# SMART-TRIAL training guideline for sites and collaborators

# Purpose

The purpose of this document is to guide SMART-TRIAL study managers on how to perform site training and final UAT of studies in SMART-TRIAL, before study start (production).

Please review the SMART-TRIAL help center for any questions you might have on using the platform: https://help.smart-trial.com/

# Guideline overview

Before a study goes live (starts enrolling subjects and enter data) the following steps must be completed.

- ✓ Data managers must ensure that study setup in SMART-TRIAL adheres to the requirements specified in study protocol
- ✓ Data managers must know how to
    - o Manage and enroll subjects
    - o Enter form data
    - o Edit form data
    - o Discontinue subjects
    - o Register AE/SAE and/or concomitant medication
    - o Create and manage queries
- ✓ Clinical study staff, such as principle investigator, coordinators, data entry staff, and monitors must be trained in using SMART-TRIAL for data entry and monitoring. Such training shall be documented with a SMART-TRIAL training log.
- ✓ Data managers should consider all changes recommended by study staff during training
- ✓ Study setup in SMART-TRIAL shall be validated by documenting a UAT (user acceptance test) in "Test mode". This shall only be done when final corrections (if any) have been implemented, together with training of study staff.

# Standard Operating Procedure for Site user training

## 1. Add collaborators

Before you conduct training with study site staff/users, especially for data entry, a rule of thumb is to add those users as collaborators to the study before you perform the training with the Site.

Start by informing the users of the set training date and time and inform them that you will add them as a collaborator to the SMART-TRIAL study before your training meeting. Tell them that they will receive an email from SMART-TRIAL with a notification.

To ensure that they have created an account and can login, you might need to have a short call with the Site before the training session, to assist with the process. If they cannot login during training, you will end up wasting valuable time on IT issues.

You can add collaborators to a study by using the collaborators menu in SMART-TRIAL. You only need an e-mail address to do so.

If the person does not have a user account in SMART-TRIAL, they will receive an email with an invitation to collaborate on your study. In this email, they will have to click on the link, and create an account.

Learn how to add collaborators here:
https://help.smart-trial.com/adding-collaborators

## 1.1 Choosing the right permissions and roles

When you add a new collaborator to your study, make sure that you use the correct email address, and select the correct site. It's very important to note that emails are CASE SENSITIVE. So make sure that if the user's email has capital letters, that these are included.

Choosing the right permissions can be confusing at first but we have already recommended a set of permissions for you to specify for each study role.

See what permissions to set for your study collaborators here:
https://help.smart-trial.com/permissions and use the SMART-TRIAL permission template to keep track of it
https://help.smart-trial.com/smart-trial-permissions-template

## 1.2 Common issues with "adding collaborators"

Because clinical sites (such as hospitals) often have strict IT systems, issues with creating an account often occur. This is very normal, and we have to take these issues into account when training sites in using SMART-TRIAL.

**A)** The most common issue is that a user doesn't receive the "invitation to collaborate" email and thus cannot create an account. This can be due to different reasons. But make sure to do the following:

- Ask them to look through their "Spam/junk" or "Other" email folder for an invitation email from "SMART-TRIAL"
- If they cannot find the email from SMART-TRIAL, ask them to create an account (using their work email) via https://www.smart-trial.com/signup

**B)** If they have created an account, but cannot login because their email is not validated, ask them to find an email from SMART-TRIAL with the subject of "Confirm your email address" and click on the link in it to validate it. This email is sent from SMART-TRIAL to the user account's email, to confirm that the email is correct.

**C)** If they did not receive the "Confirm your email address" email this can be due to the fact that the site IT department doesn't allow emails from the SMART-TRIAL domain, i.e. "smart-trial.co"

*Possible solution:* Ask the site to contact their IT department (or do it for them) and ask them to allow (whitelist) emails from the SMART-TRIAL domain (mail.smart-trial.co and mail.smart-trial.com) in order for them to use the SMART-TRIAL system

When the domain has been allowed, users can request to resend the validation email from the SMART-TRIAL login screen (by trying to login).

## 2 Training and study start

Before any training is conducted, please ensure that sites can use one of the recommended internet browsers to access SMART-TRIAL. See 5.15 in https://www.smart-trial.com/legal/security-statement for supported browsers. This is critical, as you must ensure that training can proceed as efficiently as possible.

## 2.1 Issues with browsers

Due to security measures, only modern browsers are supported with SMART-TRIAL - which also ensures speedy and optimal use. But some clinical sites only have standard browsers like Internet Explorer available. Internet Explorer version 11 can be used, but the user experience is highly degraded.

We highly recommend all sites to use a modern browser such as Chrome, Firefox, Safari or Edge. Please ask your site to install one of the modern browsers, like for example Chrome via https://www.google.com/chrome/

- If the site cannot install a browser themselves, please ask the site to contact their IT department to allow them to install a modern browser to enable optimal support for SMART-TRIAL.

## 2.2 Training

To train the study staff, make sure that you have initiated "test mode" on the study OR created a specific "Test site" OR created a specific "Test/Sandbox Study".

See how to start "Test Mode" here: https://help.smart-trial.com/test-study This will enable test-data collection for up to 5 subjects, which can be deleted from the study database before study start.

If you are using a "Test site" you can give users access to this site, and remove a couple of weeks after training, to ensure that actual subjects are not enrolled to the test site.

If you are using a "Test/sandbox study" you can give users access to this sandbox study, and leave the access as is during the Study, for them to "play with" if needed.

Before training, the data entry staff should have a user account, be able to log in, and be collaborators on your study.

Using the Standard Operating Procedure (SOP or manual), you should guide the user through the necessary elements of the study. It's often good to have the SOP printed out or and share with the site in PDF so they have it at hand.

During training you should at least guide the users through the following steps. It's important that you ask the user to use the system – you should not be the one controlling the mouse ☺

**Make sure to review the following:**

- ✓ How to access SMART-TRIAL and login. Ask them to place the SMART-TRIAL login screen in the browser bookmarks/favorites.
- ✓ How to access the study
- ✓ How to access the site and enroll a subject (enroll a test subject during training)
- ✓ How to enter data, and if possible, try to complete data entry for the complete study flow for one subject.
- ✓ Show users how to edit eCRF form answers
- ✓ Note how and when to randomize (if relevant).
- ✓ Guide in registering unscheduled "visits" and entering data (if relevant)
- ✓ Guide in creating and reviewing AE/SAE reports (if relevant)
- ✓ Guide in registering concomitant medications (if relevant)
- ✓ Guide in how to discontinue a subject (in case of drop-out)
- ✓ Guide in how to respond to a query, and where to find query notifications.
- ✓ Tell users where they can look for help, i.e. via SOP/manual, https://help.smart-trial.com/, and support@smart-trial.com

All of the elements above should be described in the SOP/manual that shall be prepared before training.

**NOTE:** Before you leave the site, please complete the training log so you have documentation on that training has been conducted. Download it here: https://help.smart-trial.com/document-templates

**This should be kept in your study master file.**

We recommend that you allow site staff to play with the study in test-mode for a few days, before validation/UAT report is created and study goes live. This will enable them to become comfortable with the system before starting the data collection.

## 2.3 End of training and study start

If no corrections have been noted during training and site-testing from site staff, validation can be conducted, and the PRODUCTION study can be initiated by pressing the "START STUDY" button in SMART-TRIAL.