STREAMLINING THE WAY RESEARCH SITES COLLECT DATA

SITE USER MANUAL

A FULLY VALIDATED AND PART 11 COMPLIANT ELECTRONIC SOURCE DOCUMENT MANAGEMENT SYSTEM FOR RESEARCH SITES, STUDIES AND PERSONNEL.
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RealTime-eSOURCE™ INTRODUCTION

RealTime-eSOURCE is an advanced data collection system that allows research sites to collect study data electronically rather than having to use paper-based source documents. With this feature, research sites are able to create custom electronic source documents that match the requirements of the protocol and sponsor EDC.

Furthermore, with our unique drag-and-drop form-builder tool, eSOURCE allows sites to create electronic source documents that match research site processes and procedural workflow. Study data can be collected using the RealTime mobile app or by using a PC/laptop utilizing any popular web browser (e.g., Google Chrome, Firefox, etc.).

GETTING STARTED

Logging-In

RealTime-eSOURCE™ is a web-based data collection system. Users will log into the system using a unique Site ID, username, and password. The login screen can be accessed by visiting www.realtime-ctms.com/login.

Your login credentials require a specific username and password in order to access the system. Your username will consist of the first initial of your first name and your complete last name. Example: John Smith, Username = jsmith. You will log in with a temporary password emailed to you for your first login. Once you have logged
into the system, you will need to change your password. Your new password *must* contain at least 8-12 characters and must contain at least 1-capital letter, 1-special character, and 1-number. Example: P@ssw0rd.

**Forgot Password/Failed Attempts**

Upon a failed login attempt, you will receive an alert that your login has failed. You will have five chances to login before you will be locked out of the system.

If you forget your password, you may contact your system administrator to request a password reset. You will also have an option to click on the ‘Forgot Password’ link on the log in screen. You may be asked to supply your email address to request a temporary password. Check your Spam/Junk folders if you do not see the email in your inbox.

**Time Out**

The system will automatically log you out after a certain time of inactivity (varies by site). Standard limits are 20 minutes of inactivity. A pop-up will alert you one minute prior to logging you out. Once the countdown has begun, you will have two options to choose from: **No, Log Out** and **Yes, Still Here**. Clicking **Yes, Still Here** will reset the clock. If no action is taken, the system will automatically log you out and the login screen will be displayed.

You will also see an alert in your browser’s tab.

**Browser Options**

RealTime-eSOURCE™ is optimized for Google Chrome, Mozilla Fox, Safari and Microsoft Edge. Internet Explorer is not recommended since this particular browser is quickly becoming outdated and no longer receives required updates from Microsoft to keep up with current technology.

**SYSTEM SECURITY REMINDERS**

To optimize security and remain compliant with 21 CFR Part 11 regulations, please remember to:

1. Assign usernames that identify the person. Generic usernames (e.g., System Admin) make it difficult for the system to assign individuals to the audit trail.
2. Never share user passwords.
3. Never email passwords or write them down.
4. Never allow browsers to save a username or password.
5. Never perform actions under someone else’s username and password.
GENERAL NAVIGATION

Upon logging into the system, the user will immediately view the Studies page. The Studies page will list all studies assigned to the user and can be filtered by study status (e.g., Upcoming, Active, Inactive).

From the Studies page, the user will be able to click the Visit Tracking button under the Options column.

This button navigates the user to the Visit Tracking page to view all study participants, their enrollment status, and projected/completed visits.
By clicking a visit date on the Visit Tracking page, the user will be able to view the Visit Assessment page for that visit. While this page allows users to indicate procedures performed/not performed at a visit, there will also be a link to view the eSource documents associated with the visit. The Subject eSOURCE button will only be viewable for studies that have eSOURCE activated (Please see section title, Activating eSource on a Study).

