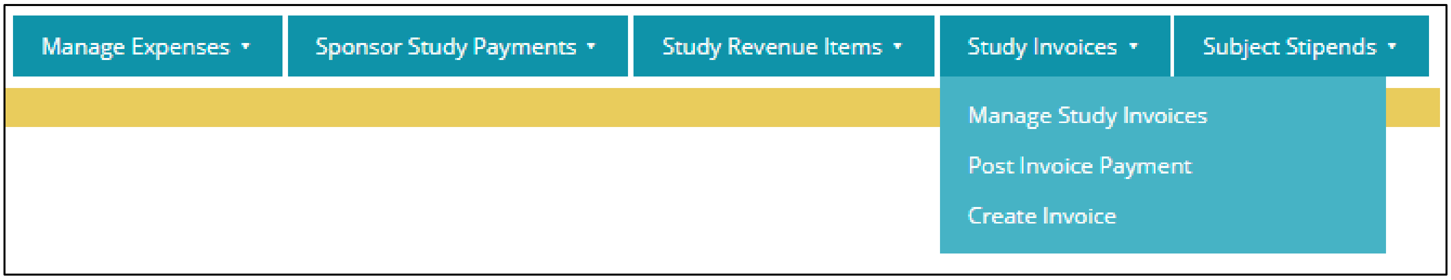
CREATE NEW STUDY REVENUE ITEMS

Click on Create New Study Revenue Item to create a new entry.



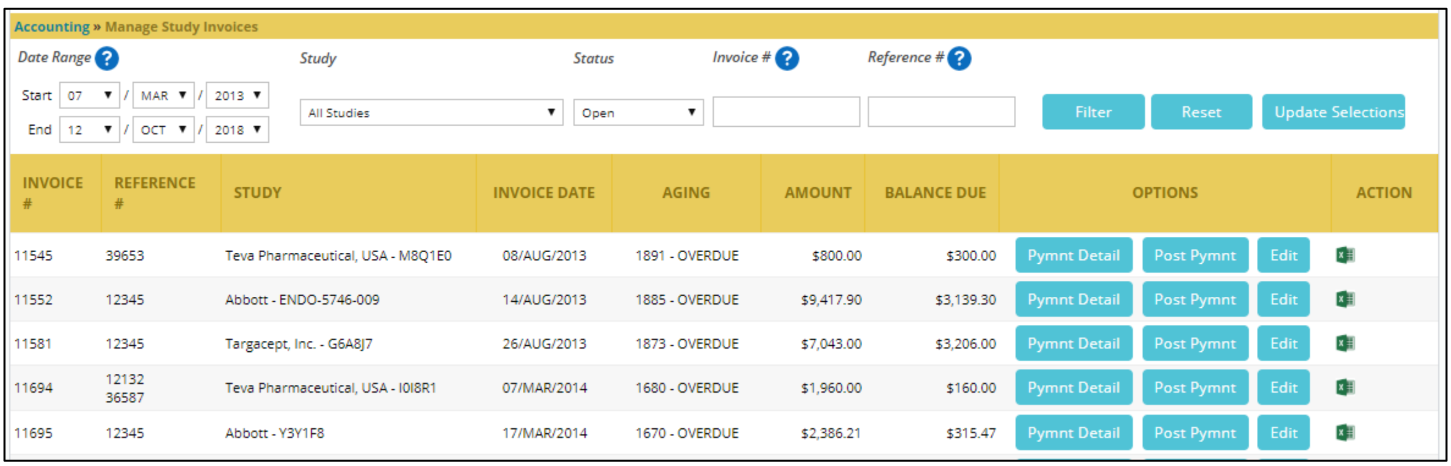
STUDY INVOICES

In the Study Invoice area, there are the following choices at the top right of the screen: Manage Study Invoices, Post Invoice Payment, and Create Invoice.



MANAGE STUDY INVOICES

When accessing the Manage Study Invoices section, a list of open study invoices will be displayed by default. To locate a specific study invoice, the invoice number can be typed into the search box. Additionally, the columns for the listed invoices can be sorted by invoice number, study date sent, aging or amount by clicking on the column heading. To view an invoice, highlight the invoice row and click. Invoices can be exported as an Excel document. The Excel icon located under the ACTION column header, when selected, downloads the invoice as an Excel document.

