



# User Manual

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7/18/2017

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## A. CRIO Overview

A few facts about CRIO before you get started:

1. We are Part 11 compliant. That means that our system adheres to the guidelines set forth by the FDA for use of electronic systems in clinical research. A Part 11 system means that electronic source is considered the equivalent of handwritten source, and electronic signatures the equivalent of handwritten signatures. Please keep in mind that Part 11 compliance is ultimately the responsibility of the principal investigator; we can help you to ensure your site is compliant and has appropriate documentation in place.
2. Our system is web-based. All data is encrypted, both at rest and in transmission. You may use our system on any web-enabled device. We do have an optional Android app you can download from the Google Play Store that helps organize your day's visits. We have guidelines on the type of tablet you may wish to purchase. You are able to save or print blank source templates in case you need hard copy back-ups in the event of an Internet outage.
3. Our system is designed to support multiple languages. Currently, we have a Spanish language version, and more languages are coming. Each site can specify its own display language, as well as time zone.
4. Our system supports organizations with multiple research sites. Each site is treated as a separate unit, with its own users and studies. A user may be a member of multiple sites.
5. Every user in our system has their own account. An organizational administrator invites those users to their organization, and, from there, each user has specific rights to each study. When a user leaves an organization, the administrator may de-activate access; however, the user keeps his or her account profile.
6. External users, which include monitors or CRA's, have read-only, remote access to the particular study he or she was invited on. All subject names are anonymized, meaning subjects are displayed by initials only, with all contact information stripped out.

We invite you to review the training videos and other support elements of our Help section. In addition, we offer LiveChat, including phone support, should you require immediate support.

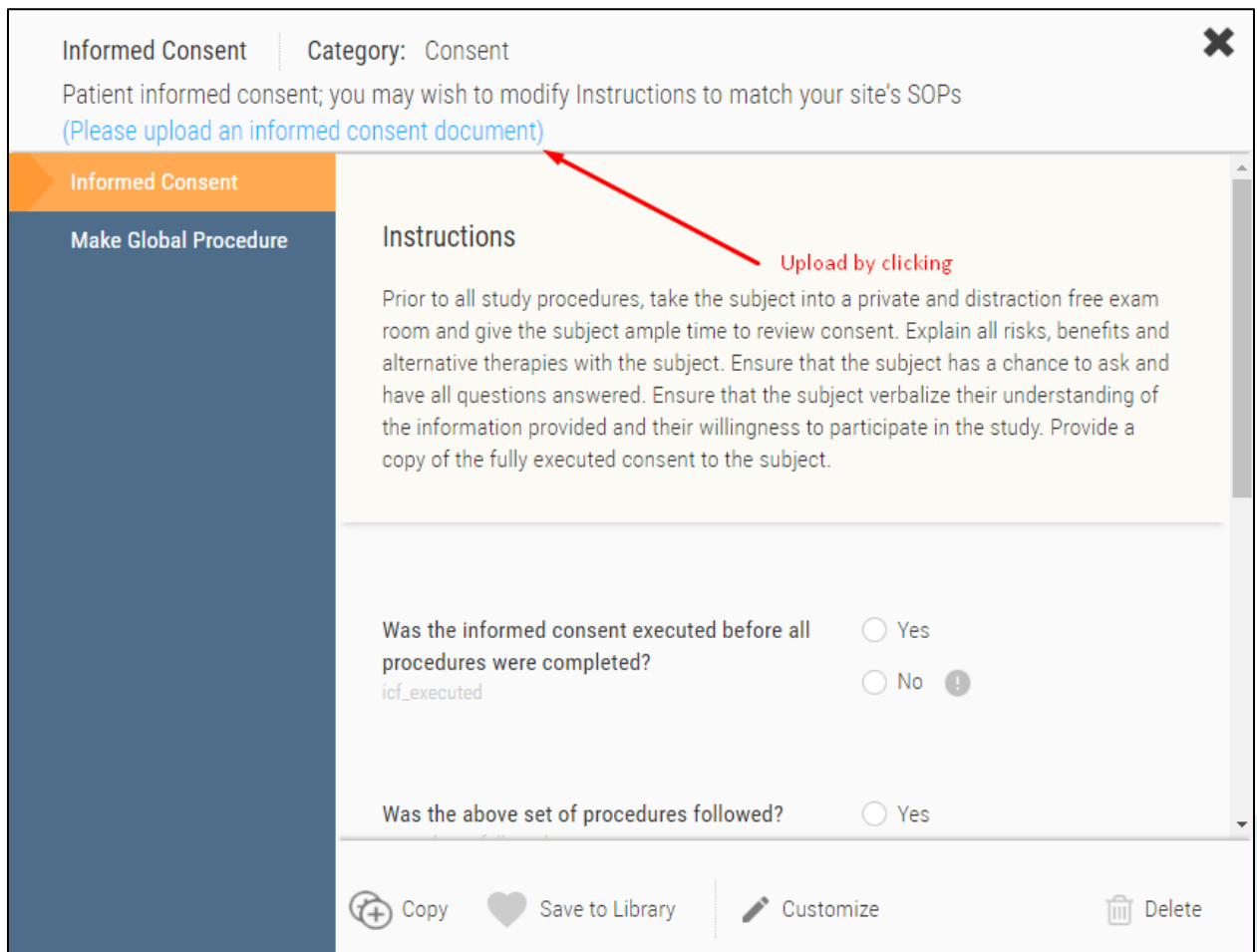
info@clinicalresearch.io / 617-302-9859

## B. Study Set-up

### B.1 Informed Consent:

In order to properly configure your informed consent procedure, first add the informed consent procedure from our global template library and modify according to your study.

In order for CRIO's ICF tracking to work properly, the category of the procedure must be "Consent", the first question within the procedure must be a Yes/No question where "yes" means that the consent was signed and there must be a timestamp in the procedure (e.g. a datetime field). The first date field in the procedure will be recorded in the ICF log as the date that the ICF was signed. After adding the procedure to your study, upload the informed consent form. This may be done in two places: by opening up the procedure and clicking the blue hyperlink at the top of the procedure or in the overview tab, scroll down to the Documents section and select the blue hyperlink to upload it.



Informed Consent | Category: Consent

Patient informed consent; you may wish to modify Instructions to match your site's SOPs  
[\(Please upload an informed consent document\)](#)

**Informed Consent**

Make Global Procedure

**Instructions**

Prior to all study procedures, take the subject into a private and distraction free exam room and give the subject ample time to review consent. Explain all risks, benefits and alternative therapies with the subject. Ensure that the subject has a chance to ask and have all questions answered. Ensure that the subject verbalize their understanding of the information provided and their willingness to participate in the study. Provide a copy of the fully executed consent to the subject.

Was the informed consent executed before all procedures were completed?  Yes  No !

icf\_executed

Was the above set of procedures followed?  Yes

Copy Save to Library Customize Delete

**Documents**

[Add New Document](#)

[Copy](#) [Excel](#) [CSV](#) [PDF](#)

Show  entries Search:

Document Name	Category	History
(Waiting on file upload)	Informed Consent (For procedure Informed Consent)	

Showing 1 to 1 of 1 entries Previous **1** Next

### Update Document ✕

Procedure: Informed Consent

---

+ 
  ?

---

No file chosen

From here you must enter the version # and an optional version/approval date may also be included. Here you may choose the file and upload the document.

Once uploaded, go back to the configure tab and ensure that the informed consent procedure is checked off for every visit that may need a re-consent. There's no need to check it off for phone visits. The procedure will call upon any new version only if the ICF procedure is checked off. Once a version of that informed consent procedure has been completed it won't pop-up for the



subsequent visits. Once a new version has been uploaded then it will be the first procedure of the next visit. If you happen to be moving to CRIO in the middle of a study, I would recommend you complete this procedure in the first CRIO visit that way this procedure doesn't pop-up during the subsequent visits. Put in the date that the ICF was actually done, and that is the date that will populate in the CRIO ICF log.


A protocol may have an optional consent form - i.e., if a subject is interested, they will sign the ICF; if not, they will not sign. To fulfill the system's logic requirements, we recommend you write the ICF template as follows:

- 1) The first question should read "Was the ICF presented to the subject?"
- 2) What time was the ICF presented?
- 3) Did the subject opt to participate by executing the ICF?

Please see our global template, "Optional Informed Consent".

## **B.2 Customizable tiles – study nicknames**


If your site prefers to use other names/nicknames other than the protocol number for your study for easier tracking, you may now create a nickname for that study. To create a nickname, go to that study's overview page and edit the Nickname field. This nickname will appear on the study cards on the Studies page and Dashboard, as well as on the study dropdown within a study.

 TEST DEMO  
Chronic Condition

Overview | Subjects | Progress Notes | Comments | Files | Logs | Configure

[Description](#) | [Documents](#) | [Users](#) | [Configuration Access](#) | [External Users](#)


### Description

Our Site #:  555

Indication: Chronic Condition

Status: Enrolling


Target: -

Nickname:  -

Comments: Injection study with take-home pills

Study Details	
Market Name	CLASSIC
CRO	-
Sponsor IRB	-
Phase	Phase III
CT Gov Identifier	-

**P** Nickname Demo

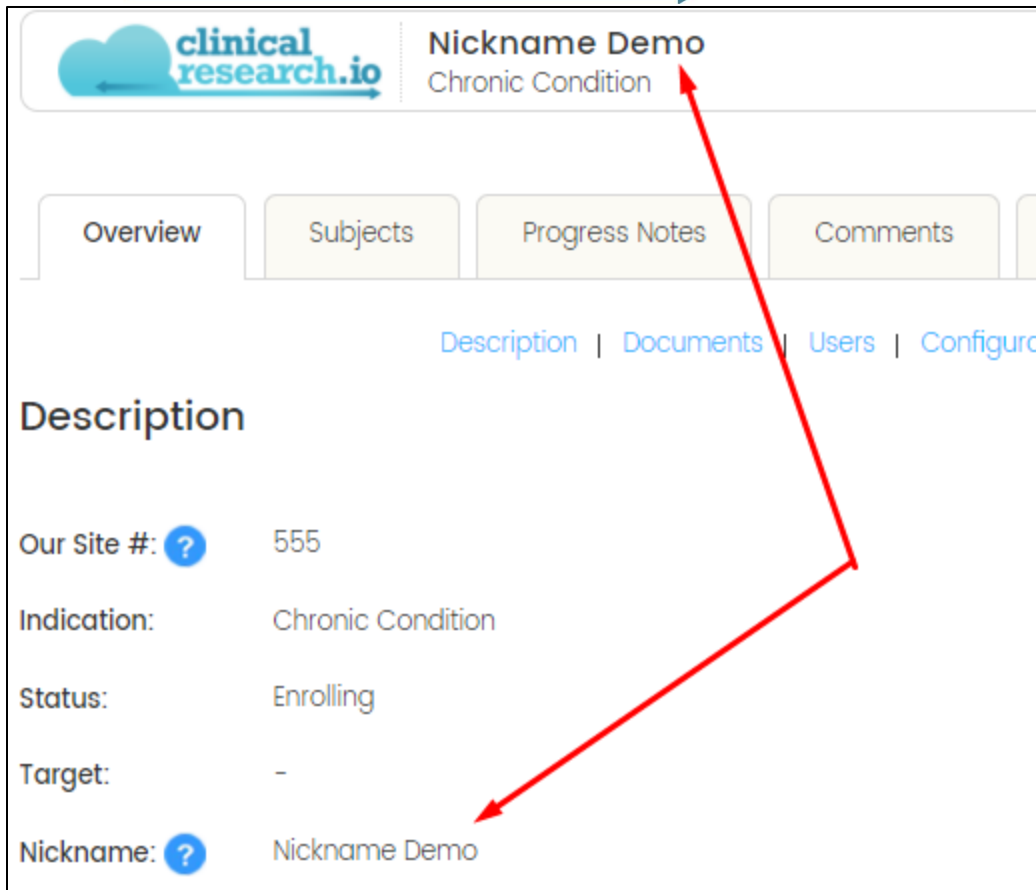


Chronic Condition

8 Screened  
6 Active

**ENROLLING**





Nickname Demo  
Chronic Condition

Overview | Subjects | Progress Notes | Comments

Description | Documents | Users | Configuration

**Description**

Our Site #: 555

Indication: Chronic Condition

Status: Enrolling

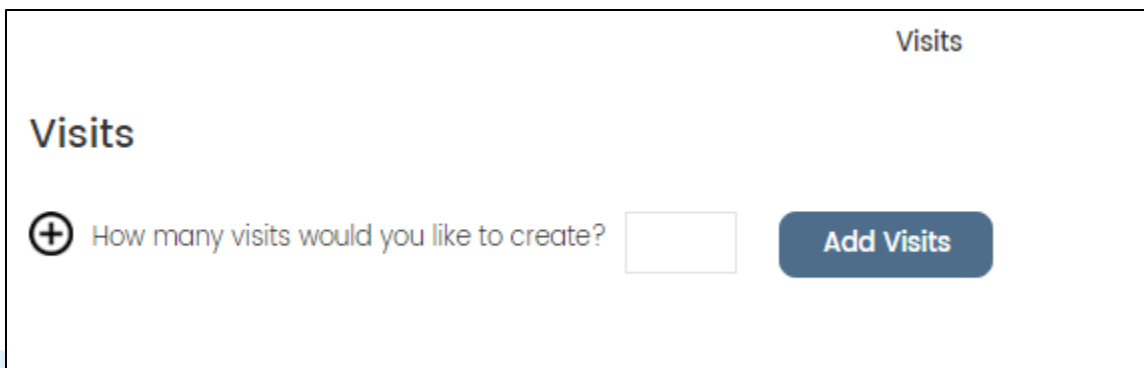
Target: -

Nickname: Nickname Demo

## C. Configuration:

### C.1 Visits:

Enter the number of visits that will be conducted for this study. The number of visits and visit windows can be found within the schedule of events in the protocol.



Visits

Visits

+ How many visits would you like to create?  **Add Visits**

Here is an example of a schedule of visits and procedures.

**Table 1 Schedule of Visits and Procedures**

Trial Period	Screening		Treatment													Follow-up
Visit Number	Visit 1 <sup>a</sup>	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14	Visit 15 <sup>b</sup> / ET Visit	Visit 16 <sup>c</sup> / Safety Follow-up Visit
Scheduled Week	-3 to -14 Days Prior to Visit 2	Day 1	4	8	12	16	20	24	28	32	36	40	44	48	52	56
Scheduling Window			± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days	± 7 days
Obtain Informed Consent and Patient Privacy	X															
Assess inclusion/	X	X														

In this example, we have 16 visits. Specify the Anchor visit by clicking on the anchor under the first column (Column A). This is typically the enrollment/randomization visit. In this case it's Visit #2. Visit #1 is two weeks prior to Visit #2 and can be conducted as soon as 3 days prior to Visit #2. Under days we would enter -14, 0 in the minus column because it cannot be more than 14 days and +11 to ensure the window is 2 weeks to 3 days prior to the randomization visit. You may change the type of visit by selecting the drop down menu from under the header "type". Under type, Visit #1 is screening, Visit #2-15 are treatment visits and Visit#16 is a follow-up visit. Ensure you select the correct type for each visit.

Visits

A	S	Type	Visit	Name	Days	-	+	Start	End
	1	Screening	1	Visit 1	-14	0	11	-14	-3
	2	Treatment	2	Randomization					
	3	Treatment	3	Visit 3	28	7	7	21	35
	4	Treatment	4	Visit 4	56	7	7	49	63
	5	Treatment	5	Visit 5	84	7	7	77	91

The visit # does not have to be a number. You can specify 1a, 1b, or whatever matches the protocol. Any name may be entered for the visit. Often times they can be indicated as Week 1, Week 2, etc. The visit's days and windows are based on the anchor visit. Visit #3 is scheduled at week 4 and is 4 weeks after Visit #2. In this case we would enter 28 days from the Anchor visit with +/- 7 day windows. The visits may also be dragged and dropped or moved by clicking the up

and down arrows next to the type of visit.