A second way to navigate to a subject’s eSource documents would be to visit the On Study page within the subject’s profile. The user will notice an eSOURCE column with a link to each visit eSource document.
After entering a subject’s eSource documents, the user will have access to the entire “Subject Chart”. With tab-navigation at the top of the screen and page-navigation on the left, the user will be able to access all visits, forms and procedures to view, collect or save data during a study.
MANAGING USERS AND STUDY ESOURCE DOCUMENTS

MANAGING SITE USERS

To learn more about adding/managing site users, please reference the RealTime-CTMS™ Administrator Manual located in RealTime University. This manual can also be obtained from RealTime-CTMS™ customer support.

*Please note that monitors/CRAs are granted remote access through the Study Contacts section of each study under the General Info tab. For more details on managing monitor portals, see the section titled Managing Monitor Portals.*

USER PRIVILEGES

Users will be assigned certain privileges depending on their role. To assign user privileges in the RealTime-eSOURCE™ system, an Administrator with the ability to Manage Entities will need to grant user permissions. Privilege settings are managed within the Managed Entities (System User Information) section.

The following is a description of each eDOCS privilege:

| eSOURCE: Source Builder                                      | • Allows user to view the form-building tool for studies they are assigned.  
|                                                            | • Allows user to build sections, tabs and source documents for studies they are assigned. |
| eSOURCE: Data Entry                                         | • Allows user to view eSource forms to collect data on studies they are assigned. |
| eSOURCE: View Only                                         | • Allows user to view eSource forms for studies they are assigned but will not be able to add/change data. |
| eSOURCE: Data Lock                                         | • Allows user to lock data entry on all forms related to a study they are assigned. Locking forms typically happens at study closeout. |
| Documents: Manage Study Contact Login                      | • Allows user the ability to issue monitor portals by setting usernames and passwords for reviewers. All of which is managed from the Study Contacts section under the General Information tab. |
CREATING SOURCE DOCUMENTS

ADD A STUDY

Administrative users have the ability to add new studies by visiting the Manage Studies tab within the administration section of the system. Simply enter the study details and assign the appropriate users before saving.

ACTIVATING eSOURCE ON A STUDY

Once a new study as added and saved into the system, a button will appear to activate eSOURCE.
Click the “Activate” button to open the eSOURCE feature for a study to start building electronic source documents, simply click the activate button. Once eSOURCE is enabled on a study, the system will display an audit trail of when it was activated and by whom. Please note, that once this button is activated, the site will start incurring charges for this study that apply to the eSOURCE feature.

LOCKING STUDIES

Feature coming soon... This feature will allow site users to lock source documents at the end of a study to prevent unwanted data changes during study archival. Users are being tracked by source document audit trails that allow sites to know if data was changed (including previous values) after a study has ended.

CREATE A VISIT TEMPLATE

After creating a new study, visit the Study Template tab for that particular study.

Within the Study Template area, create a study arm. Each study arm that is created can potentially have its own electronic source documents linked. This particular concept will be expanded upon in the next couple of
sections and allows study participants to be assigned to one or multiple study arms based on what documents are needed for data collection. As an example, a study participant may be assigned to a “Visit” arm which provides all source documents necessary to collect data at main study visits. The same study participant may also be assigned to an “Unscheduled Visit” arm to provide source documents to capture data at unscheduled visits.

After creating your study arm(s), add the appropriate visits. For eSOURCE purposes, it is not necessary to add visit financials during this process unless you are also using the CTMS feature to track study financials. The most important goal for eSOURCE purposes, is to create and project the study visits which will allow for visit tracking capabilities while subjects are participating. For more details on adding visits, projecting visit dates, and activating an arm, please refer to RealTime University → How to Create a Study Template (Video). RealTime University can be found using the University link after logging into your RealTime System.
The following is an example of a basic, five visit, study template that has been entered into the system and the arm has been activated to track study participants.
ADDING AND ORGANIZING SECTIONS & TABS

Enter the eSOURCE section of a particular study by clicking on the eSOURCE tab. This will allow the user to start organizing eSource sections and tabs.