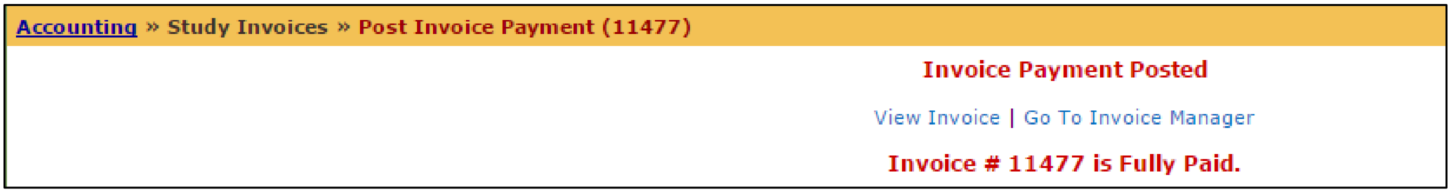


INVOICE #	REFERENCE #	STUDY	INVOICE DATE	AGING	AMOUNT	BALANCE DUE	OPTIONS	ACTION
11545	39653	Teva Pharmaceutical, USA - M8Q1E0	08/AUG/2013	1891 - OVERDUE	$800.00	$300.00	Pymnt Detail Post Pymnt Edit	
11552	12345	Abbott - ENDO-5746-009	14/AUG/2013	1885 - OVERDUE	$9,417.90	$3,139.30	Pymnt Detail Post Pymnt Edit	
11581	12345	Targacept, Inc. - G6A8J7	26/AUG/2013	1873 - OVERDUE	$7,043.00	$3,206.00	Pymnt Detail Post Pymnt Edit	
11694	12132 36587	Teva Pharmaceutical, USA - I0I8R1	07/MAR/2014	1680 - OVERDUE	$1,960.00	$160.00	Pymnt Detail Post Pymnt Edit	
11695	12345	Abbott - Y3Y1F8	17/MAR/2014	1670 - OVERDUE	$2,386.21	$315.47	Pymnt Detail Post Pymnt Edit	

POSTING INVOICE PAYMENTS

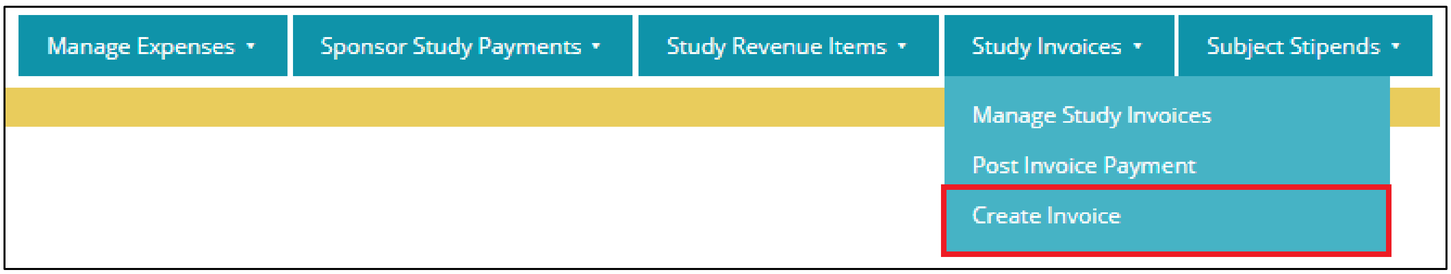
Posting payments to invoices can be done in two ways, 1) click on the Post Invoice Payment link in the Study Invoices section. Select the applicable invoice for the dropdown and enter the payment details, or 2) Click the Post Payment button next to the invoice on the Manage Study Invoices screen.

To post a payment select the items that are being paid from the 'Available Invoice Items' in the left box and move them to the 'Selected Invoice Items' in the right box and click 'Next Step'. The items selected will now appear allowing alterations to the 'To-Be-Paid' section for each item. RealTime-CTMS will require the posted "to-be-paid" amounts to equal the total payment amount. Once the correct to-be-paid amounts are entered and the payment amounts are in balance, click the 'Post Invoice Payment' button to mark the invoice items as paid.