7	↑ ↓	Treatment	6	Week 8	56	2	2	54	58
8	↑ ↓	Treatment	7	Week 12	84	2	2	82	86
9	↑ ↓	Treatment	8	Week 16	112	2	2	110	114
10	↑ ↓	Treatment	9	Week 20	140	2	2	138	142
11	↑ ↓	Treatment	10	Week 24	168	2	2	166	170
14	↑ ↓	Treatment	13	Week 36	252	2	2	250	254
13	↑ ↓	Treatment	12	Week 32	224	2	2	222	226
15	↑ ↓	Treatment	14	Week 40	280	2	2	278	282

*This is being drag-and-dropped*

You may also have multiple anchor visits and the subsequent visits will be based off of that anchor visit. For example, suppose the protocol states that visit #15 is the Early Termination Visit at week 32 and visit #16 is Follow-Up 1 at week 36. In this case, if visit #15 is made the second anchor, visit #16 would be 4 weeks from that anchor, not 36 weeks, be sure to adjust the interval based off of the new anchor.

If needed, you may always return to this page and re-configure the visits. Additional visits may also be added by selecting “Add New Visit Row” or delete visits by clicking the “X” at the end of the visit row. All of the data must be entered prior to moving onto adding procedures.

Visits										
A	S	Type	Visit	Name	Days	-	+	Start	End	
1	↑ ↓	Screening	1	Visit 1	-14	0	11	-14	-3	✕
2	↑ ↓	Treatment	2	Randomization						
3	↑ ↓	Treatment	3	Visit 3	28	7	7	21	35	✕
4	↑ ↓	Treatment	4	Visit 4	56	7	7	49	63	✕
5	↑ ↓	Treatment	5	Visit 5	84	7	7	77	91	✕
(+) Add New Visit Row										

## C.2 Procedure Library

### Select Procedures

✕

Show only custom templates
 

🔍

Consent

Informed Consent

Patient informed consent; you may wish to modify instructions to match your site's SOPs

Add

Delete

Vital Signs

Ht/Wt/BMI (cm/kg)

Height in cm, weight in kilograms

Add

Add Custom Procedure

Add

Once the visits have been configured in the study, the procedures may be configured next. To add a new procedure click "Add Procedure". Our library of Global Templates will appear on the right hand side of the page. We currently have a plethora of global templates at your disposal and each may be adjusted to fit your specific protocol. You may click on the blue titles of each procedure to preview the procedure and click "Add" to add them to your study. There is also a search bar atop the library to quickly search for procedures. If there isn't a template that fits your procedure, you may add a custom procedure by typing in the name at the bottom of the library and clicking "Add". This will add a blank procedure to your study that will need further configuration. I like to refer back to my schedule of events and go down the list of procedures and add them from the library. Of course each procedure will need to be adapted to your specific study.

### C.3 Configuring a procedure for the first time

✕

## Configure your procedure for the first time

Name	Concomitant Medications
Category	Please Pick Procedure Category ▾
Questions	<div style="border: 1px solid gray; padding: 5px;"> <div style="background-color: #007bff; color: white; padding: 2px;">Please Pick Procedure Category</div> <ul style="list-style-type: none"> <li>Consent</li> <li>Demographics</li> <li>Substance Use</li> <li>Height/Weight</li> <li>Vital Signs</li> <li>Lab Procedures</li> <li>Contraception/Childbearing</li> <li>Medical History</li> <li>Physical Exams</li> <li>Scales &amp; Questionnaires</li> <li>Drug</li> <li>Diary</li> <li>Adverse Events</li> <li>Concomitant Therapy</li> <li>Eligibility</li> <li>Washout/Compliance</li> <li>Other</li> </ul> </div>

After adding a new procedure for the first time (not a global template), click on the procedure and a pop-up will help you configure the procedure. Here you may edit the name of the procedure. Choose a category for the procedure, whether it has to deal with medical history or demographics, etc. Please note that informed consent procedures MUST be under the category of Consent in order to enable ICF tracking. From here you may enter all the questions that will be answered within the procedure. You may copy and paste questions into the Questions box but please note that each question shouldn't have any breaks in it otherwise the system will divide the question up into two separate questions.

✕

## Configure your procedure for the first time

---

Name

Category

Questions 

What is the brand name?  
 What is the dose?  
 What is the strength?

Enter your procedure questions, one line per question

After adding all the questions, select Save Procedure. You will see an orange exclamation point next to each question. That means the question hasn't been fully configured, the variable name and answer choice must be specified for each question. You can always add more questions later by returning to the customize screen.

Instructions

[Click to add instructions]

Procedure Type: Normal

<span style="color: orange; font-weight: bold;">!</span> What is the brand name?	▼
<span style="color: orange; font-weight: bold;">!</span> What is the dose?	▼
<span style="color: orange; font-weight: bold;">!</span> What is the strength?	▼

### C.4 Procedure Type

There are three different procedure types: Normal, Multi-Record and Grid (only available if all questions have the same parameters).

**Normal:** This is the basic procedure type. It can only be answered once during a visit and no data is carried forward to subsequent visits.

**Multi-Record:** Allows you to add numerous different records with the same questions. A good example would be concomitant medications. The user may enter information about one medication and then add another record for the next medication. The user may add as many

records as needed. The records will be displayed in a table format with each record shown as a row. To conserve space, only the first four fields are displayed. Therefore, make sure to put the four most important variables first. For example in Concomitant Medications or Adverse Events, you would include a start and stop date in the first four.

Concomitant Medications  
Concomitant medications
Category: Concomitant Therapy
[Back to Preview](#) ✕

**Instructions**

[Click to add instructions]

Procedure Type: Multi-Record

No Entry Text: ? Check here if no medications to report

Carry Forward Data: ? Yes

↑ ↓	✓	Medication	▼	✕
	✓	Reason	▼	
	✓	Start	▼	
	✓	Stop	▼	
	✓	Dose	▼	
	✓	Units	▼	
	✓	Route	▼	

Procedure Logic

There are two additional options when configuring a Multi-Record procedure. “No Entry Text” and “Carry Forward Data”. No Entry text refers to custom instructions for the user to select a checkbox if there are no records to be entered. In this example the instructions are “Check here if no medications to report”.

Carry Forward Data: this feature is only available for Multi-Records. Enabling this feature will prepopulate records to the next visit. For example, if 2 records are entered at visit #1, you will see those same 2 records at visit #2 and can edit them as necessary. This allows you to have a running list of concomitant medications from the previous visits.

Check here if no medications are taken

#	MEDICATION	REASON	START	STOP	
1	Flexeril	Other	00-JUN-2015	ONGOING	▼
2	Relpax	Migraine	00-JUL-2014	ONGOING	▼
3	Motrin	Other	00-000-2010	ONGOING	▼
4	Zoloft	Other	00-OCT-2014	ONGOING	▼
5	Prilosec	Other	00-000-2007	ONGOING	▼
6	Albuterol	Other	00-MAR-2009	ONGOING	▼
7	Calcium/Vitamin D	Other	00-000-2007	ONGOING	▼
8	Singulair	Other	00-000-2014	ONGOING	▼
9	Metamucil	Other	00-000-2007	ONGOING	▼

+ ADD ANOTHER RECORD
COMPLETE PROCEDURE

**Grid:** When all of the questions within a procedure have the same parameters then the grid procedure type option will appear. This can either be done by configuring all the questions to have the same parameters or by configuring the first question and copying those settings into all of the subsequent questions. Once all the settings have been copied, click “Procedure Type” and select Grid. A common example of the Grid format is the Physical Examination or Inclusion/Exclusion criteria.



**Instructions**

If you perform a physical on an Other system, add a progress note indicating which. If you don't examine any Other systems, mark as NE (Not Examined). Document any significant findings or changes since screening visit.

**GRID FORMAT**

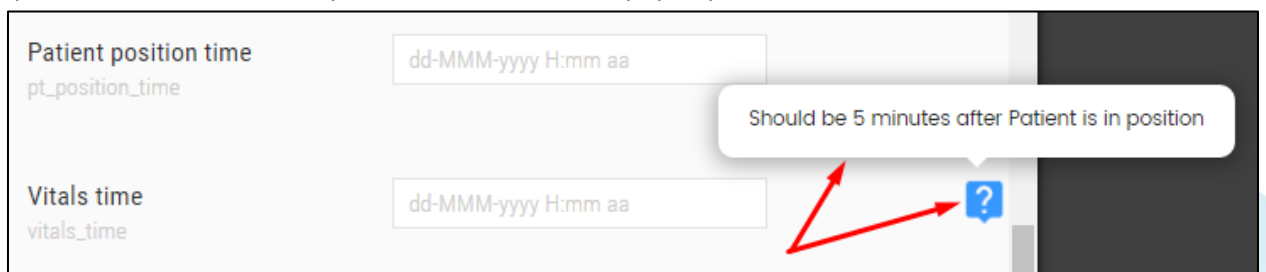
	Normal	Abnormal NCS	Abnormal CS	Not Examined
1. General appearance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Head/Neck (including thyroid)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### C.5 Configuring a question for the first time

To begin configuring a question, click on the question. Within the first field (question text) you may edit the question. The second field is for the variable name and is required. Best practices for naming variables include:

- Cannot begin with a number
- Lower case letters
- No spaces but you may use underscore ( \_ )
- Do not use other special characters such as /, ?, #, !, &, \* (These will break the system)
- Be descriptive but don't make them too long

The next field is an optional clarification field. These are clarifications/hints that may be used to assist the user during data collection. These often include what position the patient should be in prior to taking vitals or how long the patient should be seated, etc. When hovering over the blue question mark next to the question the clarification pops-up.



The screenshot shows a configuration interface with two input fields. The first field is labeled 'Patient position time' with the variable name 'pt\_position\_time' and a date-time format 'dd-MMM-yyyy H:mm aa'. The second field is labeled 'Vitals time' with the variable name 'vitals\_time' and the same date-time format. A blue question mark icon is positioned to the right of the second field. A tooltip box with a white background and a grey border is positioned above the question mark, containing the text 'Should be 5 minutes after Patient is in position'. Two red arrows point from the question mark icon to the tooltip.

“Copy settings from” will give you a drop down list of all the variable names from the previous questions that have been configured within the procedure. It will copy all of the options and settings from that question, besides the actual question and variable name. This is helpful when multiple questions have the same answer choices such as a physical exam that has the same answer choices of Normal, Abnormal NCS, Abnormal CS and Not Examined. This is the easiest

way to have the procedure type to be in grid format and if you need to make any changes, you can simply edit the first question


	Normal	Abnormal NCS	Abnormal CS	Not Examined
1. General appearance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Head/Neck (including thyroid)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Ears, Nose, Throat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Eyes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## C.6 Question types


There are four main question types: single select, multi-select, free entry, and calculation. Single select only allows for one answer to be chosen. Multi-select allow one or more answers to be chosen. In both single and multi-select questions in order to add more questions, click on the blue plus sign to add more answers or red X to delete answer choices. Free entry has several answer formats including: text, dates or numbers. There are 3 options for dates (date without ongoing, date with ongoing, and date and time). Date with the ongoing option is typically used to answer questions referring to stop dates, for example, “When did they stop using their medication?” If they are still using their medication then the ONGOING option may be selected. Date and time may be selected when there is a need to specify a time, such as “At what time was the patient given their first dose?” Finally, there’s the calculation question type. This question type can be used to execute calculations on other variables within the procedure. Typical calculations include BMI (based on height and weight entered), age (based on a birthdate) or any basic arithmetic. There is also a formula method, which we will go into more depth on in another section.

**Select Question Type:**


Single Select



Multi Select



Free Entry





Calculation

$X + Y = Z$

Possible Answers

Requires comment
 

Alert if selected (optional)

Select Question Type:

Single Select

Multi Select

Free Entry

Calculation

$X + Y = Z$

Select Answer Format:

Text Free text; no restriction

Date - without ongoing Date format without "ongoing" as an option

Date - with ongoing Date format with "ongoing" as an option

Date and time Date and time

# Number

#.# Number - Allow decimals

### C.7 Calculation question

Select Question Type:

Single Select

Multi Select

Free Entry

Calculation

$X + Y = Z$

Calculation Type

Method Average

Questions to Use Average (comma delimited)

Rounding Mode 1

Alert Rules

There are currently n

Pick a Calculation Method

- Average
- Divide
- Sum
- Subtract
- Age
- Years Between Dates
- BMI (Centimeters, Killograms)
- BMI (Inches, Pounds)
- Convert (Inches to Centimeters)
- Convert (Fahrenheit to Celsius)
- Convert (Pounds to Killograms)
- Formula

The calculation question type can be used to execute calculations on variables preceding the question.

**Average:** If you want to take an average of several different measurements for example, the average systolic blood pressure for three blood pressure measurements taken during that procedure, under Method, select Average and enter the variable names of the three systolic BPs separated by commas. Select save question. This question will now calculate the average once all fields have been entered. Rounding mode includes the standard method of Half-up, Half-down, Up or Down. Half-up: if it's at .5, it rounds up, half down: if it's at .5, it rounds down, up: if it's a decimal, it rounds up regardless of whether it's .9 or .1, down: if it's a decimal, it rounds down regardless of whether it's .9 or .1.

**Select Question Type:**

Single Select

Multi Select

Free Entry

Calculation

X + Y = Z

**Calculation Type**

Method Average

Questions to Use sys\_bp1, sys\_bp2, sys\_bp3

Rounding Mode Standard (Half Up) Decimals 1

Variable names separated by commas

The other calculation methods such as divide, sum, subtract are the same where the variables must be entered to perform the calculation. Please note that the calculations cannot be combined within the same question, e.g. you cannot select subtract and add within the same question, unless you use the formula method.

**Age:** Can be used to calculate the years from the previous date entered to the current date. If the previous variable is birthdate, it will calculate the age based on that birthdate.

**Years between dates:** If there are two previous date fields, this method will calculate the years between dates. This can be used when to determine how long a patient has smoked for. The first field can be “When did the patient start smoking?” and the second will be “When did the patient stop smoking?” The third question will then be “Years smoked”, which utilizes the Years Between Dates method. Under Questions to Use enter the two variables for the dates. This calculation may also be used when ONGOING is selected. If the second date was entered as ONGOING it would calculate the years between dates from the previous date to the time the procedure is done.

**BMI:** Automatically calculates BMI, using questions about height and weight in cm and kg respectively the third question may be used to calculate the BMI based on those variables. Under method, select BMI (Centimeters, Kilograms) and enter the variable names for the

questions about height and weight under “Questions to use”. BMI may also be calculated from inches and pounds. Ensure all units match.

Convert: These methods allow you to convert Inches to Centimeters, Fahrenheit to Celsius, Pounds to Kilograms. Ensure the first field is in the correct units. E.g. the first field should be inches, Fahrenheit, or pounds and they will be converted using the calculation method.

Formula:

To utilize formula, use the variable names and/or numbers along with various SQLite commands. Most commonly used commands are \*=multiplication and /=division. If for example, we wanted to calculate the number of packs a subject has smoked multiplied by the number of years they smoked (pack-years) based on the number of cigarettes they smoked per day multiplied by the number of years they smoked. You would select formula as the method of calculation and under “Questions to Use” you would enter the formula  $(\text{num\_of\_cigarettes} / 20) * \text{num\_yrs\_smoked}$ . The number 20 is included because that is how many cigarettes are in a typical pack. Ensure there are spaces between the operands and variable names and numbers for the formula to work properly.

Select Question Type:

<p>Single Select</p> <input type="radio"/> <input type="radio"/> <input type="radio"/>	<p>Multi Select</p> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<p>Free Entry</p> <input type="text"/>	<p>Calculation</p> $X + Y = Z$
--	---	--	--------------------------------

Calculation Type

Method

Questions to Use

Rounding Mode  Decimals

Auto-scoring:

You can now autoscore results on questionnaires scales

If you have a procedure whereby certain points are attributed to different answers, you can now create a formula that auto-scores the total. For instance, if you have this question/answer set:

Q: Describe your pain today

A:  
Mild = 1 point



Moderate = 2 points

Severe = 3 points

You can now assign a score of 1 to "Mild", 2 to "Moderate", and so on.

This is reflected in a special formula called "Case", an example of how this can be configured: (case response when '1-Mild' then 1 when '2-Moderate' then 2 when '3-Severe' then 3 else 0 end)

If you have scales or procedures that would benefit from this, and would like us to add in auto-scoring, please contact us. We can build in alerts based off of the scoring to prevent protocol deviations!