Sections and tabs are very important for organizing subject source documents, and the subject chart. Sections and tabs built with the eSOURCE building tool ultimately become the navigation tabs when navigating the subject chart to enter data for a visit.

As mentioned in the last section, users can build source documents that are linked to each study arm. Users may also build source documents that are linked to a General arm that is available to all subjects by default. The General arm is a great place to include a section for General Progress Notes. Any documents built inside the General Arm will apply to ALL study participants regardless what study arm they are assigned to. Users can add as many sections, tabs and forms as they need to the table of contents.
The following is an example of the Sections and Tabs for a basic, five visit, study. These were built inside the actual “Visit” arm, not the General arm. This doesn’t represent the only way to organize your source document sections/tabs but this example has proven to be an effective method. Notice that this example includes separate sections/tabs for Medical History, I/E Criteria and Adverse Events. While these items can be built directly into your visits source documents, providing their own separate sections in the subject chart makes them easier for Investigators and research staff to find when navigating the forms during a visit.
If the site has a standard set of sections and tabs that need to populate on every new study, users can set up a master template inside the eSOURCE Admin section. Please see the next section for more details, Creating Template Sections & Tabs for more details.

**CREATING TEMPLATE SECTIONS & TABS**

Within the eSource Admin area, users can create and save a standard template of sections and tabs that start out on every study. As a new study is added to the system and electronic source documents are being built, this template will pre-populate to standardize the organization of subject charts across studies.
LINKING VISITS TO SECTIONS & TABS

Each section/tab can be linked to visits listed on the study template. In most cases, linking the tab to a study visit rather than the section will be more beneficial. Details will be explained in the coming paragraphs.

Linking visits from the study template to the source document sections/tabs allows Investigators and research staff to navigate source documents much easier and quicker when viewing the CTMS visit tracking page. Once linked, users can click on a subject visit indicated on the Visit Tracking page or subject On Study page and find a quick link to navigate to the source documents for that particular visit.
CREATING ESOURCE FORMS

After creating, and organizing, sections and tabs, it’s time to create source documents using the RealTime form-building tool. First, select a tab. In the example below, we have selected the “Screening” tab to create screening source document. The system will give the user multiple options:

1. **Blank Form:** This option is selected if the user wants to build a document from scratch.
2. **Use Template:** This option is selected if the user wants to copy an existing template from the eSOURCE Admin area. For example, if the site has saved a Screening source document template, this template can be copied to the new study. Procedures can be add/deleted on the template to meet the protocol requirements. For more information on creating or saving templates please visit section the for Creating and Saving eSource Templates.
3. **Copy Existing Form:** this option is selected if the user would like to copy an existing source document from the current study or any other eSOURCE study inside the system. For example, if the site has a similar visit document already created for the current study, or another study, the document can be copied to the new study. Procedures can be added/deleted on the document to meet the protocol requirements.

After a selection is made, the system will walk the user through titling the new form and, if applicable, copying the appropriate template/source document. At the end of this process, the form builder will automatically open the form to start adding elements and clinical widgets. More on adding elements and clinical widgets can be found in the section titled, Building/Editing Forms.
CREATING AND SAVING ESOURCE FORM TEMPLATES

Within the eSOURCE Admin section, users can build and save source document templates. Templates in this area can be copied to new/existing studies and modified to meet the protocol/EDC requirements. This process allows sites to have standard templates based on site processes and SOPs while also reducing the time it takes to make new source documents on studies.

While users have the ability to create a template “from scratch”, the system also allows study source documents to be saved as a template for later use. The “Save as a Template” option can be found in the form options when building electronic source documents for a study.
RealTime-eSOURCE allows users to track form versions and statuses. The following are definitions for each status:

1. **Draft**: Forms with a draft status are capable of being edited and are not available in the subject chart for data collection.
2. **Active**: Forms with active status are available in the subject chart for data collection.
3. **Inactive**: This status indicates that the form version was active in the past but is no longer active.

