OpenClinica Quickstart Guide

When you first log in to OpenClinica as "root" you will be logged into a study called "Default Study." Let's start by creating a CRF to use for data entry. Click on "Administer CRFs" in the Business Admin module. You will be brought to the Administer CRFs page of OpenClinica.

- At the top of the page, underneath the title, should be a link stating "You can download
 a blank OpenClinica CRF Excel spreadsheet template here." Click on the "here" link
 to download the template.
- 2. Read the instructions tab of the CRF template and enter the correct information for any fields you require on each of the tabs.
- 3. Once you have finished entering information in the CRF template, save it and click on the "Create a New CRF" link in the table.
- 4. Enter the CRF Name and a brief Description. Click on Confirm CRF.
- 5. Click Submit CRF.
- 6. Enter the version number and click "Confirm Version."
- 7. Browse for the file and upload it to the website. If it passes validations, select the button that says "Click Here to Continue." If it does not pass validations, fix the template and resubmit it. If you are having trouble with your own CRF template, try uploading a <u>sample CRF</u>, which you can upload without editing.

You have now created a CRF. The next step is to take this CRF and assign it to an event definition.

In order to create a new definition, navigate to the Home page and click "Manage Definitions" in the Manage Study module.

- 1. Click "Create a new study event definition" in the upper right of the table.
- 2. Enter the event definition name you would like to use, and populate the rest of the information as appropriate. Click "Continue."
- 3. Click the check box of the CRF you just created, and then hit "Continue."
- 4. Click "Continue" again, and then "Confirm and Finish."

An event definition has now been created, so the last part of set up will be to create some subjects. Navigate back to the Home page and then click "Add Subject" in the Submit Data module.

- 1. Click "Proceed to Add Subject."
- 2. Enter the required information for the subject, and click "Save and Assign Study Event."
- 3. Select the event definition you created previously, enter a location and then click "Proceed to Enter Data."

You have now created a study subject, and assigned the subject to an event. You can continue on to entering data to get the feel of how the software works. Or, you can go click on "View All Subjects" in the upper right and add another subject through that matrix.

At this point, you should have a feel of how the software works, and how to create and manage a basic study. You can continue to explore the rest of the features in the application to see how it works. Use the help icons to learn more about specific features. When you are comfortable, try creating your own study.

Please feel free to sign up for <u>users@openclinica.org</u>, and post questions there. You can also send questions to <u>contact@akazaresearch.com</u> if you run into any issues or want to get more information about our Enterprise services.