Describe your pain yesterday	<input checked="" type="radio"/> Mild (1)
	<input type="radio"/> Moderate (2)
	<input type="radio"/> Severe (3)
Describe your pain today	<input type="radio"/> Mild (1)
	<input type="radio"/> Moderate (2)
	<input checked="" type="radio"/> Severe (3)
Total Score	4
	<a href="#">CLEAR</a> <a href="#">SAVE AND CONTINUE</a>

### C.8 Question alerts:

Several alerts can be configured within a question. Within a single-select or multi-select question an alert may be configured to pop-up when a certain answer choice is selected. An example of this alert is when the patient position during vitals should be sitting and the user has selected a different position. This alert can be used to ensure the position is correct.

Select Question Type:

Single Select

—

—

—

Multi Select

—

—

—

Free Entry

Calculation

$X + Y = Z$

Possible Answers

Sitting	<input type="checkbox"/> Requires comment	Alert if selected (optional)	+	×
Supine	<input type="checkbox"/> Requires comment	Wrong position! Patient should be in sitting position.	+	×
Standing	<input type="checkbox"/> Requires comment	Wrong position! Patient should be in sitting position.	+	×

Save Question
Cancel

Another type of alert that may be configured is based on the value that is entered or calculated in that question. In the free entry question configuration there is an option for alerts. We'll do an alert about respiratory rate. We have to enter the word "value", which is the # that is entered or calculated during data collection. If we want an alert to pop-up if the respiratory rate is greater than 20 or less than 12, we'll enter "value < 12 OR value > 20" and then enter the custom alert, "PI should assess clinical significance."

Select Answer Format:

- Text Free text; no restriction
- Date - without ongoing Date format without "ongoing" as an option
- Date - with ongoing Date format with "ongoing" as an option
- Date and time Date and time
- # Number
- #.# Number - Allow decimals

Alert Rules

! If query(  ) is true, then alert  + ×

Save Question
Cancel

Another example is an alert based on the subject's age. In this case we'll use two fields, one field for their birthdate and another field that automatically calculates the subject's age. Open the

question alerts and type in “value < 18” and specify the alert. “Patient is below the age of 18 and is ineligible.” We can go into the preview mode and enter the birthdate 01/20/2000 to test the alert. I like to take the inclusion/exclusion criteria and embed them as alerts within certain procedures such as demographics or vitals, etc.

**Calculation Type**

Method

Questions to Use

Rounding Mode  Decimals

**Alert Rules**

! If query(  ) is true, then alert  + ✖

## C.9 Procedure Logic

Procedure Logic is involved whenever two or more separate variables are involved. There are two types of procedure logic: disable rule or an alert rule. The disable rule allows us to disable subsequent questions based on an answer given. For example, if the first question asks, “Is the subject a woman of child bearing status?” if the answer is no, the subsequent questions regarding last menstrual period and birth control may be disabled. In order to do this all the questions within the procedure should first be configured. At the bottom of the procedure configuration select “Procedure logic” and click add new disable rule.

Procedure Type: Normal

↑ ↓
✖
✓ WOCBP status

✖
✓ Reason

✖
✓ Contraception

+ Add Questions

Procedure Logic
▲



The first part (the query) will be what the disable logic is based on. In our example, it will be based on whether or not the subject is a WOCBP. Let's find the variable name for this, copy and paste it and specify which answer will trigger the disable logic. In this case, the answer will be "N/A-male", here we enter `if wocbp_status = "N/A-male"`. Please note that you must use the exact spelling and this is case-sensitive, so if in doubt, it's best to copy and paste the desired value. We now need all the variable names of the questions we want to disable. Simply copy and paste them and separate each variable by commas in the next box. The way the procedure logic will be read as, "If the question `wocbp_status` is answered as "N/A – male", then the questions reason and contraception will be disabled. We can go back to preview and see if it works.

Procedure Logic

if query (  ) is true, then

disable

An alert may be programmed for multiple questions. For example, during vitals the patient should be in the supine position for 5 minutes prior to taking their vitals. In this case we'll have two questions: one about time the patient started sitting (`first_time`) and another when the vitals are being taken (`second_time`). We'll need both variable names and a special function called 'datetime'.

Procedure Logic

If query (  ) is true, then

alert

This alert rule will pop-up when the vitals time (`second_time`) is less than 5 minutes after the patient position time (`first_time`). This may be used to ensure the patient has been sitting for 5 minutes. This format can be used for other time-based alerts, such as time fasted or time between IP administrations. The time units may also be changed from minutes to hours.

For further help on procedure logic, please refer to the SQLite Examples (Appendix I)

### C.10 Preview, Copy, Delete, Save as template

Preview mode shows you the questions at the procedure level. In this mode the user is able to simulate the features such as disable/procedure logic/calculations/etc. To return to this mode



after configuring a procedure, click on the blue arrow at the top right hand corner of the procedure.


In this mode you may create a copy of this procedure and give it another name. This feature is useful when you want to create a procedure that is similar to one you already have.


The “Save to Library” button allows you to save this procedure into your organization’s template library for future use in upcoming configurations. The customize button will bring you back into the customization of each question and instructions.

You may also delete the procedure from the study configuration (by using the delete button)

Once all of the procedures have been configured you may return to the configure tab and preview what an entire visit would look like in the SANDBOX mode. This mode reflects what actual data collection would look like in both tablet and desktop data collection modes. Here you can see the order of the procedures and test the disable alerts and procedure logic as well as any calculations that were configured. From here you may also print all source forms for that visit by clicking the printer icon at the top right hand corner. Please note that any data entered in this mode is not actually saved.


SANDBOX ✕

Visit 1 - A4091058
Beacon Clinical ▼




**JD**  
123456789

**Visit 1**  
Screening

To print all source documentation 

Informed Consent

Demographics

Smoking Status

Alcohol Status

Childbearing and Contraception

Patient Assessments

Survey of Autonomic Symptoms

Ht/Wt/BMI (ins/lbs)

Sitting vitals

Supine ECG and BP

Central Labs

Primary Diagnosis

Medication Review

Drug Allergy

Musculoskeletal History

### Instructions

\* Please use Informed Consent Form vNA (6/14/2016)

Prior to all study procedures, take the subject into a private and distraction free exam room and give the subject ample time to review consent. Explain all risks, benefits and alternative therapies with the subject. Ensure that the subject has a chance to ask and have all questions answered. Ensure that the subject verbalize their understanding of the information provided and their willingness to participate in the study. Provide a copy of the fully executed consent to the subject.

Was the informed consent executed?  Yes

No

Was the above set of procedures followed?  Yes

No

Date/Time signed

dd-MMM-yyyy H:mm aa

info@clinicalresearch.io / 617-302-9859

26

Visits | Procedures

Procedures

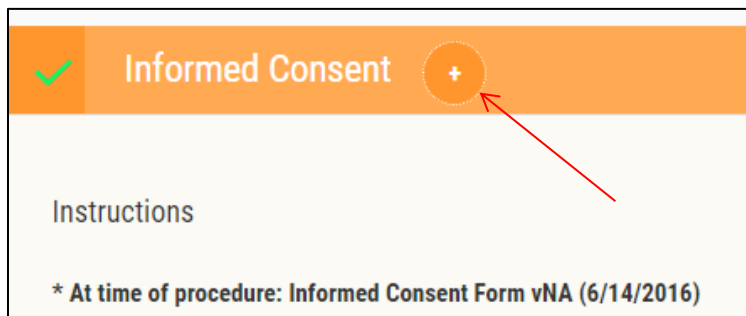
	Screening	Lab/ECG	Med record	X-Ray	MRI/DXA	IPAP	Baseline	Week 2	Week 4	Week 8
Week 24 Eligibility	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Informed Consent	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

## D. Visit Completion

### D.1 Comments

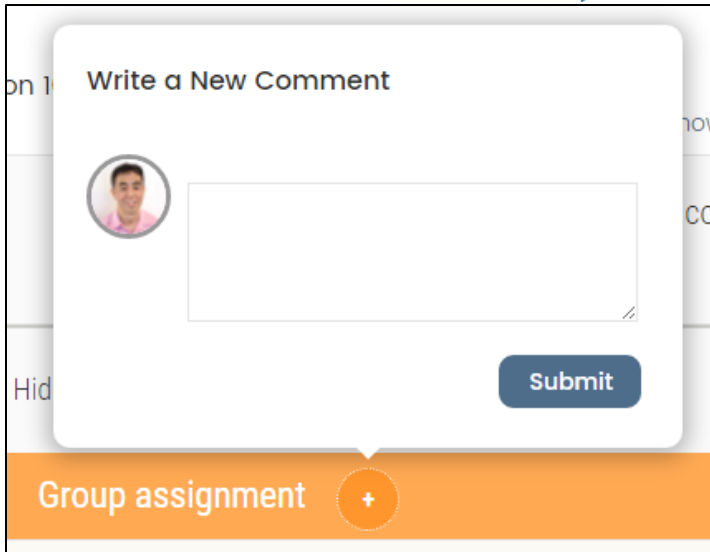
Comments can be made at the procedure level or at the question level (question within a procedure).

Procedure level: Next to the title of the procedure (orange banner) there is a small circle with a plus, click on that to add a comment.



A comment box will appear to write a new comment. Notifications for each comment will be sent to all users subscribed to the study. The “@” symbol may be used to direct the comment to a specific user. They will be notified via email regardless of their subscription status.

We strongly recommend you use the @ feature. For example, this particular value was entered by X, so if you want to direct a comment to X, simply type @ and after the first few letters of their username, you’ll be able to select the user from the dropdown list. Using the @ functionality gives you the assurance that your comment will be received via email.

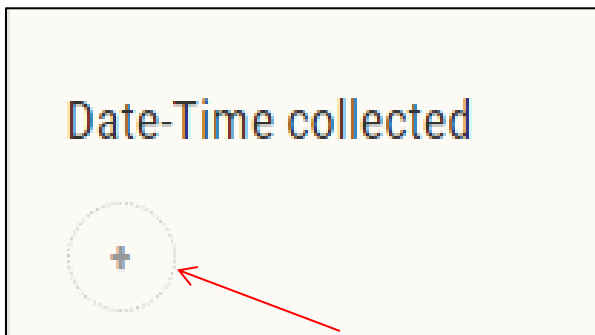


Write a New Comment

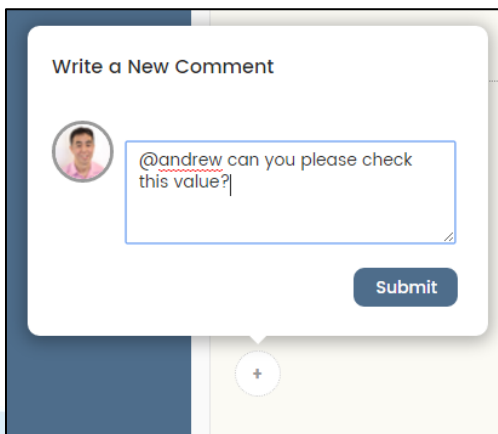
Submit

Group assignment +

Question level: Near each question the same circle with a plus can be found to leave a comment



Note that these comments all start with an “I”. I stands for Internal. Internal comments can only be viewed by internal users and external users such as monitors do not see the internal comments. When a monitor makes a comment, it will appear as an “E” comment.



Write a New Comment


@andrew can you please check this value?

Submit

All | [External Comments](#) | [Internal Comments](#)

### All Comments


Show 10 entries Status All Search:

ID	Subject	Visit/Procedure	Comment
	Danielle Tester	Visit 1 - Screening Sitting vitals	<a href="#">@andrew can you please check this value?</a> <small>Raymond Nomizu posted on 19-Jan-2017 3:12 PM</small>


Showing 1 to 1 of 1 entries Previous  Next

All comments for the study may be viewed under the comments tab. In order to view the specific comment, click on the comment and it will take you directly to where that comment was made.

Heart Rate



Mark Resolved



**Raymond Nomizu** a moment ago

[@andrew can you please check this value?](#)


[@raymond](#) I reviewed the value and it is correct.

You may then reply to the comment and mark it as resolved. Under the comments tab all of those that are checked have been resolved

Finally, how do you as a user specify your subscription preference on comments? Go to the accounts page, find the study in question, and click here to either subscribe or unsubscribe. If you subscribe, it means you receive emails every time a comment is posted, regardless of whether it's directed at you. Our system will default the prime coordinator and principal investigator to Subscribed status.

Studies

Show  entries Search:

Site	Study	Study Status	Role	Email Notification
Quincy, MA	Daiichi Sankyo DS5565-A-E310 Fibromyalgia	Maintenance	Coordinator	Subscribed 
Quincy, MA	Astellas Pharma Us, Inc. 3662-CL-0049 Diabetic Neuropathic Pain	Closed	Coordinator	Subscribed
Quincy, MA	Pfizer Inc. A4091058 Osteoarthritis	Enrolling	Coordinator	Subscribed
Quincy, MA	Egalet OC-EG-303 Chronic Pain	Enrolling	Coordinator	Subscribed
Quincy, MA	Teva Pharmaceuticals TV-45070-CNS-20013 Postherpetic neuralgia	Enrolling	Coordinator	Subscribed

## E. Subjects & Subject Scheduler:

### E.1 Add a New Subject

To add a new subject, under the study enter the subjects tab. From here click “Add New Subject”.

### Add a New Subject ✕

**Contact Information**

\* First Name

Middle Name

\* Last Name

Email

Telephone (ex. 123-456-789)

**Study Information**

Female

Subject ID

Randomization ID

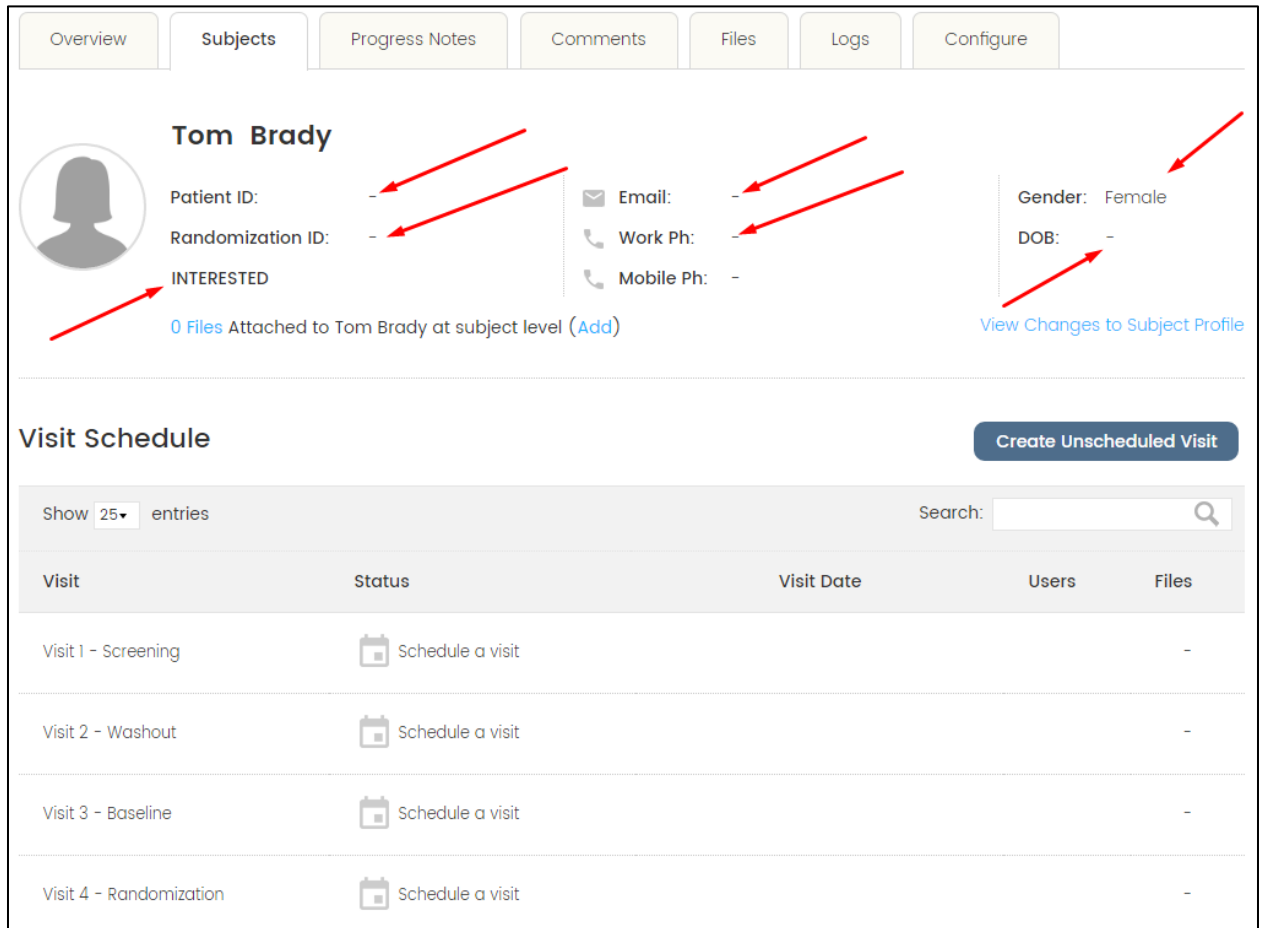
Interested 

- Interested
- Pre Qualified
- Qualified by Visit
- Not Eligible
- Not Interested
- In Screening
- Enrolled
- Screen Fail
- Discontinued
- Completed

SUBJECT

Enter the patient information here. It will be best to enter as much information as you can. Their status will automatically be entered as Interested but there are several possible subject statuses. We recommend that you do not use In Screening onwards unless the subject is already consented, as those statuses are reserved for patients officially in a study.