Depending on when a subject participates in a study, and when forms are activated, subject charts may end up as a mixture of active/inactive forms.
FORM OPTIONS

Newly created forms will display in Draft status. Draft forms are not activated and will not be available for data entry until they are changed to Active.

Each Draft form will have the following options available:

1. **Edit Form:** The pencil icon will open the draft form to allow editing.
2. **Revision History:** Allows the user to view an audit trail of users that have created/modified the form.
3. **Delete:** Allows users to delete a draft form that is no longer needed.
4. **Activate:** Changes a draft form to Active status to allow the form to be used for data collection.
5. **Create PDF Form:** Creates a template PDF version of the form for printing/viewing.
6. **Save As a Template:** Saves the form as a template within the eSOURCE Admin area. Templates can later be used to create new forms.

Active forms have similar options as Draft forms with the exception of two options:

1. **Create New Version:** Allows the user to create a new draft copy of the active form. This feature is used when amendments/changes need to be made to the source document.
2. **Deactivate:** Changes the form’s status from Active to Inactive.
BUILDING/EDITING FORMS

To build/edit a draft form, start by clicking the pencil icon.

The form-building tool will display and allow the user to add pages, title pages, drag elements onto the form, and create a procedural workflow. When building/editing forms, it’s important to always save on a regular basis, especially before you close a form.

Users can add as many pages as needed to a form. It’s best to think of each page as a procedure (e.g., vitals, ECG, Physical Exam, etc.). Each procedure will have its own page. Pages can be custom ordered to optimize procedural workflow, during the visit.
The following is an example of a screening visit form with multiple procedure pages. Keep in mind that pages can be reordered by dragging and dropping them in any order the site wants.
To test a draft form, simply click the Preview Form button at the top of the form-building tool.

Activating this button will present the draft form in a format that Investigators and research staff will experience when collecting data during a visit. The user will be able to click the buttons, enter data, and navigate pages on this draft form in an attempt to make sure that the form works as expected before changing the status to Active.

**TYPES OF ELEMENTS AND THEIR OPTIONS**

When building forms (source documents), elements are used to create fields that allow for data collection. There are two types of elements: **General** and **Clinical**. General elements are found at the top of the element
library on the left side of the screen. Each General element can be dragged onto the form to the right side of the library.

After an element is placed on the form, options and settings can be configured by clicking the element and the settings button to the right side.
The following is a list of General elements and their purpose:

**Address** – Populates all fields needed to collect a full address.

```
<table>
<thead>
<tr>
<th>What is your address?</th>
<th>Street Address</th>
<th>Street Address Line 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>City</td>
<td></td>
<td>State</td>
</tr>
<tr>
<td>ZIP Code</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
```

**Attach Resource** – Allows the ability to upload a document that users can view/print during a visit.

```
Attach Resource
MainICF_28Dec2015.pdf
12/JUN/2018 11:00 AM
Browse + Upload
```

**Camera Photo** – Allows user to take pictures using the camera on their device (Mobile App Feature Only)

```
Camera Photo
Camera Photo
Take Photo
```

**Check List** – Allows the user to select one or multiple options.

```
Click to Edit Label
- Option 1
- Option 2
- Option 3
```
**Date of Birth** – This field auto-calculates Age based on the date of birth entered.

**Date/Time** – Populates fields to enter date and time.

**Divider** – A divider is used to separate fields on a form.

**Dropdown** – A dropdown allows users to select one option from a list of multiple options.
**Electronic Signature** – Users may click the electronic signature button to sign electronic forms.

Electronic signatures can be configured to “soft” or “hard” lock pages and forms. More details on this feature coming soon.

**Email Address** – This field is special formatted to enter and save email addresses.

**File Upload** – This button allows users to upload files (PDF, DOC/X, XLS/X, PPT/X, ZIP, JPEG, PNG, MSG) when completing an electronic source document form.

**Form Section** – The Form Section element acts as a divider with a title and is used to divide sections on a form.
**Full Name** – This element populates all fields needed to collect a person’s full name, including middle name, suffix and title.