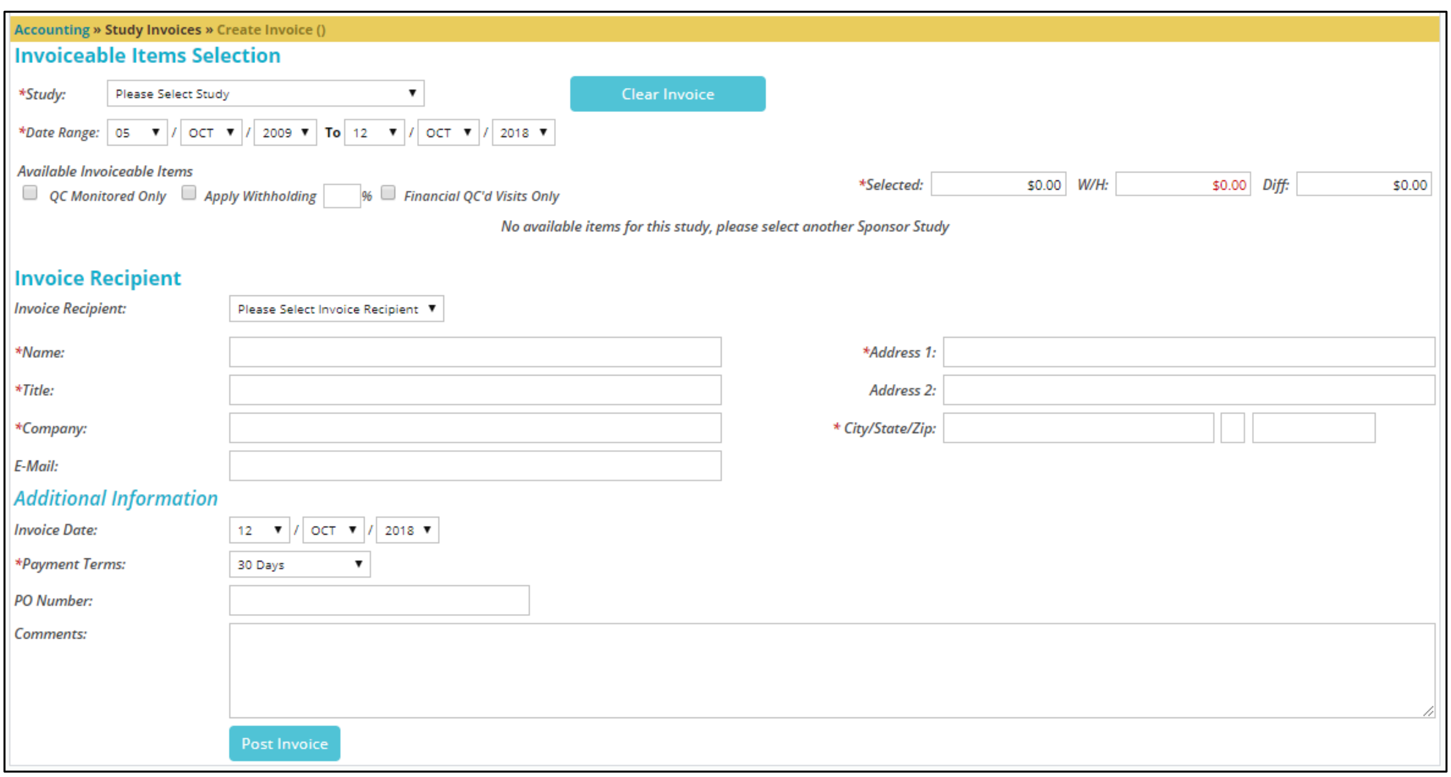


CREATING INVOICES

To create a new invoice, click the Create Invoice link in the Study Invoices section.



In the Create Invoice screen, select the desired study and a list of Invoiceable items will be displayed in the Available Invoice Items box. To exclude visits that have not been marked as QC Monitored, check the "QC Monitored Only" checkbox. Apply Withholding to items by checking the Apply Withholding checkbox.



Available Invoiceable items can also be filtered by a date range, if desired. To add items to the invoice, move them into the “Selected Invoiceable Items” box.

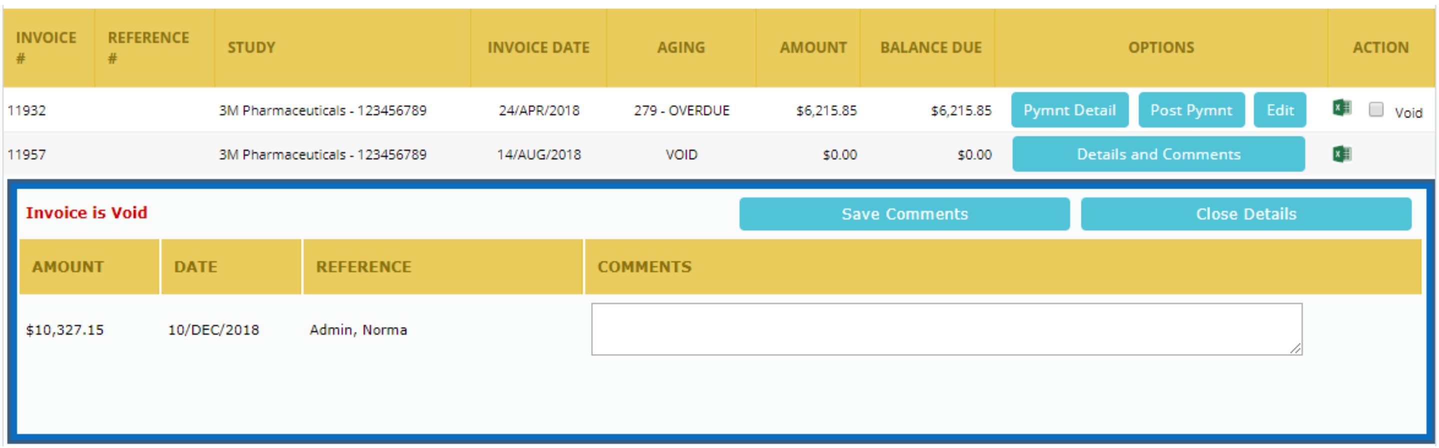
Once all desired items have been selected, complete the bottom section of the invoice details.

An invoice recipient can be selected from the drop-down, if available, or a new recipient can be created. Payment terms and comments may also be added. Once all information is entered, click the ‘Post Invoice’ button to create the invoice. The new invoice will now appear in the Manage Open Study Invoices page.

VOIDING INVOICES

To void an invoice, click the click the Void checkbox and the Update Selections button. Voided invoices will be listed and can be viewed when selected.