Once the subject has been added you may click on them in the default status view.



**Tom Brady**

Patient ID: -

Randomization ID: -

INTERESTED

0 Files Attached to Tom Brady at subject level (Add)

Email: -

Work Ph: -

Mobile Ph: -

Gender: Female

DOB: -

[View Changes to Subject Profile](#)

### Visit Schedule

Show 25 entries Search:

Visit	Status	Visit Date	Users	Files
Visit 1 - Screening	Schedule a visit			-
Visit 2 - Washout	Schedule a visit			-
Visit 3 - Baseline	Schedule a visit			-
Visit 4 - Randomization	Schedule a visit			-

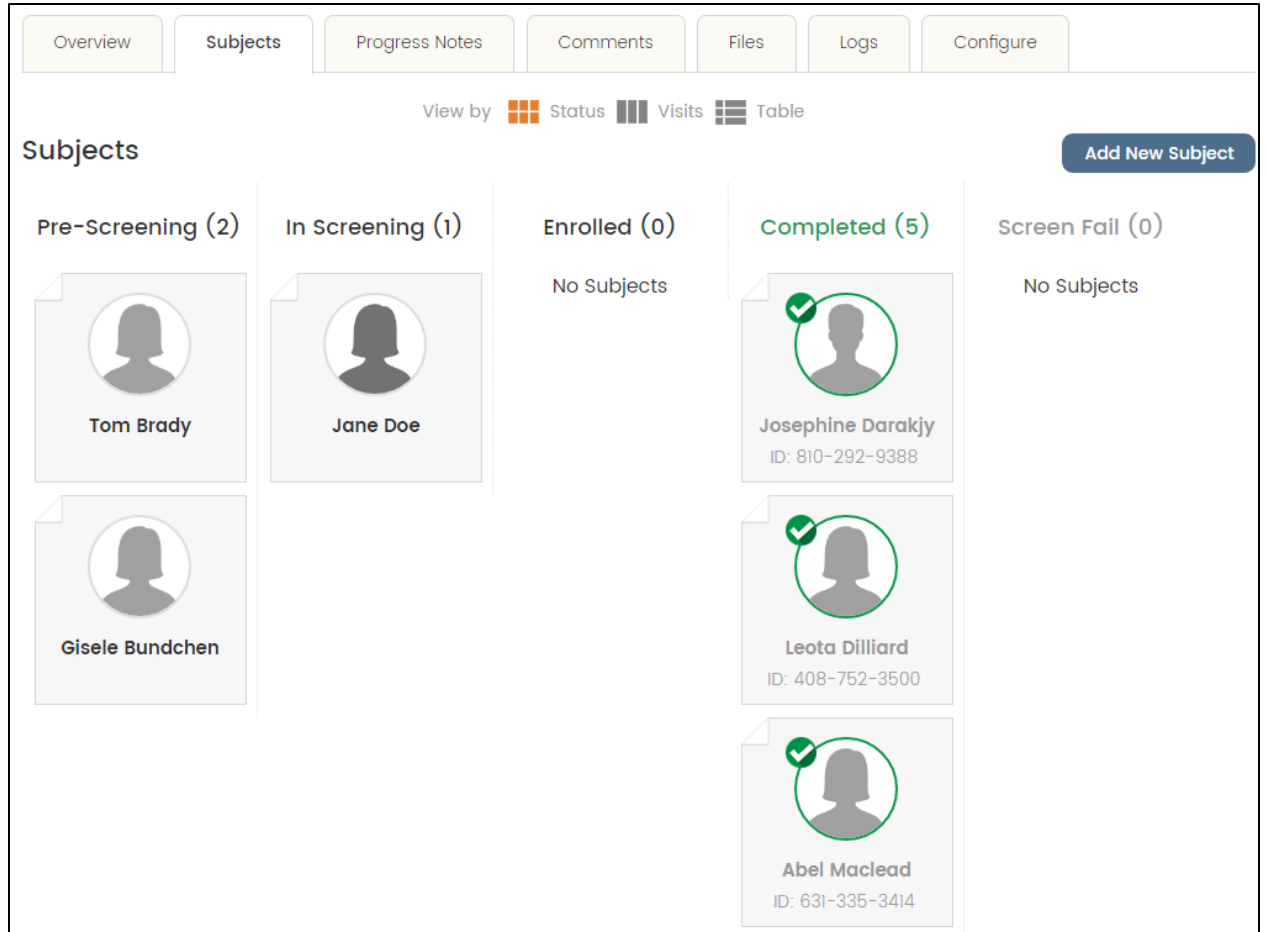
[Create Unscheduled Visit](#)

From here you may update all patient information as needed by clicking the space next to the fields. However, for most of the fields you will be prompted as to why the change is being made. This is because this applies to fields that are considered part of source and therefore subject to an audit trail. You can also view the audit trail of any changes made to the Subject's profile (by clicking "View Changes to Subject Profile"). This will show the different status changes and files attached to the subject can also be accessed under the subject profile information.




Once a subject is added you will find them under the subjects tab. There are three different views for the subjects tab:



## 1) Status



Overview Subjects Progress Notes Comments Files Logs Configure

View by  Status  Visits  Table

Subjects Add New Subject

Pre-Screening (2)	In Screening (1)	Enrolled (0)	Completed (5)	Screen Fail (0)
<ul style="list-style-type: none"> <li>Tom Brady</li> <li>Gisele Bundchen</li> </ul>	<ul style="list-style-type: none"> <li>Jane Doe</li> </ul>	<p>No Subjects</p>	<ul style="list-style-type: none"> <li>Josephine Darakjy ID: 810-292-9388</li> <li>Leota Dilliard ID: 408-752-3500</li> <li>Abel Maclead ID: 631-335-3414</li> </ul>	<p>No Subjects</p>

This is the default view and gives you the best idea of patient flow. You can see where all the subjects in your study are from pre-screening, to in screening, enrolled, completed and those that have screen failed. From here you can click on a single patient and view their subject page, which includes their entire visit schedule and subject information.

## 2) Visits

Subjects

[Add New Subject](#)

Scheduled
 Partially Completed
 Paused
 Fully Completed
 In Progress
 Cancelled

Subject	ID	Status	Screening			Treatment						
			Screening	Washout	Baseline	Randomization	Week 1	Week 3	Week 5	Week 7	Week 9	
Josephine Darakjy	810-292-9388	Completed										
Leota Dillard	408-752-3500	Completed										
Jane Doe	-	In Screening										
Abel Maclead	631-335-3414	Completed										
Vallie Mondella	208-862-5339	Completed										
Gladys Rim	414-661-9598	Completed										

The Visits view allows you to see the status of each visit for each subject. From here you can see which visits are completed, partially completed, paused, in progress, scheduled or cancelled. From here if you hover over the different visits you may either schedule a visit or indicate that the visit was done outside of CRIO (as it was done on paper, etc.). You may also view the visit details of visits that have already been completed or reschedule visits that have been partially completed. You may also click on their name to return back to view their subject page.

### 3) Table

**Subjects**

[Add New Subject](#)

[Copy](#) [Excel](#) [CSV](#) [PDF](#)

Show 25 entries Show All Search:

Name	Subject ID	Status	Next Visit	Contact Information
Tom Brady	-	Interested		No Contact Information
Gisele Bundchen	-	Interested		<a href="mailto:gbi2@pats.com">✉ gbi2@pats.com</a>
Josephine Darakjy <small>(Screened on 6/23/2016)</small>	810-292-9388	Completed	V13 - Week 14 06-Oct-2016 10:00	<a href="mailto:josephine_darakjy@darakjy.org">✉ josephine_darakjy@darakjy.org</a> <a href="tel:810-292-9388">☎ 810-292-9388</a>
Leota Dilliard <small>(Screened on 9/13/2016)</small>	408-752-3500	Completed		<a href="mailto:leota@hotmail.com">✉ leota@hotmail.com</a> <a href="tel:408-752-3500">☎ 408-752-3500</a>
Jane Doe	-	In Screening		No Contact Information
Abel Maclead <small>(Screened on 9/14/2016)</small>	631-335-3414	Completed		<a href="mailto:amaclead@gmail.com">✉ amaclead@gmail.com</a> <a href="tel:631-335-3414">☎ 631-335-3414</a>

In the table view you will be able to quickly see their name, subject ID, status, when their next visit is and their contact information. From here you may sort on these fields by clicking the header. You may also filter based on the subject's status. You may also quickly search by typing into the search field. Just like the other views you may also click on the subject's name or icon to enter their subject page. When you click on a subject's email address, CRIO will open up your default email application with their email address pre-filled in the To: section. If you click on the subject's phone number, it will open up the user's default phone application and pre-populate the phone # to dial.

## E.2 Schedule a Visit

Prior to scheduling a visit your study should be completely configured. The visits page with the correct days and windows from their respective anchor visits should be configured properly for the scheduler and visit windows to work.

To schedule a visit go to the particular study in which you want to schedule a visit. It will take you directly to the Subjects tab. Click on a Subject and click on the particular visit you want to schedule. When hovering over the visit, you'll have 2 options: schedule a visit or "Completed

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outside of CRIO". This refers to when the visit was done either on paper or through another method other than CRIO.

Click on "Schedule visit" and here you may select the desired date. You may also designate to which coordinator the appointment will be scheduled with. By clicking the "more" button next to your icon you will see a list of all the coordinators/investigators included in this study. From here you may select a coordinator and view the coordinator's schedule and assign the subject's visit. You may select and unselect a coordinator. (A checkmark beside the coordinators photo indicates that the coordinator has an appointment scheduled that day). Within the calendar you may scroll through the different days or click on the "Month View" button. Days will be colored differently, tan=today, blue=calculated visit windows, white=days not in window. We can click on today's date and we can click and drag how long you think the visit will take. It will be booked by 30 minute increments or you can update the visit details and have them be in 15 minute increments.

A screenshot of the CRIO interface. The top section is divided into two columns: "Coordinators" and "Investigators". Under "Coordinators", there are buttons for "Me" (highlighted in green), "Alex Wang", "Matt Curtin", "Natasha K...", "Michelle N...", and "Heather M.". A "Select All Coordinators" link is positioned above the "Katsue Seki" button. Under "Investigators", there are buttons for "Victoria Ku...", "Maxim Lut...", and "Gregory La.". A "Select All Investigators" link is positioned above the "Gregory La..." button. At the bottom of the interface, there is a navigation bar with a left arrow, the text "February 2017", a right arrow, and a legend indicating that a light blue square represents "= Within Visit Window".

### Visit Details ✕

---

**Study:** Daiichi Sankyo - DS5565-A-E310

**Subject:** Tom Brady

**Visit:** Screening

**Staff:** Raymond Nomizu

**Time:**  -

Once the first visit is scheduled the rest of the visits may now be scheduled. When you click on the second visit, CRIO will automatically take you to the possible visit dates, which will be highlighted in blue. From here you may schedule the visit in the same way you scheduled the first.

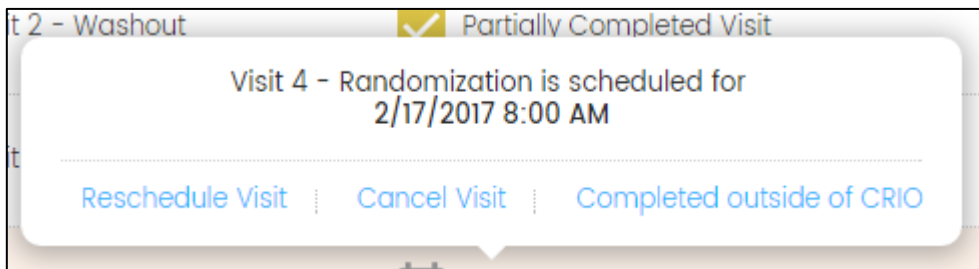
After scheduling a visit, when you click on that visit it will take you to the day of that visit. From here you can easily drag and drop that visit to reschedule it for a different time during that day. You may also delete that visit by clicking delete. You may also go into the month view and move the appointment to another date but when you do this a notification will pop-up confirming that you want to move the appointment to a different time slot. And of course you can go back into that day and move around the visit. The scheduling here is for patient visits, for non-patient visits, you may go to the Schedule tab and view the entire schedule of your site, including things like “Out of the office”, “Working from home”, etc.

If you have partially completed visits you may split visits to different days or continue the visit on another day. Simply, go to the subject page and view the partially completed visits and click on reschedule visits to reschedule the visit. The subject’s visit schedule should then be updated to include the follow-up visit has been rescheduled.

Visit Schedule					<a href="#">Create Unscheduled Visit</a>
Show <input type="text" value="25"/> entries		Search: <input type="text"/>			<input type="submit" value=""/>
Visit	Status	Visit Date	Users	Files	
Visit 1 - Screening	<input checked="" type="checkbox"/> Partially Completed Visit (Followup Visit Scheduled)	12/29/2016 (Last Completed) 1/11/2017 7:00 AM (Scheduled)	Katsue Seki, Nicole Mastacouris	0	

### E.3 Changing a visit

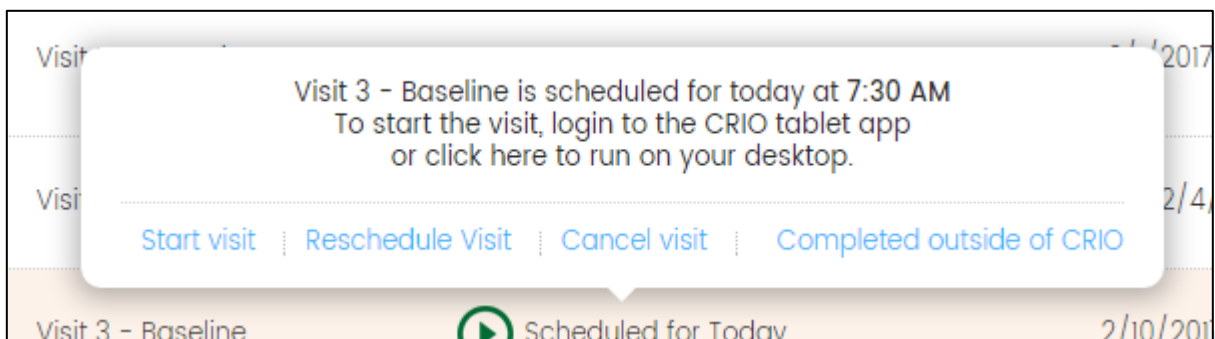
After a visit has been scheduled, you'll have several options to modify that appointment. You may reschedule the visit, cancel the visit, or indicate that the visit was completed outside of CRIO.



Visit 4 - Randomization is scheduled for  
2/17/2017 8:00 AM

[Reschedule Visit](#) | [Cancel Visit](#) | [Completed outside of CRIO](#)

If the appointment was for the same day, then you'll have the option to start the visit. Rescheduling the visit will allow you to change the date of the visit. Cancelling the visit wipes the visit out. When cancelling a visit the site will ask you for the cancellation reason



Visit 3 - Baseline is scheduled for today at 7:30 AM  
To start the visit, login to the CRIO tablet app  
or click here to run on your desktop.

[Start visit](#) | [Reschedule Visit](#) | [Cancel visit](#) | [Completed outside of CRIO](#)

## Cancel Visit

Schedule a visit

Subject: Josephine Darakjy - 810-292-9388

Schedule a visit

Visit: 13 - Week 14

Date Time: 10/6/2016 10:00 AM - 10:45 AM

---

NO SHOW     
  SITE CANCELLED     
  PATIENT CANCELLED

Reason:

Completed Visit     
 8/13/2016     
 Katsue Seki     
 Kuchung

You are also able to reschedule visits. This can be done through the calendar view you may drag and drop scheduled visits to different times within that day and who that visit is assigned to. You will be prompted to ensure the change being made is correct.