![Full Name](image)

**Image Upload** - This button allows users to upload an image file that is viewable to users when collecting data to an electronic source document form.

![Image Upload](image)

![ANATOMY OF THE HUMAN BODY](image)
Input List – Allows the creation of a repeatable table of elements.
Example Input List for an ECG Procedure

Subject must be supine for a minimum of 10 minutes prior to collection ECG.

<table>
<thead>
<tr>
<th>Time Positioned:</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time Performed:</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is ECG abnormal?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments required for abnormal findings:

Example Input List for an ECG Procedure (LIVE FORM)

Subject must be supine for a minimum of 10 minutes prior to collection ECG.

**ECG #1**

<table>
<thead>
<tr>
<th>Time Positioned:</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time Performed:</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is ECG abnormal?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments required for abnormal findings:

**ECG #2**

<table>
<thead>
<tr>
<th>Time Positioned:</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time Performed:</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is ECG abnormal?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments required for abnormal findings:

[Add Row button]
**Multi-line Textbox** – This field allows users to save comments/notes.

**Number** – This field is only for entering and saving numerical values. Text is not accepted with this field.

**Phone Number** – This field can be formatted to only collect a phone number format.

**Radio** – Radio buttons allow for multiple options but only one option can be selected at a time.
Single Line Textbox – Single line textboxes accept text, numbers and special characters.

Text – Text boxes can be used to save and display notes/instructions that users will see when navigating the electronic form.

Yes/No Toggle – Yes/No toggle buttons can be used to collect answers to questions during visits.
The following is a list of Clinical elements. Clinical elements are pre-configured “widgets” that group general elements to collect entire procedures. Typically, a clinical element will be a mixture of general elements (e.g., yes/no questions, number/text fields, dropdowns, checklists, etc.). All Clinical elements can be found in the library located on the left page of the form-builder. Once a Clinical element is dragged onto the form, it can be modified by adding/deleting General elements. At the time of this writing, the following is a list of Clinical elements.

<table>
<thead>
<tr>
<th>Clinical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Events</td>
</tr>
<tr>
<td>BMI</td>
</tr>
<tr>
<td>Blood Collection</td>
</tr>
<tr>
<td>Check-in Questions</td>
</tr>
<tr>
<td>Demographics</td>
</tr>
<tr>
<td>Diary Dispensation</td>
</tr>
<tr>
<td>Diary Return</td>
</tr>
<tr>
<td>Drug Accountability (Pill/Tablet)</td>
</tr>
<tr>
<td>Drug Dispensation (Pill/Tablet)</td>
</tr>
<tr>
<td>Drug Dosing</td>
</tr>
<tr>
<td>Drug Injection</td>
</tr>
<tr>
<td>Drug Patch Application</td>
</tr>
<tr>
<td>ECG</td>
</tr>
<tr>
<td>Imaging (Generic)</td>
</tr>
<tr>
<td>Informed Consent Questions</td>
</tr>
<tr>
<td>Medical History</td>
</tr>
<tr>
<td>Medication Washout</td>
</tr>
<tr>
<td>Medications / Treatments</td>
</tr>
<tr>
<td>Physical Exam</td>
</tr>
<tr>
<td>Prohibited Medications</td>
</tr>
<tr>
<td>Reminder Questions</td>
</tr>
<tr>
<td>Schedule Next Visit</td>
</tr>
<tr>
<td>Spirometry</td>
</tr>
<tr>
<td>Subject Scale/Questionnaire</td>
</tr>
<tr>
<td>Urine Collection</td>
</tr>
<tr>
<td>Urine Pregnancy Test</td>
</tr>
<tr>
<td>Vital Signs</td>
</tr>
</tbody>
</table>
Depending on the element, the following is a screenshot of common options you may find to customize fields.

### General Options

- **Label Field:** This option allows the user to type a custom label to the field.
- **Placeholder:** Adds placeholder text inside a field.
- **Required (Toggle):** This option indicates the field as required information.

