

3.4.5 Create a CRF

































































Before defining a CRF, you need to create the CRF you will use as a basis:

1. From the Tasks menu, in the Study Setup module, select Build Study.

The Build Study page displays.

2. For the Create CRF task, click the View icon.

The Manage Case Report Forms (CRFs) page opens.

Manage Case Report Forms (CRFs) 										
Page 1 of 1		<input type="text"/>		<input type="button" value="Find"/>		Blank CRF Template		OpenClinica CRF Library		<input type="button" value="Create a New CRF"/>
CRF Name 	Date Updated	Last Updated by	CRF_OID	Versions	Version_OID	Date Created	Owner	Status	Download	Actions
Adverse Events	05-Jul-2011	agoodwin	F_ADVERSEEVENT	(original)		05-Jul-2011	agoodwin	available		   
				v1.0	F_ADVERSEEVENT_V10	05-Jul-2011	agoodwin	available		  
				v1.2	F_ADVERSEEVENT_V12	05-Jul-2011	agoodwin	available		  
Agent Administration	05-Jul-2011	agoodwin	F_AGENTADMINIS	(original)		05-Jul-2011	agoodwin	available		   
				v1.0	F_AGENTADMINIS_V10	05-Jul-2011	agoodwin	available		  
Concomitant Medications	05-Jul-2011	agoodwin	F_CONCOMITANTM	(original)		05-Jul-2011	agoodwin	available		   
				v1.0	F_CONCOMITANTM_V10	05-Jul-2011	agoodwin	available		  
Eligibility	05-Jul-2011	agoodwin	F_ELIGIBILITY	(original)		05-Jul-2011	agoodwin	available		   
				v1.0	F_ELIGIBILITY_V10	05-Jul-2011	agoodwin	available		  
Physical Exam	05-Jul-2011	agoodwin	F_PHYSICALEXAM	(original)		05-Jul-2011	agoodwin	available		   
				English	F_PHYSICALEXAM_ENGLISH	05-Jul-2011	agoodwin	available		  
				Español	F_PHYSICALEXAM_ESPAOL	05-Jul-2011	agoodwin	available		  
Verification of Informed Consent	05-Jul-2011	agoodwin	F_VERIFICATION	(original)		05-Jul-2011	agoodwin	available		   
				v2.0	F_VERIFICATION_V20	05-Jul-2011	agoodwin	available		  

3. From the Manage Case Report Forms page, download the CRF you will use as a basis for defining the CRF.

Note that when you save the Excel file in this process, the Excel filename (the name that precedes .xls) is not used by OpenClinica in any way.

Choose one of the following options to download the CRF you will use as a basis:

- **Download an Existing Defined CRF:** When you want to define a CRF to be similar to one already in your OpenClinica system, download the existing defined CRF to use as a basis.
 1. From the Manage Case Report Forms page, click the Download icon in the Actions column for the version of the CRF you want to download.
 2. Save the file to your computer using a unique, descriptive name.

(Note that this is not the same as [Creating a New Version of an Existing CRF](#))

- **Download a Defined CRF from the CRF Library:** You can use a defined CRF from the OpenClinica library as a basis for the CRF you are defining. The library includes CRFs for common types of clinical forms that were defined by OpenClinica experts and are aligned with [CDISC Clinical Data Acquisition Standards Harmonization \(CDASH\) standards](#), as well as CRFs defined by the OpenClinica community.

1. Go to the [CRF Library](#) page of the OpenClinica documentation site.
2. Click Login, then log in using your OpenClinica username and password.
The CRF Library page displays.

CRF Library

This library provides example OpenClinica forms that you can use and adapt for your OpenClinica studies. Many of these forms are aligned with standards such as [CDISC CDASH](#)® and [PROMIS](#)®. The library also includes some proprietary validated instruments that are available for use with the appropriate licenses. If there are additional forms you would like to see here, please [let us know](#).

- [1 OC3 eCRFs](#)
- [2 OC4 eCRFs](#)

3. Select the link for the version of OpenClinica that you are using.
The list of available eCRFs displays:

1 OC3 eCRFs

-
- [1.1 Adverse Events](#)
 - [1.2 Completion/Discontinuation](#)
 - [1.3 Concomitant Medications](#)
 - [1.4 Demographics](#)
 - [1.5 Drug Accountability](#)
 - [1.6 ECG Test Results](#)
 - [1.7 Inclusion/Exclusion](#)
 - [1.8 Informed Consent](#)
 - [1.9 Labs](#)
 - [1.10 Medical History](#)
 - [1.11 Participant Diaries](#)
 - [1.12 Patient Reported Outcomes \(PROs\)](#)
 - [1.13 Physical Exam](#)
 - [1.14 Protocol Deviations](#)
 - [1.15 Treatment](#)
 - [1.16 Vital Signs](#)
 - [1.17 Randomization](#)
 - [1.18 Other](#)

4. Click the link for the domain you are interested in. For example, Adverse Events.
The domain page displays and may include multiple versions of forms.

CDASH Adverse Event - AE (Events)

This CRF can be downloaded [here](#).

*Rules associated with this CRF can be downloaded [here](#).

This domain is recommended for non-solicited or pre-specified adverse events. Sponsors can add other data variables as needed to this form to meet the needs of their specific protocol requirements. It is under the discretion of sponsors to determine the collection period for adverse events.

Generic Adverse Event Form

This CRF can be downloaded [here](#).

*Rules associated with this CRF can be downloaded [here](#).

Generic Serious Adverse Event Form

This CRF can be downloaded [here](#).

*Rules associated with this CRF can be downloaded [here](#).

5. Select the link for the form that best meets your needs.
If applicable, Rules associated with the form are available and should be

downloaded in addition to downloading the form.

6. Save the CRF and associated Rules to your computer using unique, descriptive names.
 - **Download a Blank CRF Template:** If you have experience defining CRFs or there are no existing CRFs that are similar to what you need, use a blank template:
 1. From the Manage Case Report Forms page, click Blank CRF Template.
 2. Save the template to your computer using a unique, descriptive name.

After creating the CRF, [provide content for it using Excel](#), then [upload the defined CRF](#) to OpenClinica.

Functional approval by Laura Keita. Signed on 2018-08-28 9:39AM

Approved for publication by Cal Collins. Signed on 2018-08-28 9:42AM

Not valid unless obtained from the OpenClinica document management system on the day of use.