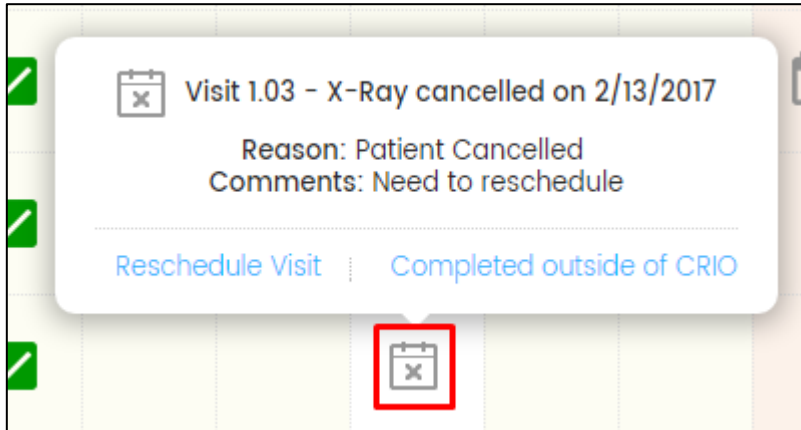
**! Already Has Visit Scheduled**

You can only schedule appointment(s) within the same visit day. Do you want to move your current visit to this time slot?

\*Note: This will remove the following visits:

- 2/10 7:30AM - 8:00AM - Natasha Khona

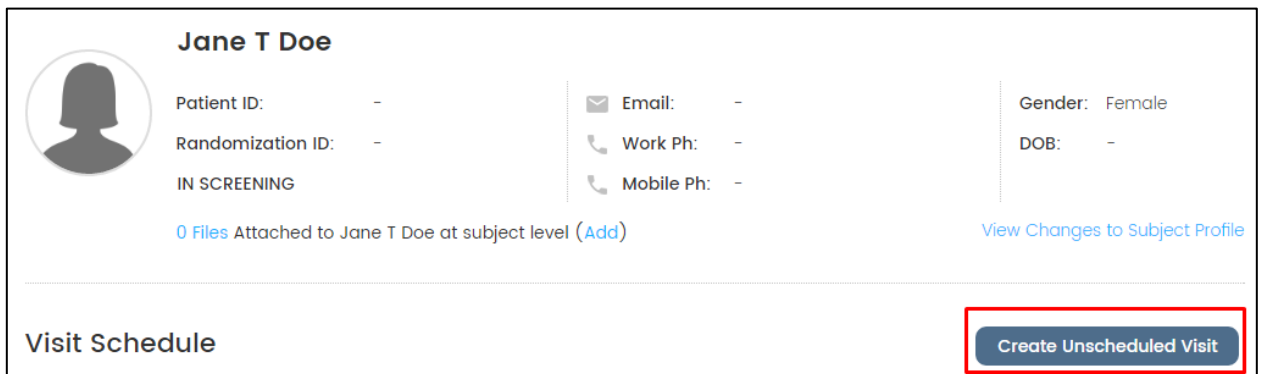
When a visit has been cancelled you'll see the calendar with an X symbol.



You may then reschedule that visit when needed.

#### E.4 Unscheduled and Split visits

For unscheduled visits, we do not recommend that you try to configure an unscheduled visit during your configuration. In order to configure an unscheduled visit go to the subject page and create an unscheduled visit.



From there you may select any pertinent procedures from the list of procedures configured for that study and schedule the time and day for the visit. When you begin that visit only the procedures that you indicated for that visit will appear. You may also reschedule the unscheduled visit if need be by rescheduling in the subject page or through the calendar view.



### Unscheduled Visit ✕

---

**Study:** Pfizer Inc. - A4091058

**Subject:** Esta Blackwall (713-936-6550)

**Staff:** Nicole Mastacouris

**Time:**  -

**Select Procedures:**

- Week 24 Eligibility
- Informed Consent
- Demographics
- Smoking Status
- Alcohol Status
- Childbearing and Contraception
- Diary Compliance
- Weekly Joint Pain Scores
- Rescue Medication Compliance to Wk 16
- Rescue Medication Compliance Wk 16-64
- Non-study NSAID prohibition
- Contraception Compliance
- Patient Assessments
- Suvey of Autonomic Symptoms

Besides and Unscheduled Visit, you might also have what is sometimes referred to as a Split Visit. A split visit is a scheduled visit that is completed over the course of two or more days.

#### **SPLIT VISIT**

Our system supports this, on the first day; you will complete a Partially Completed visit and then reschedule the visit to another day. Note that when you complete a partially completed visit, you have an opportunity to write a progress note. You may want to write a note stating that the patient will return to complete the visit.

When you reschedule, you can then enter data on that day, just like any other visit. You will of course pick up where you left off.

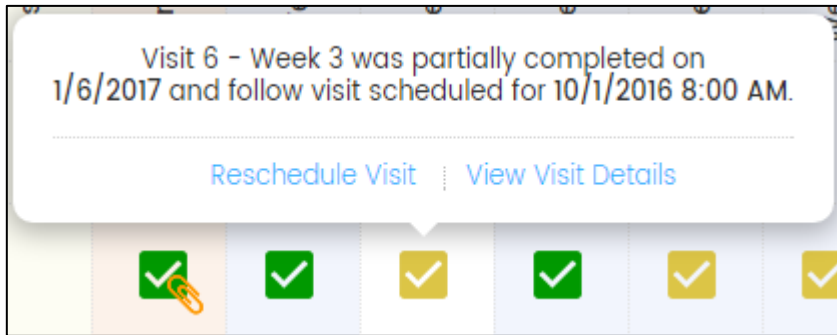
After you complete the visit, we recommend you write a visit-level progress note to explain what procedures were done on what days. You may refer to the audit trail that will indicate which procedures were completed on which days.

Note that the system will consider the first date to be the day of the visit.

Visit 6 - Week 3	<input checked="" type="checkbox"/> Partially Completed Visit (Followup Visit Scheduled)	1/6/2017 (Last Completed) 10/1/2016 8:00 AM (Scheduled)	Nicole Mastacouris, <span style="float: right;">0</span> Katsue Seki
------------------	---	--	---



When a Split visit is scheduled, it will appear in the visits table as a partially completed visit but when you hover over the visit you will see that the visit was initially partially completed on the first visit date and that the follow-up visit is scheduled on another date. From here you may reschedule the visit again or view the visit details.



## F. Document Routing

### F.1 Getting documents into CRIO

There are four ways to get documents into CRIO:

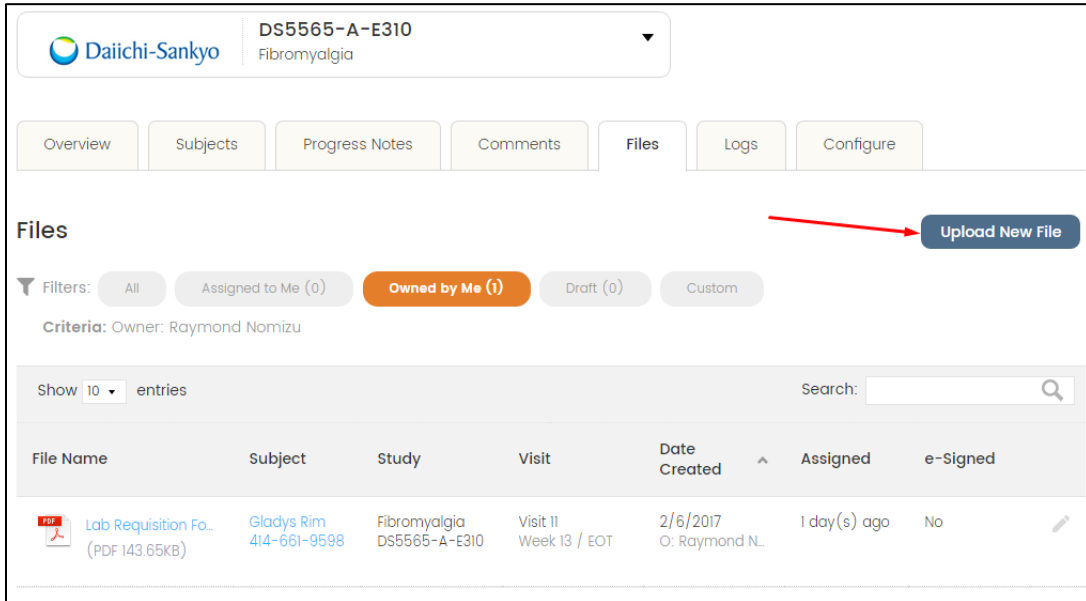
- 1) Upload them via “Upload New File” in the Files tab. This can be accessed at the higher organization level or at the study-specific level

Organization level:

The screenshot shows the 'Files' tab in the CRIO interface. At the top, there are navigation tabs: STUDIES, SUBJECTS, SCHEDULE, TASKS, FILES (selected), and ORGANIZATION. A 'Live chat now' button is in the top right. Below the navigation, the 'Files' section has a filter menu with options: All, Assigned to Me (0), Owned by Me (1) (selected), Draft (0), Incoming (0), and Custom. A red arrow points to the 'Upload New File' button. Below the filters, there is a search bar and a table of files.

File Name	Subject	Study	Visit	Date Created	Assigned	e-Signed
Lab Requisition Fo... (PDF 143.65KB)	Gladys Rim 414-661-9598	Fibromyalgia DS5565-A-E310	Visit 11 Week 13 / EOT	2/6/2017 O: Raymond N.	1 day(s) ago	No

Study-specific level:



Overview Subjects Progress Notes Comments **Files** Logs Configure

**Files** Upload New File

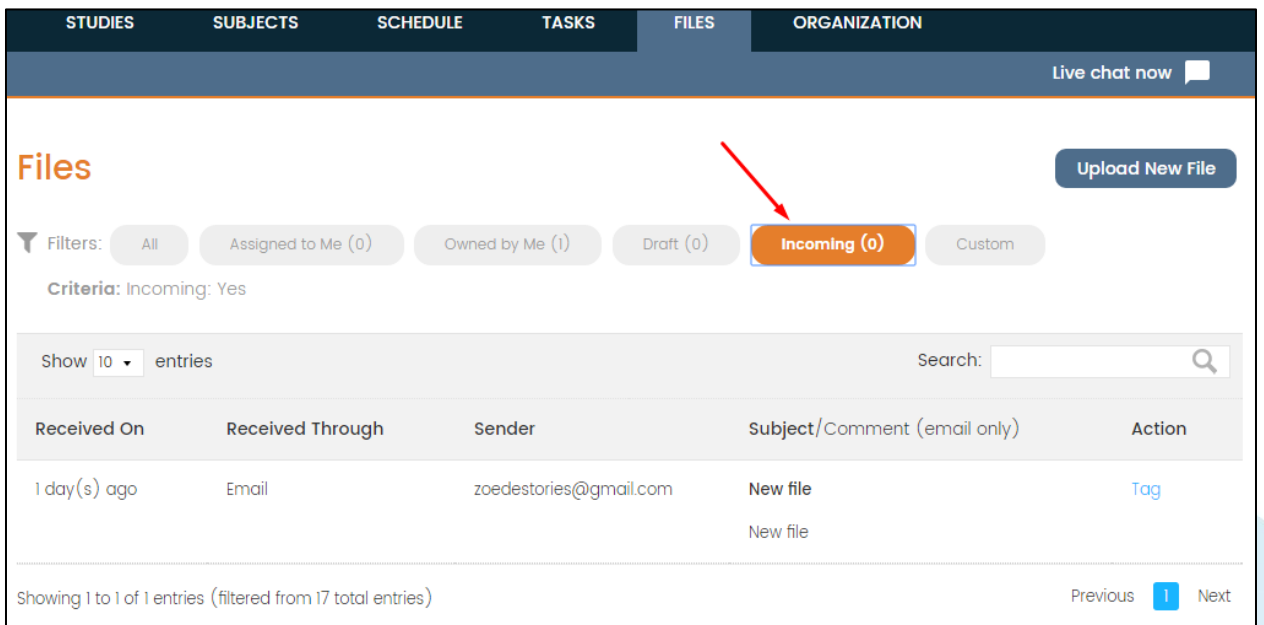
Filters: All Assigned to Me (0) **Owned by Me (1)** Draft (0) Custom

Criteria: Owner: Raymond Nomizu

Show 10 entries Search:

File Name	Subject	Study	Visit	Date Created	Assigned	e-Signed
Lab Requisition Fo... (PDF 143.65KB)	Gladys Rim 414-661-9598	Fibromyalgia DS5565-A-E310	Visit II Week 13 / EOT	2/6/2017 O: Raymond N.L.	1 day(s) ago	No

- 2) Documents may be uploaded through an e-fax/e-mail. CRIO will give you a specific email that you may use to set-up your e-fax. These documents will be routed directly to your Organization’s Files tab. It won’t be directed into the study-specific level files tab.



STUDIES SUBJECTS SCHEDULE TASKS **FILES** ORGANIZATION Live chat now

**Files** Upload New File

Filters: All Assigned to Me (0) Owned by Me (1) **Incoming (0)** Draft (0) Custom

Criteria: Incoming: Yes

Show 10 entries Search:

Received On	Received Through	Sender	Subject/Comment (email only)	Action
1 day(s) ago	Email	zoedestories@gmail.com	New file New file	Tag

Showing 1 to 1 of 1 entries (filtered from 17 total entries) Previous **1** Next

- 3) Documents can be uploaded at the subject level by utilizing the button underneath the Subject Profile header. They can also be added at the visit level by clicking the number at the right of the visit block.

**Test Test**

1 Files Attached to Test Test at subject level

Lab Report - Lab Report.pdf  
Type: Lab Report, Pdf 1.55MB

Add New Document

1 Files attached to Test Test at subject level (Add)

Create Unscheduled Visit

### Visit Schedule

Show 25 entries

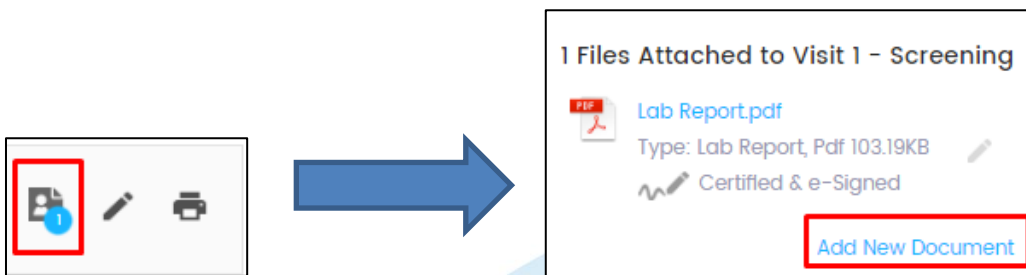
Visit	Status	Visit Date	
Visit 1 - Screening Visit 1	Partially Completed Visit	6/7/2017	Raymond Nomizu
Visit 2 - Screening Visit 2	Schedule a visit		
Visit 3 - Randomization	Scheduled	6/16/2017 8:30 AM	Raymond Nomizu

0 Files Attached to Visit 1 - Screening Visit 1

Add New Document

#### 4) Add files to the visit right from the completed visit page

You may now quickly see how many files are attached to this visit and upload files directly from this page. By clicking on the icon highlighted below you may view all documents attached, add a new document and see how many documents are already attached to the visit by the indicator on the icon.



1 Files Attached to Visit 1 - Screening

Lab Report.pdf  
Type: Lab Report, Pdf 103.19KB  
Certified & e-Signed

Add New Document

#### a. Uploading a New File

To upload a new document to the organization/study-specific file, click "Upload New File". Choose a category and the document type of the file being uploaded. The document type chosen will be the first part of the file name. The optional "Custom Name" will be appended to the file name in the format (Document Type – Custom Name).