### Study Roles

- Laboratory
- Coordinator
- Pharmacy
- Regulatory
- Quality Assurance
- Quality Control
- Principal Investigator
- Sub-Investigator

### Values

- **Empty Label:**
- **Seperate Label/Value:**

### Picker Options

- **Show Date Picker**
- **Show Picker Year**
- **Picker Months:**
- **Min. Date:**
- **Max. Date:**

### Date

- **Label:**
- **Required**
- **Hidden**
- **Allow UNK Values**
- **Confirm Changes**

### Time

- **Label:**
- **Hidden**
- **Allow UNK Values**
- **24-hour format**
- **Confirm Changes**
- **Increments:** 1
• Hidden (Toggle): This option will hide the field from view by users.
• Confirm Changes (Toggle): This option forces users to indicate a reason when deleting/changing data that has been saved inside the field.
• Assessment Icon (Toggle): This option adds a doctor assessment button to the field to support doctor notes/assessments.
• Allow Past Dates (Toggle): Indicates if past dates will be selectable by users for date fields.
• Allow Future Dates (Toggle): Indicates if future dates will be selectable by users for date fields.

Values:

• This section allows users to list options for checklist elements, dropdown elements, and radio elements.

Study Roles:

• This checklist allows users to assign one or multiple roles to a field. Once assigned, only indicated roles may enter and save data in this particular field. Roles are customized by the site (Please see section titled, Manage the Study Role Log for more details)

Picker Options:

• Allow UNK Values: Indicates if unknown values are acceptable for day and month.
• 24-hour format: Indicates if time fields will use standard time format or 24-hour clock format.
• Show Date Picker: Indicates if the date picker will be present when selecting dates on a form.
• Show Year Picker: Indicates if the year picker will be present when selecting dates on a form.
ACTIVATING FORMS

After drafting source document forms, users can determine when to manually activate a form so that it is “live” and available within the subject’s chart for data collection. While multiple versions of a form can be created, only one version can be active for data collection. Active forms can always be inactivated if needed.

REVISING ACTIVE FORMS

To revise an active form, create a new draft version before making changes/amendments.

Depending on the size of the form and number of elements, it may take several seconds to create the draft form. Once the draft is generated, users may make changes and activate the new version when ready.
MANAGING THE STUDY ROLE LOG

Each study will have its own study role log that can be managed within the Study Role Log section. Users are added to this log when they become authorized users on a study.

Once a user is listed on the study role log, study role(s) and special assignments may be assigned by clicking the View / Edit button.
After assigning user roles, source document fields/forms can be customized to only allow specific roles to enter data. This helps drive compliance by preventing users from entering/saving data inside forms that are not assigned to them.

Sites have the ability to create as many roles as they want by customizing the Study Roles table within the Manage Tables section.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Sub-Investigators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Doliitte</td>
<td>David Jones</td>
</tr>
</tbody>
</table>

Special assignments include:

- Allow user to perform safety assessments on this study
- Allow user the ability to generate Unscheduled Visit source documents for this study
- Allow user to generate SAE forms for this study

<table>
<thead>
<tr>
<th>Special Assignments</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check/Uncheck All</td>
<td>Add Entry</td>
</tr>
<tr>
<td>Coordinator</td>
<td>Update</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Update</td>
</tr>
<tr>
<td>Regulatory</td>
<td>Update</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>Update</td>
</tr>
<tr>
<td>Quality Control</td>
<td>Update</td>
</tr>
<tr>
<td>Principal Investigator</td>
<td>Update</td>
</tr>
<tr>
<td>Sub-Investigator</td>
<td>Update</td>
</tr>
</tbody>
</table>

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• **Allow user to perform safety assessments on this study:** This assignment is perfect for investigators that plan on overseeing safety assessments on source documents (Normal, Not Clinically Significant, and Clinically Significant).

