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Silent Infarct Transfusion (SIT) Trial
REDCap (Research Electronic Data Capture) System at Washington University in St. Louis, School of Medicine

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SIT Trial Data Management with the REDCap System

REDCap (Research Electronic Data Capture) is a secure, web-based application that was designed exclusively to support data capture for research studies. The REDCap system will be used to capture data from the SIT Trial, beginning on June 1, 2010.

Security and Backup

The REDCap system is hosted in the private zone of the WUBIOS Computing Resource within the Division of Biostatistics at Washington University in St. Louis. It is separated from the Internet by a firewall. WUBIOS is a professionally managed, HIPAA compliant network. Users are granted site-specific privileges on a form-by-form basis. The database is backed-up periodically throughout each day and the database is backed up offsite nightly.

Request Tracker

Request Tracker (RT) is an automated system that will be used as a tool to monitor, prioritize, answer, and document questions and requests pertaining to SITT procedures and the REDCap system. Both web and e-mail interfaces can be used with RT.

You must have a username and password to access RT, and these are sent to SIT Trial personnel at the time they join the study.

Requirements

Web Browser

You must use a web browser, such as Firefox, Internet Explorer, or Safari (on a Mac), to access REDCap. We suggest you install the most up-to-date version.

Username and Password

A user-specific username and password is required to log into REDCap. To request an account, fill out the form—Request for REDCap User Account—and return it to Robin Woltman, at the Statistical Data Center (SDC), by email at robinw@wubios.wustl.edu, or fax to (314) 362-3440.

This form must be signed by your principal investigator (PI).

Personal Sidedoor Web Certificate

Users must have a personal Sidedoor web certificate installed in their web browser in order to access the REDCap system. To request a Sidedoor certificate, fill out the form—Request for Sidedoor Web Certificate—and return it to Robin Woltman, by email at robinw@wubios.wustl.edu, or fax to (314) 362-3440.

This form must be signed by your principal investigator (PI).

Your personal Sidedoor web certificate will be sent to you by email, along with step-by-step instructions for installing it into your browser. You will not be able to access the REDCap login page until your Sidedoor certificate has been installed.
Using REDCap

Login

Once your REDCap account has been created, your username and password will be sent to you by email.

To log in, open your web browser, navigate to the SIT Trial home page, and click on the applicable button, SITT Training or SITT Data Entry, to open the REDCap login page. Enter the username and password you were assigned, and then click Log in. You should now see a web page welcoming you to REDCap.

To change your password, click on My Profile, at top right, to open the Edit Your User Profile page. Click the Reset password button at the bottom. You’ll be asked if you wish to reset your password for logging in to REDCap. Click OK. The Set Your Password page will open. Enter the password you want to use for REDCap, retype it for verification, and then click Submit. Click Continue >> on the Password Changed! page to return to your REDCap home page.

Your password must contain at least one upper-case letter, one lower-case letter, and one number.

REDCap Home

Once you successfully log in, you’ll be taken to REDCap Home page, where you are welcomed to REDCap and provided with information about the system and some of its features. In addition to Home, you’ll see two other tabs on this page: My Databases and Training Resources.

My Databases

Click on the My Databases tab to see a list of the two databases you’ll use for the SIT Trial—Scheduling & Data Entry and Ad Hoc Events. The Scheduling & Data Entry database is used to collect data from scheduled events, such as transfusions and monthly checks, defined in the study protocol. The Ad Hoc Events database is used to collect data for non-scheduled events. Open the desired database by clicking on its name.

Training Resources

Click on the Training Resources tab to open the REDCap Training Resources page, where you can learn more about REDCap by viewing examples and watching videos. The REDCap Overview will show you the basic concepts of the system, including what a REDCap database is, how to create one, and how to use one. You may also want to review the Longitudinal Database + Scheduling demo to get an idea of the functionality of the SITT database. To do this, click on the adjacent magnifying glass icon to open the REDCap Demo Database (Longitudinal + Scheduling).

Scheduling & Data Entry Database

From the My Databases tab on the REDCap page, click on SIT Trial: Scheduling & Data Entry to open that database.
Once you've opened the Scheduling & Data Entry database, look to sidebar on the left side of your screen. The sidebar, shown at left in Figure 2, contains links to the REDCap functions you will use. The sidebar is static, meaning it stays in place and remains viewable and clickable no matter where you are in the database. What you choose in the left sidebar determines what is displayed on the remainder of the screen.