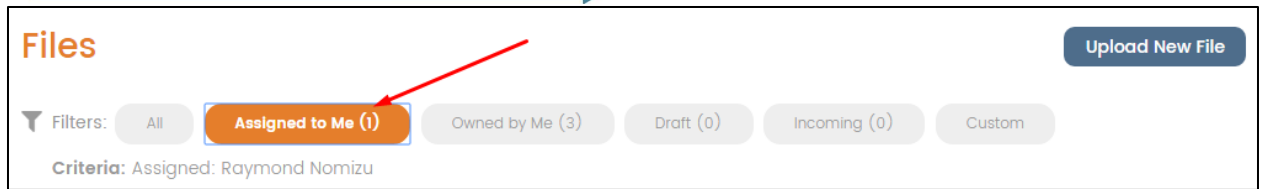


From here you may select the study the document will belong to, the subject and you may choose to select a specific visit to attach the document and enter an additional optional description. Choose the specific file and upload the document. You may save the document into the files tab or “Save and Assign” it to someone for their review. If the file is more of a subject-level attribute (e.g. a driver’s license) you may save it at the subject level (without indicating a study). The person who uploaded the document will be the default owner of the document. Uploading from the study-specific files tab will save you a stop by auto-populating the Study in which the document is to be uploaded.

The screenshot shows a modal window titled "Add New Document" with a close button (X) in the top right corner. Below the title is a grey button labeled "Choose a Category and Document Type". Underneath are two input fields: "Lab Report" and "Custom Name (optional)", separated by a plus sign (+). A blue question mark icon (?) is to the right of the second field. Below these are three search fields: "Select Study: Search by Protocol Number", "Select Subject: Search by Name", and "Select Visit (Optional)" with a dropdown arrow. Below the search fields is a text input field labeled "Enter Description (Optional)". At the bottom left is a file selection area with a "Choose File" button and the text "No file chosen". To the right of this is a grey "Upload" button. At the very bottom are four buttons: "Save", "Save and Assign", "Cancel", and "DELETE DOCUMENT" (in blue text).

#### b. Assigning a document

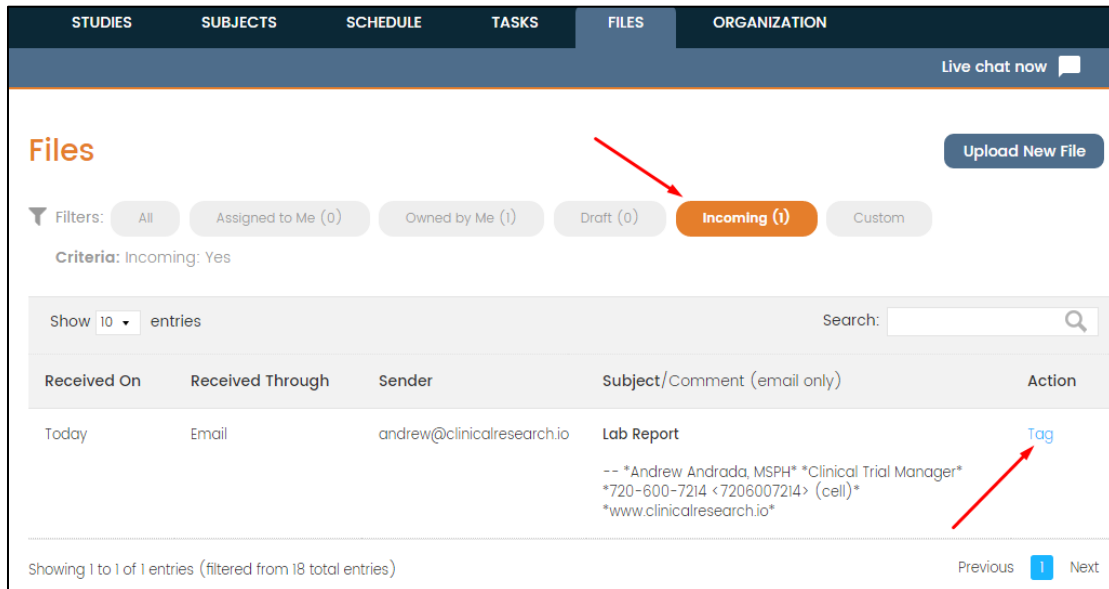
Once all the necessary information has been entered the document may now be saved and assigned. You may assign the document to any user registered within your organization by entering their name and selecting them from the dropdown. You may also add a message for the reviewer. This is an internal message and is not viewable to external users. The person being assigned the document will then get an email notifying them that a document has been assigned to them. When they log in, under the files tab, all documents assigned to them will appear under the “Assigned to Me” filter.



The owner of a document by default is the person who uploaded the document. The owner of the document may be changed to another user. The assignee may be different than the owner. The assignee is typically someone who will be reviewing/annotating the document (e.g. the physician/PI). Documents that are uploaded through an e-mail/e-fax will not have an assigned owner.

**c. E-fax/E-mail:**

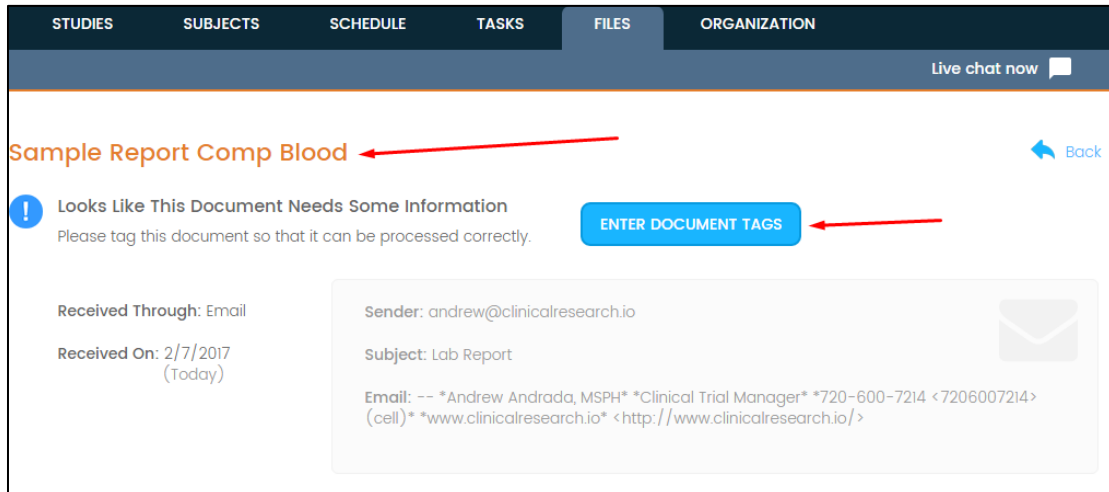
After a document has been sent via e-fax or e-mail it will appear in the Incoming tab under Files and you may then tag that document and fill required information and assign that document. Our system will grab the attachment and place it in the folder for review. It will also show the sender, the subject line and any text in the body of the email message to provide context. We recommend that you send one file at a time to the e-fax/e-mail.



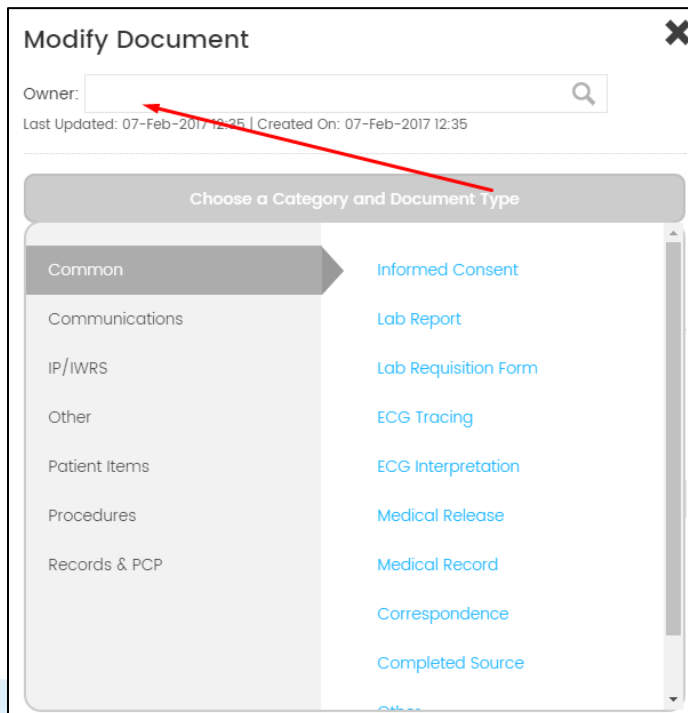
Received On	Received Through	Sender	Subject/Comment (email only)	Action
Today	Email	andrew@clinicalresearch.io	Lab Report -- *Andrew Andrada, MSPH* *Clinical Trial Manager* *720-600-7214 <7206007214> (cell)* *www.clinicalresearch.io*	<a href="#">Tag</a>

#### d. Tagging a document

After clicking “Tag”, you will find the file name in orange at the top and you may then enter the document tags.



We recommend that you enter an owner for the document for ease of tracking. Currently, we only allow for one owner and one assignee. You may designate the owner at the top of the “Modify Document” pop-up. You will have to designate the study and subject similar to when uploading a file through the “Add New File” button. You may also designate the specific visit. From here you may also Save or Save and Assign.



### Modify Document ✕

Owner:  🔍

Last Updated: 07-Feb-2017 12:35 | Created On: 07-Feb-2017 12:35

---

Choose a Category and Document Type

+

?

---

🔍

🔍

▼

Save
Save and Assign
Cancel

DELETE DOCUMENT

#### e. Annotating a document



The annotation toolbar gives you different options when annotating a document. You may:

**Draw:** You may use your mouse or finger (if using a tablet) to either right or scribble on the document.

**Square:** You may draw a box around certain items that you may want to highlight.

**Circle:** You may draw a circle around certain items that you may want to highlight.

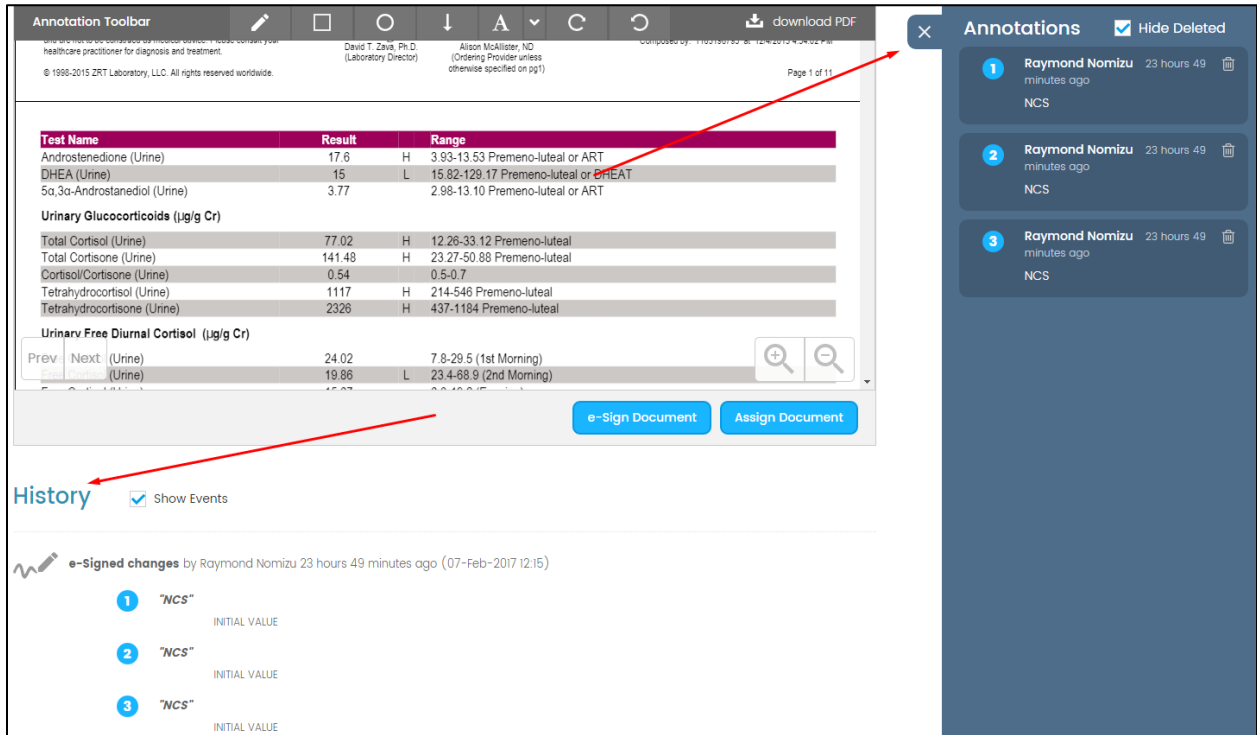
**Arrow:** You draw an arrow pointing to certain information.

**Text:** You may type out comments using this feature. Under the dropdown you have NCS and CS which can be quickly placed throughout the document simply by clicking a specific area.

**Rotate:** These two buttons orient the document by rotating in either clockwise or counterclockwise. It is best practice to rotate your document prior to annotating it because the annotations will not rotate with the document.



Once all annotations are made you may download the PDF and save/print them for your records. The file will also stay in the files tab under your organization. Once a document has been e-signed it cannot be deleted. All annotations are recorded in the history tracker. The History may be found at the bottom of the page and contains everything including who uploaded it, when it was assigned, when it was signed, etc. You may also find a complete list of the annotations in the right-side toolbar. Within the right-side toolbar you may delete, hide deleted, and click on the annotations to take you directly to that annotation.



The screenshot displays the clinicalresearch.io interface. At the top, there is an 'Annotation Toolbar' with various editing tools and a 'download PDF' button. Below this is a lab report with the following data:

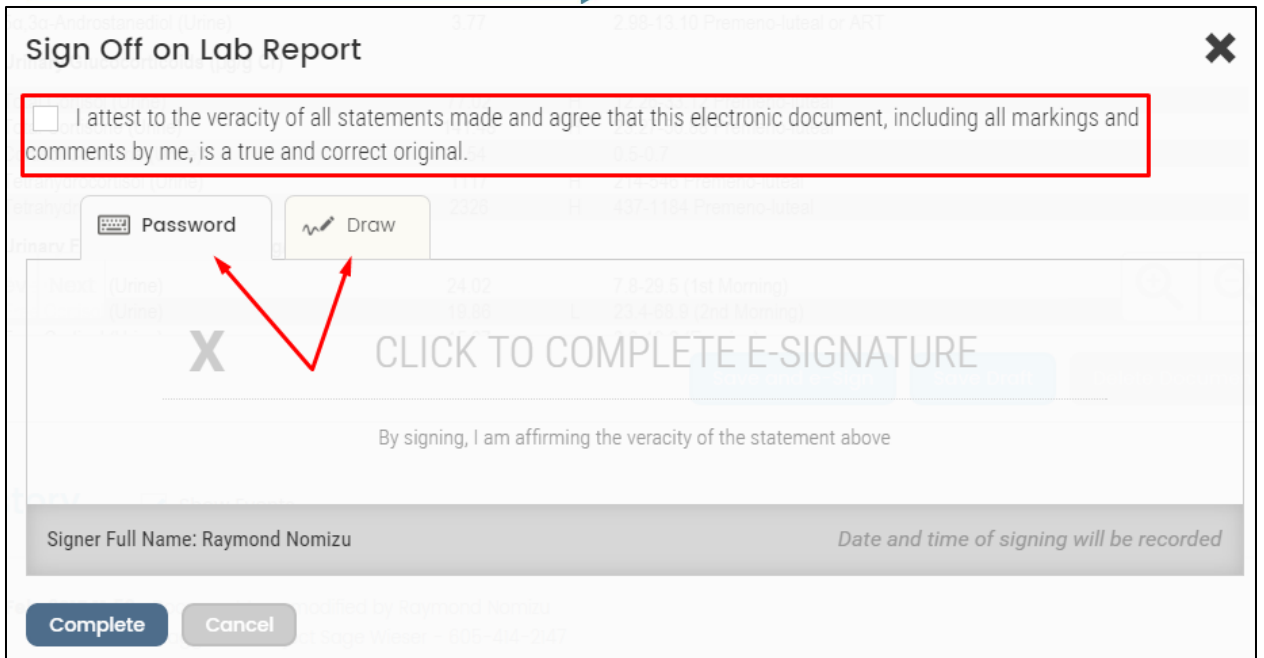
Test Name	Result	Range
Androstenedione (Urine)	17.8	H 3.93-13.53 Premeno-luteal or ART
DHEA (Urine)	15	L 15.62-129.17 Premeno-luteal or ART
5α,3α-Androstane-2,17-diol (Urine)	3.77	2.98-13.10 Premeno-luteal or ART

Below the table are sections for 'Urinary Glucocorticoids (µg/g Cr)' and 'Urinary Free Diurnal Cortisol (µg/g Cr)'. At the bottom of the report are 'e-Sign Document' and 'Assign Document' buttons. To the right is an 'Annotations' sidebar with three entries, each by 'Raymond Nomizu' with a timestamp of '23 hours 49 minutes ago'. At the bottom is a 'History' section showing 'e-Signed changes by Raymond Nomizu 23 hours 49 minutes ago (07-Feb-2017 12:15)' with three entries, each marked with a circled number and the text '"NCS" INITIAL VALUE'.