• **Allow user the ability to generate Unscheduled Visit source documents for this study:** Users that need the ability to generate an unscheduled visit source documents will need this assignment.

• **Allow user to generate SAE forms for this study:** Users that need the ability to generate SAE forms will need this assignment.

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**ENTERING DATA**

RealTime-eSOURCE™ offers two options for entering and saving data during a visit. One method is to utilize the web-browser forms accessed through the main browser-based system. Web-browser forms allow users to enter data using a PC/laptop and are best accessed using an up-to-date browser such as Google Chrome or Firefox. It is not recommended to use Internet Explorer because Microsoft is no longer supporting updates for this browser and will not offer the latest technology to keep up with updates made to the RealTime system.
In addition to entering data on a PC/laptop, users have the option of utilizing the RealTime mobile app available for Apple (iOS) and Android devices. While the mobile app will scale down to the size of a mobile phone, it is best to use a tablet with a screen size of about 7 inches or larger. We have found that a 9.5 inch iPad works perfect.

The mobile app can be downloaded from the Apple App store or the Google Play store.
ELECTRONIC SIGNATURES

Users have the ability to sign eSource documents that have the Sign Electronically button. This feature allows users to electronically sign without logging the current user off. During the process, the audit trails keep track of the user that is logged in as well as the user that signs.

Once the button is clicked, the user is presented with a popup to select a statement of testament, select a username, and enter a PIN/Password.

Once the signature has been established, full details will display in place of the signature button.
SOURCE DOCUMENT NOTES

At the bottom of each page/form, users will have the ability to add notes. Notes added to this section of the form will include a date and time stamp. This section is great for documenting CRC/Investigator notes about the subject's visit/procedures.
INVESTIGATOR ASSESSMENT OF UPLOADED DOCUMENTS/RECORDS

Users can use the File Upload buttons to upload visit records (e.g., Labs, ECGs, and other reports).

After uploading a record, two new icons will appear next to the file name. One icon is for deleting/removing the record. The other icon is for activating the document review tool.

Activating the document review tool allows users to make notes/assessments, or sign the record using the buttons at the top of the page.
Notes and assessments can be placed anywhere on the form. There is no limit to the number of notes/assessments that can be applied to the record. This tool allows investigators and staff to view and assess records at the site or remotely without the need to print paper.
Users delegated the ability to make safety assessments on the Study Role Log will be able to click the doctor icon to the right of select fields and indicate if a value is Normal/Abnormal. All users have the ability to click this icon to write notes but only those with the appropriate privilege will be able to select/make an assessment. Once a note or assessment has been made, the icon will turn yellow.
AUDIT TRAILS

The system tracks user actions and generates full audit trail details during data collection and the form-building process.

Data Collection

Form-Building
MANAGING MONITOR PORTAL

The monitor portal allows sponsor CRAs/monitors to access their assigned study records. A monitor portal unique to each user can also be assigned to Sponsor/IRB auditors and FDA inspectors as needed. The monitor portal only reveals records specific to the user’s study assignment (managed by the site) and records cannot be altered through this portal. eSOURCE documents are in read-only format when accessed through the monitor portal.

SETTING UP A MONITOR PORTAL

Setting up a monitor portal is simple. After identifying the assigned study, locate the Study Contacts section at the bottom of the General Info tab.

Ensure that the contact is added to the study contacts list and click the Edit/View button under the Options column for that individual. The webpage will expand and allow you to assign a username and temporary password for the contact.
The study contact must have a valid email address since the person will receive their temporary password and portal access link via email. A username must be set up by the site user. It is suggested to use the person’s first initial combined with their last name. For example, if the person’s name is John Smith, then his username will be jsmith. Another simple option would be to use the person’s email as their username.

Next, select the user’s Access Type from the dropdown menu.

Lastly, assign the appropriate study access using the list of Available Studies.

Before sending a temporary password to the study contact, you must save this contact’s information with their newly assigned username.