The sections that follow describe the functions that are listed in the sidebar for this database.

**My Databases**

Click My Databases to return to the tab on the REDCap page that lists the databases to which you have access.

**Database Information**

Clicking Database Information opens the Database Information page, which displays information specific to the database, including current users, database statistics, and upcoming calendar events. If you wish to send an email to a SITT user, just click on the individual’s name, listed in parentheses, in the Current Users table.

**Scheduling**

Click the Scheduling link to open the Scheduling page, where you'll see two tabs: Create Schedule and View or Edit Schedule. Choose Create Schedule to generate a new schedule for a new or existing SITT participant. Choose View or Edit Schedule to view or edit an existing schedule of events for a participant.

View [VIDEO: How to use this page (6 min)](#) to learn more about Scheduling.

**Data Entry**

Click the Data Entry link to open the SITT Data Entry application. From here, you will choose an existing SITT Study ID, or create a new one, for the participant whose data you wish to enter.
**Calendar**

Clicking the Calendar link opens a project calendar that will help you organize your schedule and keep track of upcoming events. Events for SITT participants that are set up using the Scheduling function will appear on your study calendar. As you can see in Figure 3 above, each entry on the calendar shows the time, followed by the Patient ID and event name.

You can add unscheduled, or Ad Hoc, events by clicking on +New in the box for the day you'd like to schedule. The Add New Calendar Event screen will open, where you can add details about the new event. Clicking on an existing event will open the View/Edit Calendar Event page, which will provide you with further information about the event and allow you to make edits. You can also access the data entry forms for the event from the View/Edit Calendar Event page.

You can choose how you want to view your calendar—Day, Week, Month, or Agenda—just click the appropriate tab. Click the printer icon or Print Calendar link, if you'd like to print a paper copy of the calendar.

View **VIDEO: How to use this page (5 min)** to learn more about using the Calendar.

**File Repository**

Click the File Repository link to open the File Repository page, where SITT study documents can be stored and retrieved. For example, as shown in Figure 4, the Toxicity and Non-Neurologic Outcomes Criteria Worksheet (#27), which is needed to complete the Serious Adverse Event Form (#25), has been uploaded to the File Repository. You can download documents in the File Repository, as needed, by clicking the green arrow icon in the Action Column.

Documents in the File Repository can be accessed by personnel from all sites. **Do not upload Private Health Information (PHI) to the File Repository!**
General Help
The General Help link can be disregarded, as the information found here pertains mainly to developing a database, rather than generating schedules and entering data.

Video Tutorials
Click the Video Tutorials link to bring up a list of instructional videos for various REDCap functions. Click on the name of a video to begin playing it immediately.

Data Entry
The Data Entry application is used to enter data collected during regularly-scheduled study events. To begin, click the Data Entry link in the sidebar to bring up the Data Entry home page. As shown in Figure 5, this is where you choose the Study ID of the participant for whom you want to enter data.

Selecting a Participant
To open a record for a participant, you need to first choose the applicable arm, as shown above in Figure 5. The arm you select determines the Study IDs that appear in the adjacent dropdown box. Each of the four arms is described below:

1. Arm 1: Treatment: Transfusion – Select this arm to access Patient ID numbers for participants assigned to the Treatment Arm, and for whom you wish to view or enter forms associated with regularly-scheduled study events, except interim medical histories and transfusions, which are accessed through Arm 2: Transfusion & Interim Med History.

2. Arm 2: Transfusion & Interim Med History – Select this arm to access Patient ID numbers for participants for whom you wish to view or enter the Interim Medical History Form (S17r1) and/or Transfusion Form (S31r4). This arm includes Patient ID's for all randomized participants, those assigned to Treatment: Transfusion and Observation: Non-Transfusion.
3. **Arm 3: Observation: Non-Transfusion** – Select this arm to access Patient ID numbers for participants assigned to the Observation Arm, and for whom you wish to view or enter forms associated with regularly-scheduled study events, except interim medical histories, which are accessed through Arm 2: Transfusion & Interim Med History.

4. **Arm 4: Screening** – Select this arm to access Patient ID numbers for all participants who were screened, and for whom you wish to view or edit forms associated with screening events. Additionally, you need to select Arm 4: Screening to access the Ad Hoc Event Tracking Form (see page 10). The Patient ID numbers shown for Arm 4 include those for all randomized participants, as well as those for participants who were screened but not randomized.