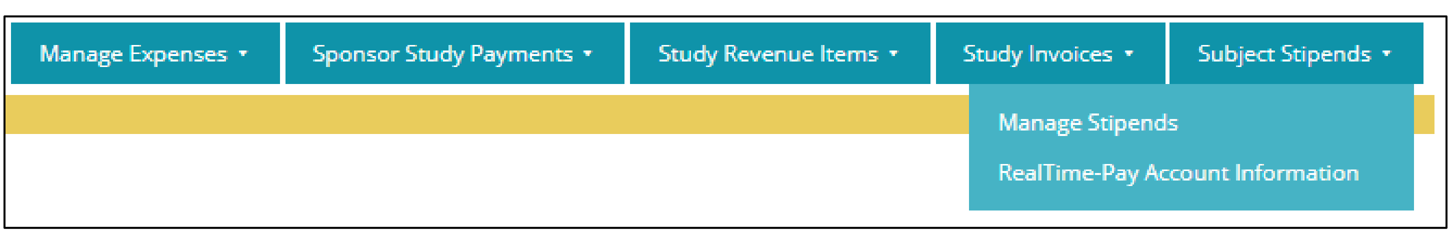
The items on the voided invoice are made available for future invoicing, the voided invoice amount and details of who and when the invoice was voided are captured, and comments can be added.



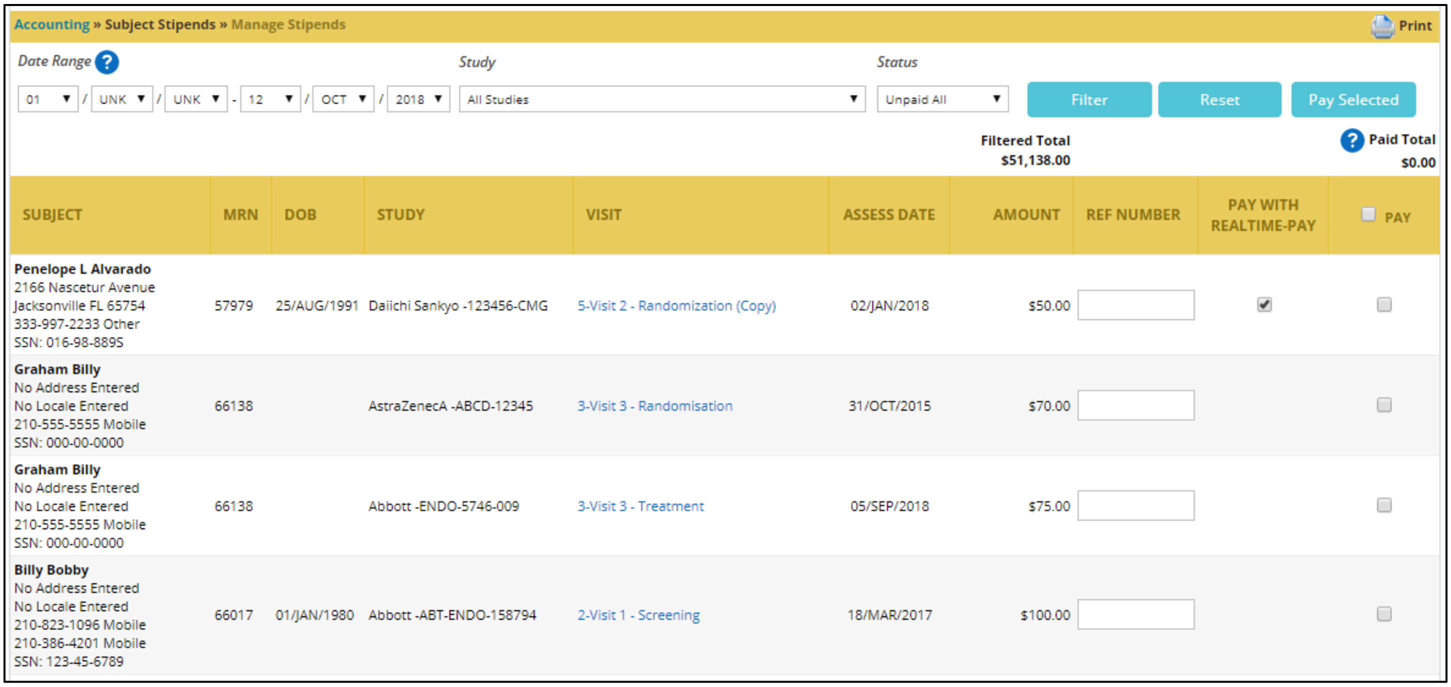
Voided invoices do not age, and the invoice amount is changed to $0 and are not reported as receivables.

SUBJECT STIPENDS

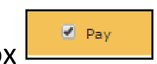
In the Subject Stipends area, there are the following choices at the top right of the screen: Manage Stipends and RealTime-Pay Account Information (when applicable).



As visits are submitted by coordinators, stipends due to subjects are listed in the stipend payment section of RealTime-CTMS. The Manage Stipends screen will display a complete list of all payable stipends.