Note that external users do not see documents that are not e-signed, and when they do, they do not see the history of upload and assignment; they only see the date/time stamp of e-signature.

#### f. E-Signing a document

You may e-sign a document via two methods: password or draw. You must first check the box attesting to the veracity of all statements. You may then e-sign the document by entering your login credentials or by drawing with either your mouse or finger (when using a touch-screen).



Once a document has been e-signed the file will move from the other filters within the files tab and remain in the “All” filter. This is useful when keeping track of documents that need to be verified/annotated/e-signed. The document may also be assigned to someone after the document has already been e-signed. The new assignee may also annotate the document but must e-sign it to save the annotations.

#### g. Rejecting and deleting documents

If a document was incorrectly assigned to you, you may re-assign the document by clicking “Reject Document” at the bottom of the annotation page.



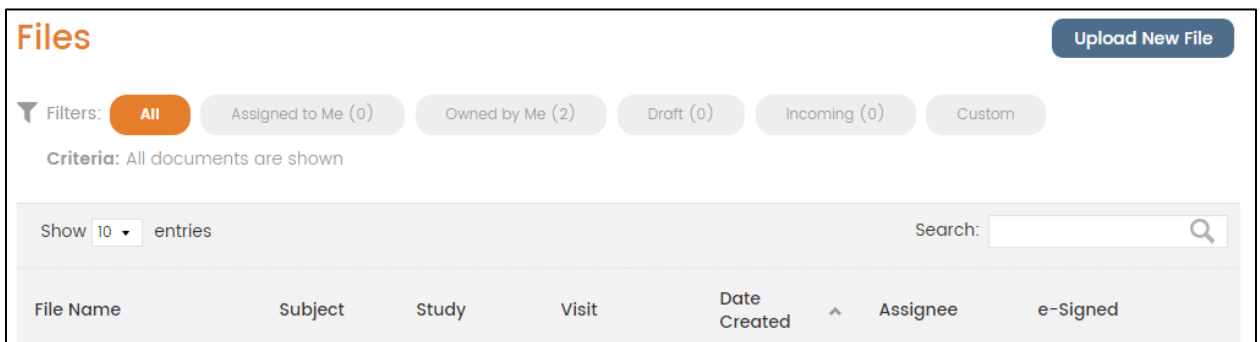
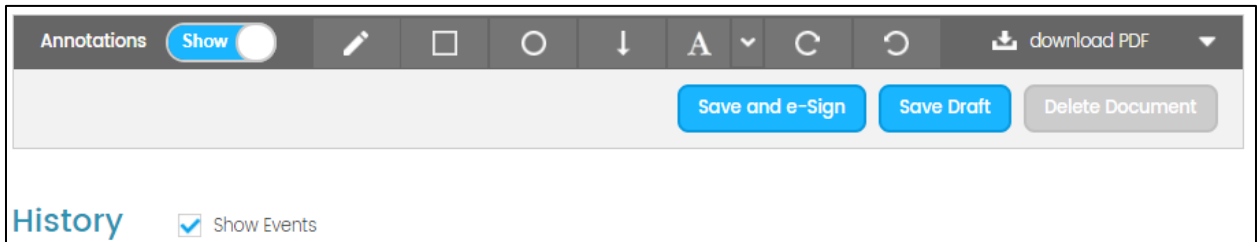
If you accidentally uploaded a document you may also delete the document by clicking the “Delete Document” button or by clicking the “DELETE DOCUMENT” button in the Modify Document pop-up. However, you may not delete a document that has already been e-signed.

#### h. Filters

The filters at the top of the page: All, Assigned to Me, Owned by Me, Draft, Incoming, Custom are there to assist in your workflow.

**i. Collapse uploaded documents for ease of e-signature and history view**

You no longer have to scroll all the way down in order to find the e-signature button by clicking the small triangle in the upper right hand corner of the document you can now collapse the entire document and be able to quickly see the document’s history and have easy access to the save and e-sign button.



All of the files will be listed under the “All” tab. Files that are assigned to you and have not yet been e-signed will be listed under the “Assigned to Me” tab. Files that you’ve uploaded and/or have been indicated that you are the owner and have not yet been e-signed will appear in the “Owned by Me” tab. Documents that have been uploaded, annotated and saved as a draft, appear in the “Draft” tab. All of the files that have been e-mailed/e-faxed into our system and have not been tagged and e-signed will be in the “Incoming” tab. The custom filter allows you to filter out all of the documents based on different characteristics of the files. You may sort on Assigned Status, Tag Status, e-Sign Status, Owned Status, and who they have been assigned to. This is a great way to observe all of the documents within your study/organization that have not yet been e-signed. You may also use the search bar to quickly search for different documents.

### Document Filter ✕

<p><b>Assigned Status</b></p> <p><input type="checkbox"/> Assigned    <input type="checkbox"/> Unassigned</p> <p><b>Tag Status</b></p> <p><input type="checkbox"/> Tagged    <input type="checkbox"/> Untagged</p> <p><b>e-Sign Status</b></p> <p><input type="checkbox"/> Signed    <input type="checkbox"/> Unsigned</p> <p><b>Owned Status</b></p> <p><input type="checkbox"/> Owned    <input type="checkbox"/> Not Owned</p>	<p><b>Assigned to</b> <span style="float: right;"><a href="#">Select All</a></span></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> ME</li> <li><input type="checkbox"/> All Coordinators</li> <li><input type="checkbox"/> All Investigators</li> <li><input type="checkbox"/> Raymond Nomizu</li> <li><input type="checkbox"/> Natalie Shaw</li> <li><input type="checkbox"/> Alex Wang</li> <li><input type="checkbox"/> Katsue Seki</li> <li><input type="checkbox"/> Nicole Mastacouris</li> <li><input type="checkbox"/> Tulani Tiah</li> <li><input type="checkbox"/> Natasha Khona</li> </ul>
---	---

Apply Filters
Clear All

## G. Multi-records/Logs

- a) Multi-records have been completely revamped! Now when looking at the completed visit page you'll be able to quickly view any changes that have been made since the last visit (denoted in orange). For example, in con meds, you'll be able to quickly see what specific change has been made to which medicine and you can see if any medicines have been deleted.

✓ **Concomitant Medications**
↗

● Denotes change from last visit (Unscheduled visit)

Check here if no medications to report ✎ **False**  
*Raymond Nomizu, 03-Jul-2017 10:13*
+

#	MEDICATION	REASON	START	STOP	C
✓ 1	advil	headache	28-MAR-2017	03-JUL-2017	▼ 1
✓ 2	xanax	anxiety	28-MAR-2017	ONGOING	▼

1 Deleted Records (1 deleted from last visit) ▼

✓ **Concomitant Medications**
↗

● Denotes change from last visit (Unscheduled visit)

Check here if no medications to report **False**  
*Raymond Nomizu, 03-Jul-2017 10:13*

#	MEDICATION	REASON	START	STOP	C
✓ 1	advil	headache	28-MAR-2017	03-JUL-2017	▼ 1
✓ 2	xanax	anxiety	28-MAR-2017	ONGOING	▼


1 Deleted Records (1 deleted from last visit) ▲

✖ **DELETED RECORD - 7/3/2017 10:13 AM**  
 3 er wr 02-MAY-2017 ONGOING ▼

Concomitant Medications						
Check here if no medications to report		<span style="color: orange;">●</span> Denotes change from last visit (Unscheduled visit) <span style="color: red;">New record since last visit</span>				
		<b>False</b> <i>Raymond Nomizu, 03-Jul-2017 10:13</i>				
#	MEDICATION	REASON	START	STOP	C	
✓ 1	advil	headache	28-MAR-2017	03-JUL-2017	▼ 1	
✓ 2	xanax	anxiety	28-MAR-2017	ONGOING	▼	
✓ 3	Tums	tummy ache	01-JUL-2016	ONGOING	▼	

b) Logs –easily access all carry forward multi-records in one place

All multi-record carry forward procedures configured within your study can now be found as a current running log. When opening the logs from this page you are actually opening the last visit which contains this log. These logs will provide you with the latest information recorded in each procedure. For example, you’ll be able to see all of the latest con meds for that patient in one place instead of having to enter the last visit and find their con meds procedure. If you edit from the Logs page, changes will be applied to the most recent visit in which that procedure appeared. All multi-records that carry forward will appear in Logs.



**Jerry MaGuire**

**Patient ID:** 200-1001

**Randomization ID:** -

**ENROLLED**

**Email:** jerrymaguire66@gmail.com

**Work Ph:** -

**Mobile Ph:** 617-555-1234

**Gender:** Male

**DOB:** -

Visit Schedule | 
 Progress Notes | 
 Profile Changes | 
 Logs

Medical History

✓ Concomitant Medications

✓ Adverse Events

Medical History

No data until first procedure at Visit 1 - Screening

✓ Concomitant Medications 📄

Values taken from Visit 9 - Week 20 (Completed on 7/3/2017)

**Check here if no medications to report** **False**  
*Raymond Nomizu, 02-Mar-2017 16:48*

#	MEDICATION	REASON	START	STOP	C	
✓	1	Gabapentin	Neuropathic pain	00-JAN-2014	ONGOING	▼
✓	2	Aspirin	Cardio health	00-JUL-2015	ONGOING	▼
✓	3	tylenol	back pagin	08-FEB-2017	ONGOING	▼ <span style="background-color: orange; border-radius: 50%; padding: 2px;">1</span>

CONCOMITANT MEDICATIONS - PROGRESS NOTES (0)
+ ADD PROGRESS NOTE

## H. External Users

### H.1 General overview

Welcome to Clinical Research IO. In order to get access to our system ask the Organization administrator to give you access to the specific studies that you are monitoring. You will receive an email inviting you to the system and that specific study. Click on the link to create your account in CRIO.

Hi Angela,

You have been invited by Raymond Nomizu to join Test Organization - Cambridge, MA as an external user on the following study:  
null - 747-303

To accept this invitation and join, please click on the link below:  
<https://qa.clinicalresearch.io/account/invitation/9654d63c-de9e-4aba-b7e3-5ebc0db0a3c4>

Cheers,  
The ClinicalResearch.IO Team

Once you've created your account you may update your profile (update your contact information and profile photo if you'd like).

You may then view all studies you are assigned to. Please note that if you don't see any studies ask the coordinators to ensure you've been added to that specific study. You may enter a study

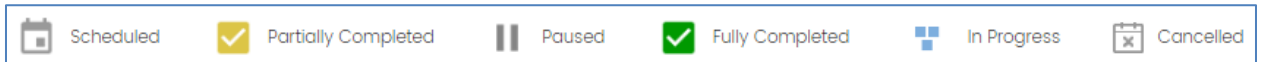
info@clinicalresearch.io / 617-302-9859



to view all subjects and visits. To quickly navigate between studies you may click on the study toolbar for a dropdown list of all the studies or you may click on the blue “View All Studies” hyperlink.

## H.2 How to view data

There are several tabs that you may view: subjects, progress notes, comments, files and logs. Within the subjects tab you may view all of the subjects within that study and their visit schedule. The different icons within the visits represent scheduled, partially completed, paused, fully completed, in progress and cancelled.



Hovering over the different visits gives you a specific date regarding that visit. You may click on those visits that are fully or partially completed to view the data.

When entering a specific visit you will initially see the time that visit was scheduled, the subject’s initials and their subject ID, what visit it is and visit title, who the principal investigator is and who the contributing users are. Hover over the blue hyperlink to view the contributing user’s names. You may also print the entire visit if need be. If you would like to view all the visits for that particular subject you may click on their icon and it will take you to their subject page and you may view their entire visit schedule.

When entering a specific visit, on the left hand side you’ll see a blue side bar, which indicates all of the procedures within that visit:

A screenshot of a web interface showing visit details. At the top, it displays "10:00 AM W-B 1240-1086" and "Visit 1 Screening". To the right, it lists the "Principal Investigator Victoria Kuohung" and "1 contributing users" with a printer icon. Below this is a list of procedures: "Informed Consent" (green checkmark), "Demographics" (green checkmark), "Smoking Status" (yellow exclamation mark), "Alcohol Status" (green checkmark), and "Childbearing and Contraception" (yellow exclamation mark). To the right of this list are checkboxes for "Hide Audit Trail" and "Hide Resolved Comments", and a "View Comment Log" button. A large orange bar highlights the "Informed Consent" procedure. Below the list, there is an "Instructions" section with the text "\* At time of procedure: Informed Consent Form vNA (6/14/2016)".

The green check mark means that the procedure is completed and the yellow exclamation point means that that procedure is incomplete. You may click on the procedure to quickly jump to that procedure. In incomplete procedures you’ll see that the unanswered question is highlighted in red.





When reviewing the data within CRIO there are important things to note: The values recorded during the visit are marked in bold:

<b>Patient position</b>	<b>Sitting</b> Raymond Nomizu 2/26/2017 2:14 PM Initial Value
<b>Patient position time</b>	<b>26-FEB-2017 14:08</b> Raymond Nomizu 2/26/2017 2:14 PM Initial Value
<b>Vitals time</b>	<b>26-FEB-2017 14:14</b> Raymond Nomizu 2/26/2017 2:14 PM Initial Value

The information below the data entered indicates the audit trail, the user that entered the data and the time that the specific procedure was saved. In our system, answers are saved for the entire procedure at once. Therefore you'll see that each question within that procedure will often have the same time stamp. The actual time that each question within the procedure was completed will vary.

If any data has been updated since the visit you may view the audit trail below the entered values

<b>Units</b>	<b>micrograms (ug)</b> Katsue Seki 9/26/2016 4:42 PM Change Reason: Clarification/New Info <i>Details: unit change</i> <ul style="list-style-type: none"><li>Katsue Seki, 9/26/2016 3:53 PM Initial Value milligrams (mg)</li></ul>
--------------	--

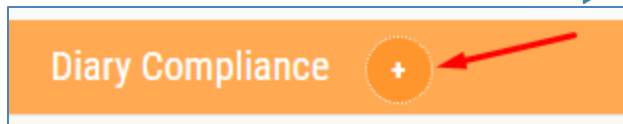
In this example you can see the initial value was milligrams and was changed later that day to micrograms by the same user. The change reason is even indicated there.

### H.3 Generating queries/stickers

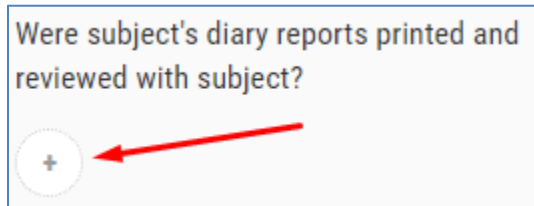
When reviewing the data there are three places you may generate a query: at the procedure level, question level and on progress notes.

Procedure level:

info@clinicalresearch.io / 617-302-9859



Question level:

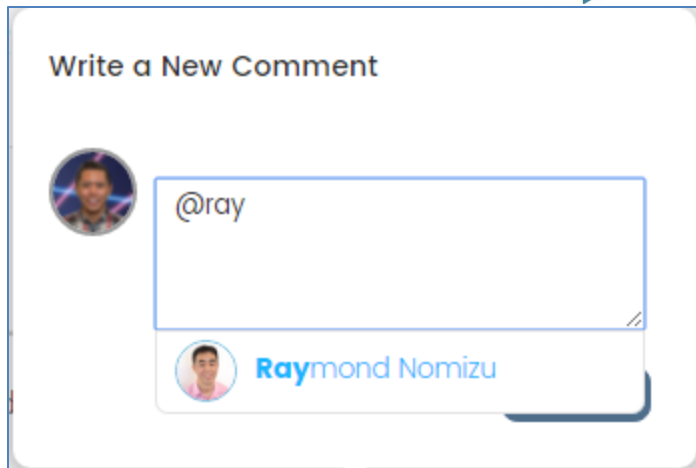


Progress notes:



From there you may use the "@" symbol to direct the comment to a specific user. Begin typing their name and their username will appear in a drop-down list. They will receive an email alerting them that a comment has been made.