Once you select an arm, click the dropdown box for Choose an existing Patient’s Identification Number, scroll down to find the ID you need, and click it to open the Event Grid for that participant, or click on the Choose an existing Patient's Identification Number dropdown and manually type in the ID, which will take you directly to that number in the list and highlight it, then click the ID or press Enter to open the participant’s event grid.

**Do not use the Enter a new or existing Patient’s Identification Number field to open a participant's record!** If you enter the Study ID incorrectly, you’ll create a new ID. Likewise, if you enter the ID correctly, but choose the wrong arm, you’ll create an identical Study ID in the wrong arm.

### Event Grid

The Event Grid displays all of the defined events for a specific Patient ID, along with all of the data entry forms required for each event. The Event Grid also lists the specific forms required for each event and shows the data entry status of each form. A portion of the Event Grid for Patient ID "1234567" is shown below in Figure 6.

![Figure 6: Event Grid of defined study events for Patient 1](image)

The events for this participant, assigned to Arm 1: Treatment: Transfusion, are listed across the top of the grid, and data entry forms are listed in the first column. A red button indicates that a particular form is required for a particular event. For example, if you refer to Figure 6, you’ll see that Forms S20r0, S21r0, and S22r0 are required for the Events C&B Tests 1 (Cognitive & Behavioral Tests 1) and C&B Tests 2 (Cognitive & Behavioral Tests 2).
In referring to Figure 6, you will notice that some events on the event grid are not needed, or show in what appears to be the wrong place. These events appear because visits/events were numbered in the MMRI system differently than they are numbered in REDCap. These inconsistencies will be corrected at a later date.

**Status of Data Entry Forms**

You can easily determine the data entry status of a form by referring to the color, red, yellow, or green, of the button in the event grid:

- **Red = Incomplete**: The CRF has not been started.
- **Yellow = Unverified**: The CRF has been entered, but some values are missing or need to be confirmed, so the form is not considered to be finished.
- **Green = Complete**: The CRF has been completed in its entirety. All values have been entered.

**Opening a Data Entry Form**

From the Event Grid, click the colored button in the field that corresponds to the form for a particular event. That form will open and you can begin entering data.

Once you open a form, a list of all other forms required for the event will show in the sidebar under Data Entry, as shown at right in Figure 7. Here, too, the status of each form is denoted by a colored button, red, yellow, or green. To open a form from the sidebar, click on its name. Just make sure you save your current form first to prevent any loss of data.

**Data Entering a Form**

Once you’ve selected the Study ID to open the Event Grid, and then clicked the colored button for the form you want, it will open and you can begin entering data.

⚠️ **Save your work frequently, at least every 20 minutes!**

In REDCap questions on forms are listed in rows, one after another, on a single page. Each row contains two columns: questions are shown in the first column and data is entered in the second. The types of fields used in the SIT Trial databases are described below.

- **Text Box Field**: Enter text or numeric values in this field. Each numeric value must be entered in the specific format denoted by (x), with each x representing one numeric character. When you enter a lab value, enter only the numerical result, and not the unit of measure. Validation testing, such as range checks, will be implemented in certain text box fields to warn of invalid entries that require resolution.

- **Time Field**: To enter a time, click the clock icon to open a set time window with two columns: Hour and Minutes.
In the Hour column, first choose AM or PM, then choose the hour between 1 and 12, and advance to the Minutes column. Minutes are listed in 5-minute increments, so choose minutes from between 00 and 55. The time you select will appear in red at the top of the time window. If it is correct, click Set to populate the field and close the set time window.

Though the set time function uses a 12-hour clock, the time field is populated with a 24-hour time.

We do not recommend it, but you may also enter a time manually. However, you must be sure you enter the time in the correct 24-hour clock format: hh:mm.

- **Date Field**: To enter a date, click the calendar icon, which will open a calendar set to the current month and year.

![Figure 9: Selecting a date](image)

Select the month and year from their respective dropdown lists, and then click on the day of the month to select it. As soon as you select the day, the calendar will close and the field will be populated with the date you chose. The month and year can also be selected by clicking 🔄 or 🖇 to move backward or forward through the calendar.

We do not recommend it, but you may also choose to enter a date manually. However, you must be sure you enter the date in the correct format: yyyy/mm/dd.