Easily filter the stipends by date range, study and/or payment status (paid vs. unpaid). By default, the system will show you all UNPAID stipends for ALL STUDIES. Additionally, Customers using RealTime-PAY reloadable stipend cards will be able to filter by RealTime-Pay stipends. Refer to the RealTime-PAY manual with any questions.

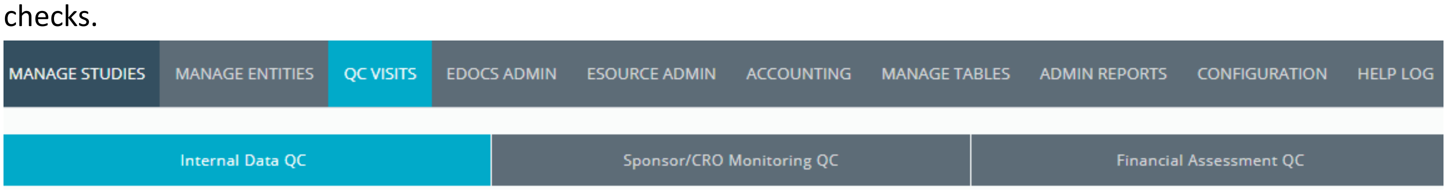
If you need to recall past stipend payments, simply switch the payment status to PAID and RealTime-CTMS will display a list of all PAID stipends for a given date range or for a certain study. At the top of the PAID column there is a universal checkbox. If you want to mark all stipends as PAID, simply click the checkbox 

. Directly above the Paid Checkbox, is a 'PAID TOTAL' summary. It will automatically total all of the stipends you have marked for payment. Stipend payment information will be available in the visit details screen and on the visit tracking log. To view stipend payment information in the Visit Tracking Tab, hover your mouse of the visit date and a tool-tip will provide stipend details.

QC VISITS

Quality Control (QC) checks are performed on submitted visits for the purpose of verifying that all information has been documented completely and properly, as well as verifying and adjusting any financial information.

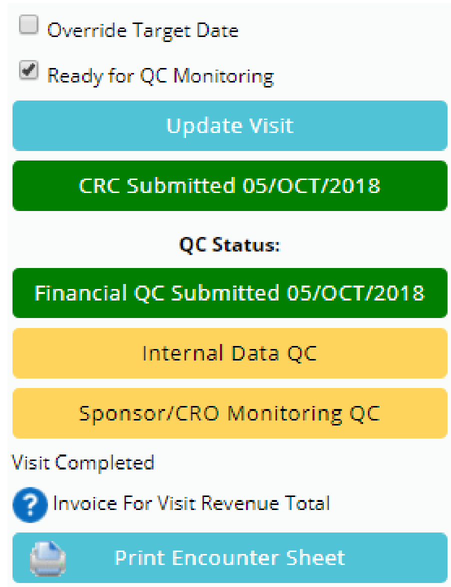
Visits that have been completed and submitted are listed on the QC VISITS tab(s) of the ADMINISTRATION page. System users with the Administration privilege can access the QC VISITS tab for the purpose of conducting QC checks.



Realtime provides three types of QC: Financial Assessment, Internal Data, and Sponsor/CRO Monitoring. The Financial Assessment QC section is enabled by default and is not configurable. The Internal Data and Sponsor/CRO Monitoring sections are optional and can be enabled on the CONFIGURATION tab.
See QC Audit Functions in the Configuration Tab section.

Visits listed on any enabled section in the QC VISITS tab have been submitted by clinical staff and are pending the type of QC under which the visit is listed.

At the visit level, a checkbox labeled "Ready for QC Monitoring" may or may not be selected. Visits with the checkbox selected will have a yellow button displayed at the visit level to submit the available types of QC.



If the checkbox is not selected, on the QC VISITS tab the visit will be listed with an orange checkmark. If the checkbox is selected, on the QC VISITS tab the visit will be listed with a blue checkmark. Visits that have been completed will have a green checkmark.

Click on a listing to view the assessment screen.

	STUDY
☑	Daiichi Sankyo - 123456-CMG
☑	Abbott - ABT-ENDO-158794
☑	Abbott - ABT-ENDO-158794
☑	Abbott - ABT-ENDO-158794
☑	Abbott - ABT-ENDO-158794

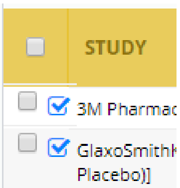
Visits may be accessed from the list by clicking on the listed visit. The visit will be opened in a new tab for QC review and submission as needed, then the tab can be closed. Once the visit is marked as "Financial QC Submitted", no additional modifications to the visit can be made by clinical staff. Only administrators can modify a visit that is marked as "Financial QC Submitted".

Visits that have the Financial QC Submission retracted due to a Milestone Action will be listed under QC VISITS>Financial Assessment QC. Retracted visits will have a red icon and only be listed on the Financial Assessment QC tab.

The Financial Assessment QC tab also has a checkbox to “Show only visits that have been Retracted”. Selecting this checkbox and applying the Filter will results in a list of visits that have had the Financial QC Submission retracted due to a Milestone Action.

