

3.4.3 Overview of Creating and Modifying CRFs

Before defining the CRF, design it by identifying all the Items that will be on it, the parameters for each Item, and how they will be organized on the form. For guidelines, see Designing a CRF.

This is the overall process for defining a Case Report Form (CRF) for use in your OpenClinica system:

- 1. Download the CRF template or an existing, defined CRF. For detailed instructions, see <u>Create</u> a CRF.
- 2. Modify the Items and other content in the defined CRF using Microsoft Excel. See <u>Providing Content for a Defined CRF.</u>
- 3. <u>Upload the defined CRF</u> to your OpenClinica system, then identify and correct any errors.
- 4. <u>Assign the defined CRF to an Event Definition in a Study</u> as part of the Build Study process. Review the Event Definitions for the Sites in the Study, and if necessary, modify the parameters for the defined CRF at the Sites in the Study.

This page is not approved for publication.

3.4.3.1 About CRF Versions

You can use a defined CRF in multiple Event Definitions and in multiple Studies in OpenClinica. You can also <u>create different versions of the defined CRF</u>. When you assign a CRF to a Study Event, you can specify which versions of the CRF are available to that Event and can specify the default version to be used. For example, you can create a defined CRF in English and create another version in Spanish; then, when a user completes the CRF for a Study Subject, the user can choose the version of the CRF based on the language they prefer to work with.

When you define a CRF, OpenClinica creates a parent record (called the "original"), and a version that can be used to collect data. When you create a new version of the CRF, it has the same name as the "original," but has a different version label assigned to it. When you make a change to a defined CRF, if there are other versions of the defined CRF that the change applies to, you will need to make the change to each version of the defined CRF.