- **Radio Button Field**: Choose one correct answer, from multiple choices, by clicking in the circle next to your selection. Just one choice is allowed. In a Radio Button field, you can change your response by selecting a different value. To clear your response, click the "reset value" link, as shown in Figure 10 below.

- **Dropdown List Field**: Click within a dropdown box to reveal a list of answers and then select the one you need. Just one choice is allowed.

- **Checkbox Field**: Choose all that apply by clicking the box next to each of multiple answers.

- **Upload Document Field**: This field allows you to upload a document and associate it with a specific form. Click on the Upload Document link to open the Upload Document for: window and browse for the file you wish to upload; then click the button Upload Document to add it to your form.

- **Required Field**: All fields are required. If you do not enter a response for a required field, you'll receive a warning at the time you save your data. The warning message will inform you of what specific fields are missing values and prod you to enter them. However, a missing value will not prevent you from saving your form and going on to another.

- **Branching Field**: Branching is utilized for cases in which the answer entered in a particular field determines what data is requested in one or more subsequent fields. For example, as shown in Figure 10 below, by entering SI: Kilograms (kg.) for #1, the next item, #1A, requests weight in (xxx kg.) Alternately, had #1 been entered as Conventional: Pounds (lbs.), the following item, #1A, would have asked for weight in (xxx lbs.)
• **Hidden Field:** To streamline data entry, some fields remain hidden until they are needed. For example, as shown in Figure 10 above, because #2 was answered "abnormal," the next item, #2A, was revealed. Had the answer to #2 been "normal," #2A would have remained hidden.

• **Form Status Field:** It is here that you enter the data entry status for the current form. To answer the question "Complete?", shown in Figure 11 below, you'll be presented with the three options—Incomplete, Unverified, and Complete—shown in the adjacent dropdown list. Choose your answer, either Incomplete (not started), Unverified (entered but values missing), or Complete (all fields have been entered and form is finished). The default answer is Incomplete.

Your answer to the question "Complete?" determines the color of the status buttons for the forms shown in the Event Grid and sidebar.

### Ad Hoc Events

The Ad Hoc Events database is used to collect data for non-scheduled events that are not tied to a specific protocol-defined event. Examples of ad hoc events are headaches, adverse events, serious adverse events, transfusion reactions, infection complications, and chelation therapy complications. Some forms, such as the Transcranial Doppler (TCD) Performance Form (S05r1), Neurological Consultant Report (S10r1), and Transfusion Form (S31r40), are found in both the Ad Hoc and Scheduling & Data Entry databases, as these forms are completed for regularly-scheduled events, but are sometimes needed for unscheduled events.

Before you can begin entering data into the Ad Hoc Events database, you must first enter the Scheduling & Data Entry database and add the event(s) to the Ad Hoc Events Tracking Form, found in the Screening arm event grid.
**Ad Hoc Events Tracking Form (Scheduling & Data Entry Database)**

The Ad Hoc Event Tracking Form, found in the Scheduling & Data Entry database, is used for two purposes: 1) to keep a cumulative record of all ad hoc events for each participant; and 2) to generate a new record for each event in the Ad Hoc Events database. Every ad hoc event must be added to the participant's Ad Hoc Event Tracking Form before form(s) can be entered in the Ad Hoc Events database.

To add a new ad hoc event to the cumulative tracking form, open the Scheduling & Data Entry database, click Data Entry in the sidebar, choose Arm 4: Screening, and then choose the Patient ID to open the Screening event grid. Once the grid opens, locate the dot for the Ad Hoc Event Tracking form in the Screening column (third from the top), as shown in Figure 12 below, and click on it to open the form.

![Figure 12: The Ad Hoc Tracking Form in the Arm 4: Screening Event Grid (Scheduling & Data Entry DB)](image)

Ad hoc events are tracked by Patient ID, Event Date, and Event No, but all you need to enter are the date and event number, as in the example below in Figure 13.

![Figure 13: Enter the date and number of each event to the Ad Hoc Events Tracking Form](image)
- **Event Date** – The event date is the date on which the event actually occurred. Click the calendar icon to select the year, month, and day of event.