Visits that have had the Financial QC Submission retracted can be submitted again at the visit level or via the Batch QC function but will be subject to retraction by any future Milestone Action.

Multiple visits can be QC submitted via the Batch QC button.



When the Batch QC button is selected, the option to select all visits or specific visits is displayed to the left of each visit in the list of visit. Selecting the Mark QC Completed button will display a verification box and provide that “Selected visits will be marked as QC Completed with today’s date.”

The Sponsor/CRO Monitoring QC process can be used to track when a visit becomes payable by a sponsor. Some sponsors will only pay for completed visits that have been monitored by a study representative. The QC Monitoring process can be used to track or delay those study visits until the study monitor (CRA) has reviewed and approved those visits for payment. RealTime-CTMS has a report that can be provided to the monitor that will display all un-monitored visits and allows the monitor to mark which visits were reviewed and approved.

For more information, see the *Monitoring Visit Progress Report* details in the User Manual.

ADMINISTRATIVE REPORTS

ADMIN REPORTS TAB

The Admin Reports tab is where reports containing financial and management data can be utilized. RealTime-CTMS will come with a handful of Administrative Reports; however, reports can be created for your site upon request from RealTime-CTMS Success Team. Because RealTime-CTMS is built on a powerful relational database, reporting capabilities are nearly limitless. Contact RealTime-CTMS Success Team for questions regarding adding new reports.

Administrative Reports in RealTime:

Business Development

- Investigator History Report
- Sponsor/CRO Study Matching Report
- Study Indication Matching Report
- Study Metrics

Financial Reports

-Advertising Expenses Report
-Phone Verifications Report
-Procedure Budgeting Report
-Provider Cost Totals Summary Report
-Provider Earnings Summary Report
-Provider Payment Transaction Detail Report
-Provider Workload and Expense Summary
-Revenue Forecast Report
-Sponsor Payments by Study Report
-Sponsor Payments by Transaction Report
-Stipend Payments (1099)
-Stipend Payments by Study
-Stipends Upcoming
-Study Financial Detail – Single Page Report
-Study Financial Detail – Tabbed Export Report
-Study Financial Overview Report
-Study Financial Summary
-Study Invoice Report
-Study Receivables Aging Report
-Text Message Usage

Managerial

-Active Studies Progress Report
-Audit User Access Report
-Help Log Report
-Mass Texting Report
-QC Submitted by Date Range
-Scheduling Chart Report
-Study Arm Template Export
-Submitted Visits by Date Range
-Trial Master Log Report
-User Privilege Report
-Visit Status – QC Submitted
-Visit Totals by CRC
-Visits Not CRC Submitted

RealTime-PAY

-Audit Stipend Loads
-Balance Detail
-Card Load History
-Payment Detail by Study
-Stipend Card Request
-Stipend Funding Request
-Study Payment Totals by Date
-Subjects Totals by Study
-Voided Transactions/Cards

Recruitment and Enrollment

-Recruiter Workload – Contact Outcomes Report
-Recruitment Funnel Report
-Recruitment Progress Report
-Red Flagged Subjects
-Subject Visit Forecasting

Scheduling and Enrollment

-Calendar Event Log (Beta)
-Scheduled Events Forecasting
-Scheduled Visits that are Past Due (Beta)
-Staff Workload Based on Upcoming Visits (Beta)

BUSINESS DEVELOPMENT

Investigator History Report

The Investigator History Report can be helpful when filling out Feasibility Questionnaires for studies. If a sponsor wants to know how many studies a particular Investigator has conducted, simply run the Investigator History report. The results displayed will show all studies the investigator has ever conducted as a Principal Investigator or Sub-Investigator. By clicking on the study name, a Study Enrollment Report will be displayed. This contains more detailed information about the study (Recruitment Start/Stop Dates, Recruitment Goal, Screened/Randomized Subjects, etc.).

Sponsor/CRO Study Matching Report

Displays all studies in system associated with the chosen sponsor or CRO. Information includes study phase, indication, status, and start/close date. Clicking on a displayed study will open that study's Study Enrollment Report for recruitment/enrollment statistics.

Study Indication Matching Report

An HTML or Excel report that shows any study that meets the selected options of Investigator and Indications. The HTML report allows you to click on a study to access the Study Enrollment Report for that specified study. This report can be helpful when filling out study feasibility questionnaires.

Study Metrics

Sort by Sponsor, CRO, Study Indication, Principal Investigator, and Phase. This report will display all information that you will need to help fill out feasibilities such as Goal, Actual Recruitment & Enrollment numbers, SIV Dates, Enrollment Dates, Study End Dates, etc.

FINANCIAL REPORTS

Advertising Expenses

Creates an Excel or HTML report, based on a selected date range, that shows advertising budget overview to include the advertising budget, advertising costs, balance remaining, and non-deducted ad costs.

Phone Verifications

Creates an Excel or HTML report, based on a selected date range, that shows by day how many valid and invalid phone numbers for new patients were entered into the system. Also provides the total cost to perform phone verification.