Once the username is saved within the system, a new link will appear within the Password section to Set & Send Temporary Password to User. Once this link is clicked, the study contact will be assigned a monitor portal for viewing study records and will receive an email with their portal web address and temporary password. Due to security reasons, the site user will need to inform the study contact of their username. The username will not show up in the same email as the temporary password.
WHAT IF A MONITOR LOSES HIS/HER LOG-IN INFORMATION?

If the study contact has already been issued a monitor portal, you will see that it is Currently Set under the Password section. If the study contact has lost his/her username and password, a site user can inform the monitor of their assigned username and use the Set & Send Temporary Password to User to send a new temporary password to their email.

MONITOR QUERIES

QUERY NOTIFICATIONS

Users can issue comments and queries through the monitor portal. Queries can be reviewed and responded to by site staff by visiting the subject’s source documents. An eSOURCE Query notification page is coming soon.
To view a query/conversation, simply click the query icon 📤 on the eSOURCE page. This will activate a pop-up window that catalogues all discussions about a particular query between the monitor and the site user.
RESPONDING TO A QUERY

To respond to a monitor’s comment, simply type your message in the message box at the bottom of the pop-up window and click the [Post New Message] button. This button only posts the message to the discussion board and does not indicate to the monitor that the query has been addressed.
MARKING A QUERY AS “ADRESSED”

To mark the monitor’s query as Addressed, simply click the Mark as Addressed button next to the monitor’s comment.

Once the Mark as Addressed button is clicked, the monitor will be notified through the monitor portal that the site has addressed the query. Please note that this button does not close out the query. Only the monitor will have the ability to close out a query/discussion after verifying that appropriate actions have taken place.

For more details about the query system, specifically from the monitor’s point of view, please reference the Monitor Portal User Manual provided by Real Time Software Solutions, LLC.

QUERY STATUSES

The Query button will display an appropriate color during the query process to indicate the query status. Below are the statuses:

Red Query icons indicate Unaddressed Queries, or a query from the monitor that needs to be addressed by the site.

Yellow Query icons indicate Addressed Queries, or a query that has been addressed by the site and is pending response from the monitor.

Grey Query icons indicate fields without active queries.
GENERATING ADMIN REPORTS

A detailed description of administrative reports is coming soon.

GENERATING FRONTEND REPORTS

A detailed description of frontend reports is coming soon.
While there isn’t a standard process, below is an example workflow when creating electronic source documents for a new study. eSource documents can be activated for data collection at any time, but to ensure quality, an internal QC review process is highly recommended before activation.

**Step 1**
- **Create Study Visit Template**
  - Procedures with costs and revenues are not required before starting to build eSource documents.

**Step 2**
- **Create Initial eSource Packet**
  - The initial packet may include Medical History page, Inc./Exc. Criteria, Screening Visit, Baseline Visit, Early Termination Visit, Unscheduled Visit, AE Log, ConMed Log, and General progress Notes page.

**Step 3**
- **Review Initial eSource Packet**
  - An internal QC review process helps make sure that eSource documents meet site SOPs and the protocol.

**Step 4**
- **Create Remaining eSource Visits**
  - Previous visits can be copied and modified for future visits. This speeds up the source building process.
Active eSource documents can be revised at any time during a study to add/remove fields and settings. All new versions of a form with revisions will be applied to visit forms that have not already had visit data saved. This logic prevents study data from accidently being removed which means that each subject may be on a different version of the eSource document depending on the timing of the changes and the subject’s visit. Below is a typical process for making revisions to an eSource document.

**Step 1**
- **Create a Draft Version of the Active Document and Make Changes**
  - Unless the active form is deactivated, the active form will remain in use for data collection while the draft is being altered.

**Step 2**
- **Review Changes to the Draft Document**
  - An internal QC review process helps make sure that eSource documents meet site SOPs and the protocol.

**Step 3**
- **Activate New Version of the eSource Document**
  - Once a draft form is activated, the status will be updated. The previous active form will no longer be in use except for subjects that have already saved data in that version of the form.