- **Event No** – Click the dropdown to select the event number. If a *single* ad hoc event occurred on a particular date, select "1" from the Event No dropdown, as shown in Figure 13 for the dates 2010-06-01 and 2010-06-08. If there are *multiple* ad hoc events for a participant on the same date, 3 different AE’s, for example, you’ll need to enter each separately, as in the example in Figure 13 showing 3 events, numbered 1, 2, and 3, on 2010-06-16. Note that a single event may require multiple forms. For example, if the AE for the first event on 2010-06-16 involved a hospitalization, then both the Adverse Event Reporting (S25r1) and Hospitalization (S34r0) forms will need to be entered for Event No. 1.

After entering the event(s), scroll to the bottom of the Ad Hoc Events Tracking Form and save it. REDCap runs a check on the Ad Hoc Events Tracking Form every 5 minutes, and creates an Ad Hoc Event ID in the Ad Hoc Events database for each newly-saved event it finds (see Ad Hoc Event ID Numbers below). Thus, it will be approximately 5-7 minutes before you can choose your new Event ID from the Ad Hoc Events database. In the meantime, however, you can continue to enter other forms.

### Ad Hoc Events Database

From the REDCap Home page, click on SIT Trial: Ad Hoc Events to open that database. As in the Scheduling & Data Entry database, you’ll see a sidebar on the left, with links to My Databases and Database Information located at the top, and a link to the File Repository located under Applications. However, rather than providing links to Scheduling and Data Entry, the Ad Hoc Events sidebar provides a direct link to each ad hoc form in the database, as shown at left in Figure 14.

### Ad Hoc Event ID Numbers

When you enter and save an event in a participant’s Ad Hoc Events Tracking Form in the Scheduling & Data Entry database, a record is generated in the Ad Hoc Events database. The ID number for each record (event) consists of the Patient’s Identification Number, Event Date, and Event Number. An example is shown below:

**4900102_20071008_3**

The number 4900102 is the Patient ID; the number 20071008 is the date 8 October 2007, and the number 3 is the event number. Because the event number is 3, there will also be records for at least 2 other events for this participant—4900102_20071008_1 and 4900102_20071008_2—for 8 October 2007 (as described above under Event No).

### Accessing Ad Hoc Events Forms

Forms in the Ad Hoc Events database can be accessed in two different ways:

1. The first is to click the link for Ad Hoc Participant Events, select the Event ID from the Incomplete Records dropdown, and then select the form you need. This method is most useful when you want to find out which forms were entered for an event.

2. The second is to select a specific form from the sidebar and then select the Event ID from one of the three dropdowns—Incomplete, Unverified, or Complete. This method is most useful when you need to enter a new form or edit an existing form for an event.
**Selecting an Ad Hoc Event**

To review the forms you entered for an event, find the link to Ad Hoc Participant Events in the sidebar and click it to open the Ad Hoc Participant Events index page. An example is shown below in Figure 15.

![Ad Hoc Participant Events](image)

*Figure 15: List of all Ad Hoc Participant Events*

On the Ad Hoc Participant Events index page, you’ll find all Event ID’s for your site in the Incomplete Records dropdown box, regardless of the status of the forms for the events, whether Incomplete, Unverified, or Complete. Scroll down to find the event you need and select it to open the Ad Hoc Participant Events form for the event you chose. You do not need to do anything on this form. Its purpose is to bring up the sidebar to show you the forms that were entered for the event, denoted by yellow or green buttons, according to the status—Unverified or Complete—you selected at the time you entered them. If you wish to view or edit one of the forms you entered, click the link for the form you wish to open. That form’s index page will load, and you’ll need to select the Event ID from the applicable dropdown box, as described in the following section.

**Selecting an Ad Hoc Form**

To open the index page for a specific ad hoc form, click on its name in the sidebar. The index page for the Headache Event Form is shown below in Figure 16.

![S14r0 Headache Event Form](image)

*Figure 16: Selecting an Event ID*

Select the Event ID you need from one of the three dropdown boxes—Incomplete Records, Unverified Records, or Complete Records—described below. Note that only participants from your site will appear in the dropdowns.

- **Incomplete Records** – If the specific ad hoc form, the Headache Form (S14r0) in our example, has not been entered for an event, you will find the Event ID in the Incomplete Records dropdown box.

- **Unverified Records** – If you started a Headache Event Form for this event, but have not finished it—and you changed the status field to Unverified—select the Event ID from Unverified Records. By default, the Unverified Records dropdown box is hidden. If you want it to be visible, click on Show Unverified Records. The Unverified Records dropdown box will be added to the list, and the link will now read Hide Unverified Records dropdown, as shown in Figure 16.
• **Complete Records** – If you finished entering a Headache Event Form for this event – and you changed the status field to Complete – select the Event ID from Complete Records. Figure 16 shows a partial list of Event ID’s from the Complete Records dropdown box.