Procedure Budgeting Report

Creates an Excel or HTML report, based on the selected budgeting variables and procedures. The report shows average revenue from each procedure generated from all applicable studies. Also includes how much each procedure was paid for by each study.

Provider Cost Totals Summary Report

The Provider Cost Totals Summary will display the amount each provider has earned, how much you have paid them, and the remaining total due.

Provider Earnings Summary Report

Based on date range and payee selection, creates an HTML report which shows, by visit, of how much the provider has earned as well as the amount paid to the provider. Also includes sponsor payment information for each visit and tracks how many days have passed from the date that sponsor payment was received to when the provider was paid.

Provider Payment Transaction Detail Report

When a provider payment is created, a Transaction ID is generated. This report generates a nice detail of all payment information which can be printed to accompany a check to the provider. Select the desired Trans ID and click Display Report.

Provider Workload and Expense Summary

Creates an Excel or HTML report, based on a selected date range and provider selection, that shows the procedures performed by the selected provider. Information includes if the procedure has been paid and what date it was paid on.

Revenue Forecast Report

Easily forecast your projected revenues by running the Revenue Forecast report. Choose a date range and study. The report will compile the revenues based on the active subjects currently enrolled with future visits, and also will add in the per visit revenue per patient, if you are able to meet your monthly enrollment goals. See additional study information on how to change your monthly enrollment goals.

Sponsor Payments by Study Report

Run this report to view a quick listing of all payments received on a study. Payment amounts, dates, comments and a grand total are included.

Sponsor Payments by Transaction Report

Each time a sponsor payment is posted, a payment transaction ID is created. To view the details of a posted sponsor payment, select the desired ID and click the Display Report button. A list of all visits or other revenue items paid in the transaction will be generated in addition to other payment details.

Stipend Payments (1099)

Per Federal regulations, you are required to provide a 1099 to all study subjects that receive $600.00 or more in a calendar year. This report allows you to quickly compile a list of all 1099 eligible subjects in an Excel spreadsheet.

Stipend Payments by Study

Creates an Excel or HTML report, based on a selected date range and study selection, that displays patient/study/visit information and stipend payment details.

Stipends Upcoming

Displays upcoming stipends based on date range and Target/Scheduled date.

Study Financial Detail – Single Page Report

Based on study selection and date range, shows each visit completed, by subject, as well as financials tied to the visits. There is also an option to Display Revenue Totals Only.

Study Financial Detail – Tabbed Export Report

Uses selected date range and selected study(s) to generate a very extensive Excel financial report. Report contains multiple worksheet tabs which include Financial Summary, Earnings, Expenses, and Payments. Each respective tab contains every financial item tied to the study(s) and allows for easy filtering to help manipulate the data, as needed.

Study Financial Overview Report

This report provides a less detailed overview of all study earning, expenses, receipts and payments associated with the selected study.

Study Financial Summary

Generates an Excel summary report based on a selected date range that shows how much each study has earned and payments received on each study.

Study Invoice Report

When an invoice is created, an invoice number is created. To view an invoice, select the desired invoice and click display report.

Study Receivables Aging Report

Run this report to see a quick breakdown of how your earnings are aging for a particular study. This report will show just how far out your payments are from the sponsor as well as the date and amount of your last payment.

Text Messaging Usage

Provides a breakdown of the quantity of TEXTs sent and received by the site per day, over a selected date range, and calculates the total TEXT cost for each day.

MANAGERIAL REPORTS

Active Studies Progress Report

This report displays all of the information collected from the Study Progress tab. Managers may find this report helpful when trying to determine their site's effectiveness during study start-up and recruitment. The report can be run in two ways: display all active studies, or display one study at a time. When displaying the report for one study in particular, the progress notes section will be included. However, if you run the report for all active studies, then only the dates will be displayed.

Audit User Access Report

This report provides an accounting of user sessions (log-in, log-out, or session expirations) for one or more users within a user-selected date range.

Help Log Report

The items listed in the help log can be compiled and printed by running this report. All, Open, Info or Done items can be selected for inclusion into the report.

Mass Texting Report

Creates an HTML report, based on selected studies, which displays text message details including Study, Text Campaign ID, Patient Name/Phone/Email, Delivery Status, and Text Responses. Also, the report allows you to click on the text message details to take you directly to the patient's contact attempts page.

QC Submitted by Date Range

A report that provides when and by who each active visit QC area was completed, as well as when and by who the visit was Completed and Submitted. The report output is an Excel spreadsheet.

Scheduling Chart Report

Based on date range and CRC's selected, generates an Excel report that displays CRC, Study, Visit Name, Visit Date, Total Points, and CRC Cumulative points.

Study Arm Template Export

The Study Arm Template exports revenue and cost details for a selected template arm into Excel.

Submitted Visits by Date Range

Shows all submitted visits within selected time frame and organizes the visits by CRC. This HTML report also allows you to click on any visit and launch directly into the visit.

Trial Master Log report: Provides a listing of all subjects Enrolled into the selected study. An option to group the subjects by Study Arm is available. Output includes subject information such as Enrollment Status, name, address, screening/randomization number, DOB, and phone number.