By default, you will also receive an email any time a user replies to one of these comments. If you would like to turn off email notifications and manually check the system, you may go to your Profile and toggle your subscription status to Unsubscribed for any study.



You may view the comment log to view the comments within that visit and you may toggle all resolved comments. Click on the comments tab to view all comments within that study. Comments are numbered by visit and reset their number for each visit. From there you may see all of the comments and the ones that have been marked as resolved will have a checkmark. You may even click on the comment and it will take you directly to where that comment was made.

The other tabs within the study allow you to view all progress notes and quickly jump to where those progress notes were published, all comments within the study, any files uploaded and the different logs (screening log, subject ID log, ICF log). Within the Files tab, you may view all annotated files that have been e-signed. These files may include: lab reports, ECGs, consents, etc. You may view all annotations in the annotations side bar. Click on a specific annotation and it will take you directly to where that annotation is. You may also view files attached to that subject within their subject page.

#### H.4 Help

If you need help at any moment feel free to use the LiveChat feature. Our customer support team is readily available from 9am to 9pm EST. We're happy to help you resolve any issue that you may encounter while conducting your visit. Please don't hesitate to reach out to us.

### I. Miscellaneous Updates

#### I.1 Audit trail

The audit trails regarding multi-records shows the initial value that was recorded and all the times that it was re-affirmed. Once a value has been changed that latest value will appear and information regarding who modified that value will appear as the latest information.

Stop 03-JUL-2017  
Raymond Nomizu, 03-Jul-2017 10:45

- 03-JUL-2017  
Re-affirmed by Raymond Nomizu, 03-Jul-2017 16:22
- 03-JUL-2017  
Change Reason: Clarification/New Info  
Modified by Raymond Nomizu, 03-Jul-2017 10:45
- ONGOING  
Re-affirmed by Raymond Nomizu, 02-May-2017 12:38
- ONGOING (initial value)  
Recorded by Raymond Nomizu, 02-May-2017 12:36

## I.2 Screen fail auto-complete

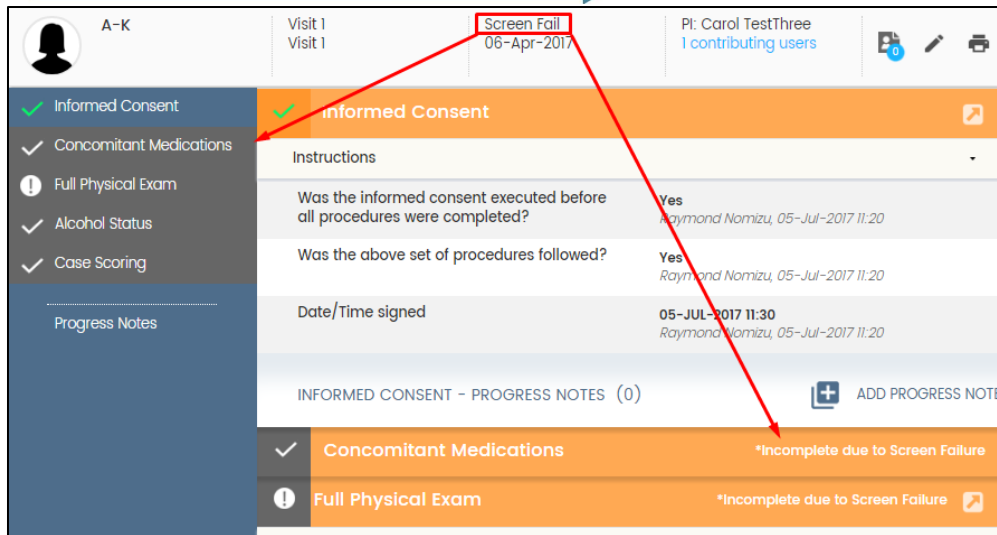
No longer have to worry about showing fully completed procedures when a subject screen fails. Once the subject screen fails, complete the visit and update the subject's status to screen fail. Once the subject's status is updated to screen fail all empty/incomplete procedures will be grayed out and those incomplete will be noted as "Incomplete due to Screen Failure". Any procedures that were completed or incomplete will have a green check mark or white exclamation mark, respectively. When viewing the Subject Status page, a new symbol will appear denoting that the subject has screen failed (a gray check mark). This allows for coordinators and monitors to quickly differentiate between an actual incomplete visit and a screen failure.

Subjects

Add New Subject

Scheduled
  Partial
  Screen Fail
  Completed
  Paused
  In Progress
  Cancelled

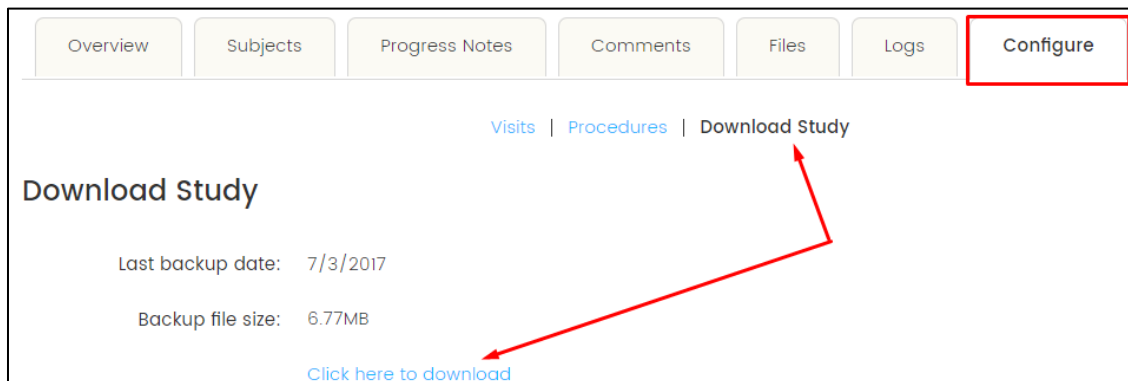
Subject	ID	Status	Screening		Treatment		
			Visit 1	Randomization	Visit 3	Visit 4	Visit 5
O-B 555	555	In Screening ⚠️ 1 UNSCHEDULED VISITS	✅	✅	✅	📅	
T-B	-	In Screening ⚠️ 1 UNSCHEDULED VISITS	✅	✅	📅		
J-J 444	444	Screen Fail	⊠️				
A-K	-	Screen Fail	⊠️				



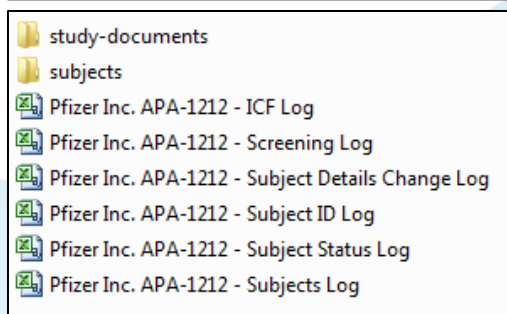
The screenshot shows a user interface for a clinical trial. At the top, there is a header with a user profile icon, the text 'A-K', 'Visit 1', and a 'Screen Fail' notification dated '06-Apr-2017'. Below this is a sidebar with a checklist of items: 'Informed Consent' (checked), 'Concomitant Medications' (checked), 'Full Physical Exam' (with a warning icon), 'Alcohol Status' (checked), and 'Case Scoring' (checked). The main content area shows details for 'Informed Consent', including instructions and two questions: 'Was the informed consent executed before all procedures were completed?' (Yes) and 'Was the above set of procedures followed?' (Yes). Below this is a section for 'INFORMED CONSENT - PROGRESS NOTES (0)' with an 'ADD PROGRESS NOTE' button. At the bottom, there are two orange bars indicating incomplete items: 'Concomitant Medications' and 'Full Physical Exam', both marked as '\*Incomplete due to Screen Failure'.

### I.3 Download all study source data

You may now download all files for your study with the simple click of a button. To do this - those with configuration access – go to the configure tab and select download study. From there you will get a zip folder, which contain all of your logs in CSV format (ICF, Screening, Subject Details Change, Subject ID, Subject Status, Subjects logs), a folder containing any study documents (general ICFs, etc.) and a folder containing all your subjects and any data collected on them (every visit, lab/documents uploaded and progress notes).



The screenshot shows the 'Configure' tab selected in the top navigation bar. Below the navigation bar, there are three tabs: 'Visits', 'Procedures', and 'Download Study'. The 'Download Study' tab is active. Below this, the text 'Download Study' is displayed. Underneath, there are two lines of information: 'Last backup date: 7/3/2017' and 'Backup file size: 6.77MB'. At the bottom, there is a blue link that says 'Click here to download'. A red arrow points from the 'Download Study' tab to the 'Click here to download' link.

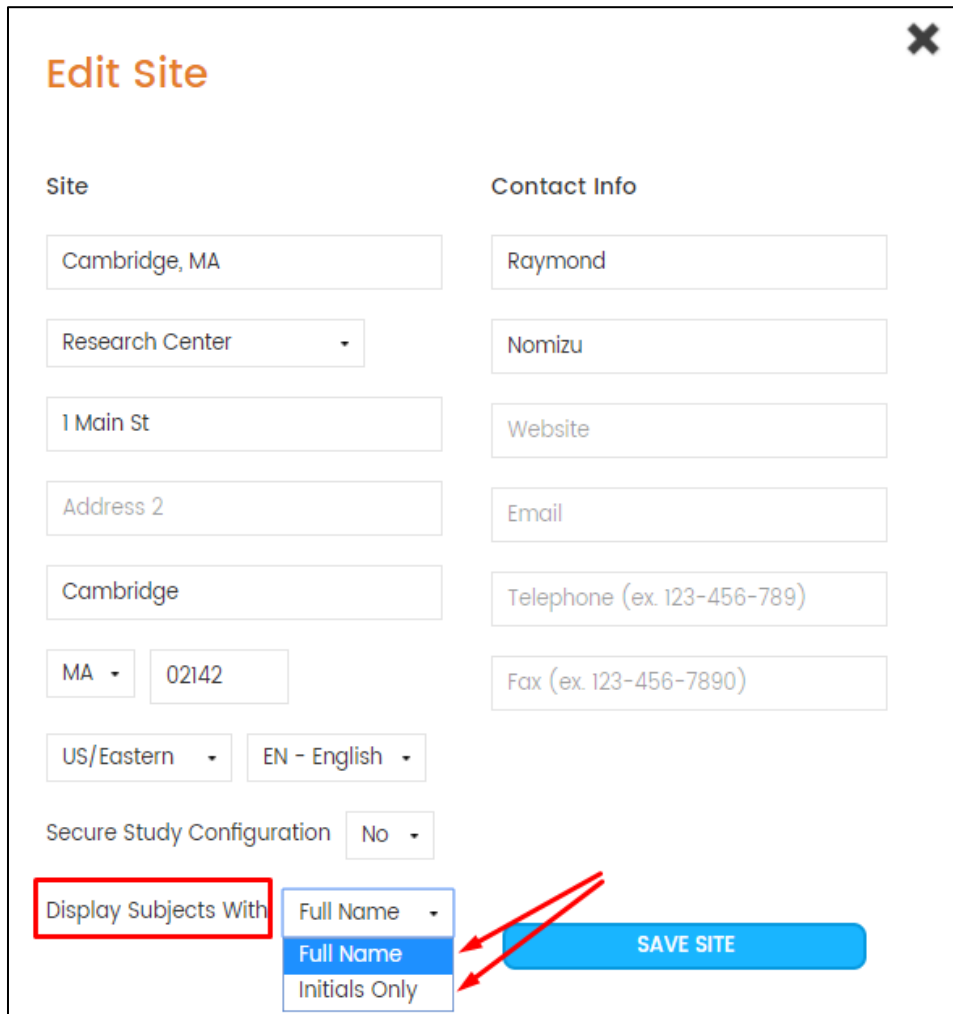


The screenshot shows a file explorer window displaying the contents of a downloaded zip file. The files are listed as follows:

- study-documents
- subjects
- Pfizer Inc. APA-1212 - ICF Log
- Pfizer Inc. APA-1212 - Screening Log
- Pfizer Inc. APA-1212 - Subject Details Change Log
- Pfizer Inc. APA-1212 - Subject ID Log
- Pfizer Inc. APA-1212 - Subject Status Log
- Pfizer Inc. APA-1212 - Subjects Log

#### I.4 Site-wide settings for patient initials or full names

The option to display your subjects with either their full name or their initials is now available within your organization. To toggle this option, enter the organization tab, select sites and edit your site to find the option on the bottom left. The settings will be reflected on the cards on the Subjects page, on the Visits table, on the Completed Visit page, and on Desktop and Android data collection.

A screenshot of the "Edit Site" form in the clinicalresearch.io interface. The form is divided into two columns: "Site" and "Contact Info". The "Site" column contains fields for "Cambridge, MA", "Research Center" (dropdown), "1 Main St", "Address 2", "Cambridge", "MA" (dropdown), "02142", "US/Eastern" (dropdown), "EN - English" (dropdown), and "Secure Study Configuration" (No dropdown). The "Contact Info" column contains fields for "Raymond", "Nomizu", "Website", "Email", "Telephone (ex. 123-456-789)", and "Fax (ex. 123-456-7890)". At the bottom left, the "Display Subjects With" dropdown menu is open, showing options for "Full Name" (selected), "Full Name", and "Initials Only". A red box highlights the "Display Subjects With" label, and red arrows point from the "Full Name" and "Initials Only" options to the "SAVE SITE" button. The "SAVE SITE" button is a blue rounded rectangle at the bottom right of the form.

## Appendix I

### SQLite Examples

#### QUESTION LOGIC

*Example: Score needs to be between 4-8 to be eligible*

If query ( `value < 4 or value > 8` ) is true, then alert ( **Patient is not eligible** )

*Example: Unknown day or month not allowed*

If query ( `value like '00-%' OR value like '%-000-%'` ) is true, then alert ( **Unknown day or month is not permitted; you must input an exact date** )

*Example: Unknown day not allowed*

If query ( `value like '00-%'` ) is true, then alert ( **Unknown day is not permitted** )

*Example: On a multi-choice, do not select "None of the above" and another selection*

If query ( `value like '%\n%neither%' or value like '%neither%\n%'` ) is true, then alert ( **You have selected None of the above and another selection** )

*Example: if fewer than two selections are made in a multi-select question, create alert*

If query ( `length(value) - length(replace(value, '\n', '')) < 1` ) is true, then alert ( **" Patient must agree to use at least 2 forms of contraception or they cannot participate in the study."** )

#### PROCEDURE LOGIC

*Example: if wocbp\_status is Yes, then disable the question associated with reason\_for\_ncbp\_status*

If query ( `wocbp_status = 'Yes'` ) is true, then disable **"reason\_for\_ncbp\_status"**

*Example: if stop\_date is ONGOING and outcome is something other than Not Resolved, then provide alert*

If query ( `stop_date = 'ONGOING' AND outcome != 'Not Resolved'` ) is true, then alert ( **"You have indicated the AE is ongoing but something other than Not Recovered; the two answers are incompatible"** )

*Example: vitals\_time should be 5 minutes after pt\_position\_time*

If query ( `vitals_time < datetime(pt_position_time, '5 minutes')` ) is true, then alert ( **Patient has not rested 5 minutes; please wait a little longer** )

- OR -

If query ( `vitals_time < datetime(pt_position_time, '0.083 hours')` ) is true, then alert ( **Patient has not rested 5 minutes; please wait a little longer** )



Other Operators:

<> = not equal to

### FORMULAS

To utilize formulas, use the variable names and/or numbers, along with various SQLite commands. Most commonly used commands:

\* = Multiplication

/ = Division

*Example: Calculate number of pack years using multiplication and division (# of cigarettes per day/20) \* # years smoked. Variable names: num\_of\_cigarettes, num\_yrs\_smoked*

Method: **Formula**

Questions to use: **(num\_of\_cigarettes / 20) \* num\_yrs\_smoked**

### ROUNDING MODE

There are 4 rounding modes. The default is Standard (Half Up), basically rounds to the nearest integer with .5 going up. The 4 modes and examples are:

- Standard (Half Up): 4.5→5
- Half Down: 4.5→4
- Up: 4.01 to 4.99→5
- Down: 4.01 to 4.99→4