If you wish to download a blank copy of the form to your computer, click **Download page as PDF**, as shown at top right in Figure 16.

**Data-Entering an Ad Hoc Form**

Once you select the Event ID from the appropriate dropdown on the form’s index page, the data-entry form will open. Additionally, the sidebar will show a yellow or green dot next to any other forms that were entered under this Event ID, as long as the status field was updated at the time the form(s) were completed. As in the Scheduling & Data Entry database, the questions on ad hoc forms are listed in rows, one after another, on a single page. Each row contains two columns: questions are shown in the first column and data is entered in the second. You’ll enter data in the same types of fields used in the Scheduling & Data Entry database. Be sure you complete the Form Status section, found at the bottom of every form, to indicate whether the form is Incomplete, Unverified, or Complete, and save the form frequently, using one of the options described in the next section.

**Saving a Form**

To keep from losing any data you’ve entered, it is extremely important that you save often, at least every 20 minutes, particularly if the form you’re working on is a long one. In addition, it is always good idea to first save your work whenever you go away from your desk.

The Save buttons, shown in Figure 17 at left, are found at the bottom of every form.

Press Ctrl + End from anywhere in a form to quickly advance to the bottom and save your data.

You have four options for saving data: Save Record, Save and Continue, Save and go to Next Form, and –Cancel–. Each option is described below.

1. **Save Record** – Click Save Record to save the form you are currently working on. In the Scheduling & Data Entry database, REDCap will save the data and then display a confirmation page. The confirmation page for a saved record looks like that shown below in Figure 18.
When you save a form in the Ad Hoc Events database, REDCap displays a similar "successfully edited" confirmation on the form's index page.

2. **Save and Continue** – Click Save and Continue to save the current form and continue working on that same form. REDCap will return you to the top of the form after saving the data. Save and Continue is particularly useful when you are entering a long form.

3. **Save and go to Next Form** – Click Save and go to Next Form to save the current form and advance to the next form for the event. This option is not available if you are working on the last form for an event. You'll recall that the forms required for each event are displayed in the Event Grid (Figure 6); and when you are entering data in a form, the other forms required for the event are listed in the sidebar under Data Entry, along with the name of the event and arm (Figure 7).

4. **Cancel** – Click Cancel if you do not wish to save your data, and REDCap will return you to the participant's Event Grid, if you are working in the Scheduling & Data Entry database, and to the home page for the specific form, if you are working in the Ad Hoc Events Database. Note that any data entered since your last Save will be lost when you click Cancel.

⚠️ **Save your work frequently—at least every 20 minutes!**

**REDCap Timeouts**

To maintain the security of its data, REDCap is set to time out after 30 minutes of inactivity, which means that REDCap will log you out if you have not saved your work or refreshed your web browser for more than 30 minutes. Performing one of the following three actions regularly will prevent REDCap from timing out:

- **Save your work** – Whenever you save your work, using one of the options described above, REDCap restarts the 30-minute clock, so this is another good reason to save frequently. Remember—pressing CTRL + End will quickly take you to the save options at the bottom of your form.
- **Press the F5 key on your keyboard** – This will reload the page on which you are currently working and restart REDCap’s 30-minute clock.
- **Press the Reload button in your web browser** – This will also reload the page on which you are currently working and restart REDCap’s 30-minute clock.

REDCap will warn you twice—at two-minutes, as shown below in Figure 19, and at 30 seconds—before it logs you out.

![Figure 19: Timeout Warning](https://sitedoor.biostat.wustl.edu)

**Data Verification**

Checks are performed on certain fields, such as those containing dates or lab values, to verify that the data entered falls within the ranges that have been defined for SITT. If you’ve entered a value that is out of range, when you save your data, you will receive a warning similar to that shown in Figure 20 below.
Missing Values

If you are missing values for some fields, leave those fields blank. When you save your form, you may receive a warning that values are missing; but you will not be prevented from saving the form and going on to the next one. The Statistical Data Center will routinely run a check on all forms with a Complete status, and generate queries for any missing values (blank fields). When you receive a query, you will need to either make a correction to the REDCap form or notify the SDC that the value cannot be obtained.