User Privilege Report

Creates an Excel or HTML report, based on user selection, that shows all the privileges tied to that user profile.

Visit Status – QC Submitted

A report that provide an overview of the QC activity in a date range. Visits Submitted (Partial and Fully), and for each QC area, visit with Completed QC or Pending QC status. Details for each QC area include when and by who the visit was Completed, Submitted, and QC'd. The report output is an Excel spreadsheet.

Visit Totals by CRC

This report can be a useful management tool to assess the productivity of site coordinators. The report will generate a list of visits completed by each applicable study coordinator over the selected date range period. Checking the Display Revenue Totals checkbox will pull in the earned revenue amounts per visit.

Visits Not CRC Submitted

This report shows you which visits have not been submitted by the CRC but do have a completion date associated. The report will display how many visits are missing submission, the Sponsor/protocol, visit date, and visit name. Clicking a visit will open a new tab, allowing you to submit the visit. This can be very helpful since RealTime-CTMS cannot start tracking any invoiceable or financial information until a visit is fully submitted.

REALTIME-PAY

Audit Stipend Loads

Use this report to show all stipends loaded within a given time frame and the associated RealTime-CTMS user that loaded the stipend.

Balance Detail

Creates an Excel or HTML report, based on a selected date range, that shows a RealTime-Pay Account activity summary. Information includes both deposits and withdrawal transactions.

Card Load History

Creates an Excel or HTML report, based on a selected date range and MRN/Control Number, that will show all stipend payments that occurred.

Payment Detail by Study

Generates an Excel or HTML report that details each stipend payment based on study and date selection.

Stipend Card Request

Displays RealTime-Pay Card Request Report, based on selection, that gives details on the card request.

Stipend Funding Request

Allows selection of any past RealTime-PAY Funding Request submitted by the site and shows the RealTime-Pay Account Funding Report for that selection.

Study Payment Totals by Date

Displays unique subjects paid, number of payments, total payments and average payment across study/studies.

Subjects Totals by Study

Displays all subjects that have received stipends for a given study. Displays the number of payments, total payments, average payment and number of studies.

Voided Transactions/Cards

Displays any transaction associated with a card that was replaced and/or voided.

RECRUITMENT AND ENROLLMENT

Recruiter Workload – Contact Outcomes Report

Managers will find this report helpful when wanting to keep an eye on their team member's productivity. The Recruiter Workload report will display all progress notes left by a particular employee during a given time period. The total numbers will be displayed at the bottom of the report along with a recruitment status breakdown.

Red-Flagged Subjects

Managers will find this report helpful when wanting to keep an eye on their team member's productivity. The Recruiter Workload report will display all progress notes left by a particular employee during a given time period. The total numbers will be displayed at the bottom of the report along with a recruitment status breakdown.

Study Recruitment Progress Report

The Recruitment Progress Report can be run for all studies or by individual user. The report displays the most up to date recruitment information as captured by the recruitment and enrollment rosters. It is recommended that this report is run on a weekly or bi-weekly basis and reviewed by management in order to quickly identify potential recruitment barriers.

Recruitment Funnel Report

This new Excel report will provide a breakdown by study of subject recruitment efforts as subjects progress through the recruitment phase of a study up to the point of randomization.

Subject Visit Forecasting: Creates an Excel report, based on a selected date range and study arm, that forecasts upcoming visits by month.

SCHEDULING AND ENROLLMENT

Calendar Event Log (Beta)

Creates an Excel or HTML report, based on a selected date range, that groups calendar events by event status that includes the following information: Event Status, MRN, Patient's Name, Event Name, Study, Revenue, and Current Event Status.

Scheduled Events Forecasting

Creates an Excel or HTML report, based on end date and study selection, that provides a breakdown of upcoming visits. Information includes Scheduled Completion Date, Potential Revenue, and Current Status of the visit. Also, the HTML report allows you to click on the visit to take you directly to the scheduled visit event.

Scheduled Visits that are Past Due (Beta)

Creates an Excel or HTML report, based on user selection, that shows visit information such as Date Scheduled, Target Date, and Days Past Due. Also, the HTML report allows you to click on the visit to take you directly to the scheduled visit event.

Staff Workload Based on Upcoming Visits (Beta)
Creates an Excel or HTML report, based on a selected date range and user selection, that shows upcoming visits information such as Target Date, Scheduled Event/Date Time, Duration, Visit Name, and Revenue. Also, the HTML report allows you to click on the visit to take you directly to the scheduled visit event.

HELP LOG

The Help Log in RealTime-CTMS is a way for your site to communicate questions, problems or concerns to RealTime-CTMS Success Team. Adding a new item to the help log will alert RealTime-CTMS Success Team of your need, and a resolution process will begin during support hours. The help log will keep a chronology of Help Items and their statuses.

CALENDARING

The Calendar section of RealTime-CTMS allows users to keep track of patient visits, site initiation visits, monitor visits, and more. Other users can be invited to appointments on the calendar. For a full explanation of the calendar section, refer to the User manual.