Editing a Data Entry Form

To edit a data entry form, select the participant's Study ID to open the Event Grid, and then click the button in the Event Grid that corresponds to the form you wish to edit. The form will open, displaying the most recently-entered data for the event. Navigate to the Correction field and select the Yes button; navigate to the field(s) you wish to edit and make your change(s); and then scroll to the bottom and save the form. If your edits complete the form, be sure you change the status to Complete before saving and exiting the form.

In the Ad Hoc Events database, select the form you wish to edit from the left sidebar and then choose the Event ID from the dropdown box on that form's home page. Select Yes in the Correction field and make your change(s) to the field(s) you wish to edit. When you are finished, scroll to the bottom and save the form. If your edits complete the form, be sure you change the status to Complete before saving and exiting the form.

REDCap keeps a behind-the-scenes list of all edits made to SITT forms.

PDF Forms

All REDCap forms can be downloaded and saved as PDF documents. At the top of each form, to the right of the form name, you'll find two links, Download page as PDF and PDF with saved data, as shown in Figure 21 below:

To download a blank copy of the Demographic / Phenotypic Information form to your computer, click Download page as PDF. To download a completed copy of the form to your computer, click PDF with saved data. Once you've downloaded a PDF to your computer, you can print it out on paper, as needed.

Click PDF with saved data, prior to entering any data, to download a blank form that includes the Participant ID or Event ID in the upper right hand corner.
Scheduling

The Scheduling application is used to generate a schedule of events for each SITT participant in the Scheduling & Data Entry database. Schedules are based on required events for the arm to which the individual is assigned. To generate a new schedule, click Scheduling in the left sidebar to open the Scheduling application at right. You have two tabs to choose from: Create Schedule and View or Edit Schedule. Create Schedule is the default view, as shown below in Figure 22. As all participants should be randomized at the time you begin using REDCap, you should not need to generate any schedules for new participants. However, it is possible that you may need to generate one for an existing participant whose schedule has not yet been created.

![Scheduling](image)

To generate a schedule for Participant 123, choose the arm from the Select Arm: dropdown and then select the Patient’s Identification Number: from the – choose existing unscheduled – dropdown. Next, choose the Start Date: by clicking on the calendar icon and choosing the date on which the first event is to take place. Finally, click the button Generate Schedule to bring up the projected schedule, shown below in Figure 23. Here you can enter times and change dates, as needed. When you are finished, click Create Schedule to generate the final schedule.
You can make changes to a schedule by clicking on the View or Edit Schedule tab and then selecting the Patient’s Identification Number from the dropdown box. Participant 123 was selected to bring up the existing schedule shown below in Figure 24.

![Figure 24: A portion of the existing schedule for Patient “123”](image)

If you wish to change the time, date, status, and/or notes for the event, click the pencil icon. The event will change to the editable view shown in Figure 25 below. When you are finished with your edits, click Save to commit your changes and return to the normal, non-editable view. To delete an event, click the red x icon.

![Figure 25: Editing the project schedule for Patient “123”](image)

You can also edit an event by clicking the magnifying glass icon, which opens the View/Edit Calendar Event screen. You cannot edit the event date here, but you can edit the status, time, and notes. You can also access CRFs required for a particular event from the View/Edit Calendar Event screen, which is particularly useful if you’ve edited a status to confirm that an event took place, and would now like to proceed with entering the associated forms. In the example shown in Figure 26 below, note that the red dots indicate that these forms are incomplete. To return to the schedule of events, click view schedule, located next to Patient’s Identification Number.
If you wish to add an ad hoc, or unscheduled, event to the participant's schedule, scroll down to **+Add new Ad Hoc calendar event on (date)** at the bottom of the schedule, as shown in Figure 27, and select the date from the calendar that pops up when you click the date field, then click the Add button.

The Add New Calendar Event screen, shown below in Figure 28, will open, giving you the option to add the time and a description or note about the ad hoc event.

To add the event to Participant 123’s schedule, and to the study calendar, click the Add Calendar Event button.
These types of Ad Hoc events cannot be linked to data-entry forms. SITT Ad hoc events, such as serious adverse events, adverse events, headaches, etc., must be recorded on the Ad Hoc Events Tracking form and the forms subsequently entered into the Ad Hoc Events database.

Since ad hoc events cannot be linked to forms, they are more useful as a tool for including notes, reminders, and confirmations, in general or for a specific participant, on the study calendar.