

## **1.4 Manage CRFs**

If your <u>User Role or Type has appropriate permission</u>, you can access a table of all defined CRFs in your OpenClinica system. To do so, in the Tasks menu, under the Monitor and Manage Data module, select CRFs. The Manage Case Report Forms page opens, presenting the table. Use this page to view information about defined CRFs and to find and organize the CRFs.

You can also use this page to create <u>defined CRFs and modify them</u>. Certain User Roles and Types can perform additional actions: see <u>Remove, Restore, and Delete Defined CRFs</u>.

Page 1 of 2 >> >>>>				Find Blank CRF   OpenClinica CRF   Create   Template Library New CF								
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		٩.		
				v1.0	F_ADVERSEEVENT_V10	05-Jul-2011	agoodwin	available		٩.		
				v1.2	F_ADVERSEEVENT_V12	05-Jul-2011	agoodwin	available		٩.		
Agent Administration	05-Jul-2011	agoodwin	F_AGENTADMINIS	(original)		05-Jul-2011	agoodwin	available		5	6	
				v1.0	F_AGENTADMINIS_V10	05-Jul-2011	agoodwin	available		٩.		
Concomitant Medications	05-Jul-2011	agoodwin	F_CONCOMITANTM	(original)		05-Jul-2011	agoodwin	available		5	6	
				v1.0	F_CONCOMITANTM_V10	05-Jul-2011	agoodwin	available		٩.		
CT_BL_SELECT_HZ001	28-Dec-2011	acoates	F_CT_BL_SELECT	(original)		28-Dec-2011	acoates	available		5		
				1.1	F_CT_BL_SELECT_11	28-Dec-2011	acoates	available		٩.		
CT_D34_HZ001	28-Dec-2011	acoates	F_CT_D34_HZ001	(original)		28-Dec-2011	acoates	available		<b>S</b>	E	
				1.2	F_CT_D34_H2001_12	28-Dec-2011	acoates	available		٩.		
CT_FU_H2001	28-Dec-2011	acoates	F_CT_FU_HZ001	(original)		28-Dec-2011	acoates	available		5	6	
				1.1	F_CT_FU_HZ001_11	28-Dec-2011	acoates	available		٩.		
CT_Screen_HZ001	28-Dec-2011	acoates	F_CT_SCREEN_HZ	(original)		28-Dec-2011	acoates	available		5	6	
				1.2	F_CT_SCREEN_HZ_12	28-Dec-2011	acoates	available		٩.		
CT_TL_Table_HZ001	28-Dec-2011	acoates	F_CT_TL_TABLE_	(original)		28-Dec-2011	acoates	available		5	6	
				1.2	F_CT_TL_TABLE12	28-Dec-2011	acoates	available		٩.		
DCE-MRI_Analysis_HZ001	28-Dec-2011	acoates	F_DCEMRI_ANALY	(original)		28-Dec-2011	acoates	available		5		
				1.3	F_DCEMRI_ANALY_13	28-Dec-2011	acoates	available		٩.		
Eligibility	05-Jul-2011	agoodwin	F_ELIGIBILITY	(original)		05-Jul-2011	agoodwin	available		5	•	
				v1.0	F ELIGIBILITY V10	05-Jul-2011	agoodwin	available		8		

If you want to view and manage CRFs that contain Subject data for Study Events, see <u>View Event</u> <u>Details in Subject Matrix</u>.

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:22AM

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

## **1.4.1 Find and Organize CRFs**

By default, defined CRFs in the Manage CRFs table are listed in alphabetical order by CRF Name. If there are more CRFs than can be viewed on the page, access other pages using the arrows at the top of the table.

You can sort the data by another column if that column header is a link: click the column header. To reverse the sort order in the column, click the column header again. An arrow next to the column header indicates the current sort order: up for ascending and down for descending.

To find a defined CRF that includes a string you specify, enter the string in the Find field, then click the Find button. The table shows only those CRFs whose name includes the string you entered. For example, type CT to find all defined CRFs whose name includes CT.

## **1.4.2 View Original CRF and CRF Versions**

From the table of CRFs, you can view information about the parent record (termed "original version") for a CRF and the versions for it. To view the parent record, click the View icon in the row where the version is "original". The View CRF Details page opens. The Studies to which the defined CRF is assigned are listed under Studies Using This CRF for Data Entry (the current Study is not listed).

View	CRF D	etails @									
Name:				5927_3							
Description:				Physical Exam							
OID:					F_5927_3						
Version(s	0										
Version Name oid De			Description	Status		Revision Notes			Action		
2	F_5927_3_2		Physical Exam	availab	le agoodwin		2011-03-09	٩	<b>_</b>	<.>	
1	F_5927_3_1		Physical Exam	availab	ble agoodwin		2011-03-09	٩	<b>b</b>	<.>	
Items Name	Item_OID		Description	Data Type		e	Version(s)	Integrity Check		heck	
item1a	I_5927ITEM1A		item1a	character string		string	1,2	ок			
item3a	I_5927ITEM3A		item3a	character s		string 1,2		ОК			
item4a	I_5927ITEM4A		item4a	character s		string	1,2	ок			
item5a	I_5927ITEM5A		item5a	character		string	1	ок			
item6a	ia I_5927ITEM6A		item6a	character		string 1		ок			
Studies U	sing This	CRF For Dat	a Entry								
Study Na	ime Unio	que Protocol I	Id Actions								
There w	ere no i	results foun	d.								

## Rules

Run All Rules for this CRF

The Items table has been introduced in OpenClinica version 3.1.3 to allow viewing which items are part of which CRF versions and provide a check on CRF integrity. OpenClinica 3.1.2 and earlier versions allowed items to be moved from one group to another in different CRF Versions. At the same time OpenClinica ODM does not support this type of structure change between different CRF versions, meaning data extracts can be broken for items that changed their group from one CRF version to another. If CRF has items moved from one group to another the Items table will show error message for the such items.

Items		1		1	1	
Name	Item_OID	Description	Data Type	Version(s)	Integrity Check	
item 1	I_TESTITEM1	item 1	date	2.fields added	ок	
item2	I_TESTITEM2	item2	character string	2.fields added	ок	
item3	I_TESTITEM3	item3	date	2.fields added,3.fields deleted,4. one moved from group	Problem! This CRF Item exists across different groups in more than one active CRF version: • Group Label 'Group_1' in CRF Version '2. fields added'; • Group Label 'Ungrouped' in CRF Version '4. one moved from group;	
TC_adv_primary_(	01 I_TESTTC_ADV_PRIMARY_01	Patient_Name	character string	1,2.fields added,3.fields deleted,5,4. one moved from group	Problem! This CRF Item exists across different groups in more than one active CRF version: • Group Label 'Group_1' in CRF Version '1'; • Group Label 'Ungrouped' in CRF Version '4. one moved from group;	
TC_adv_primary_(	02 I_TESTTC_ADV_PRIMARY_02	Gender:	integer	1,2.fields added,3.fields deleted,4. one moved from group,5	ок	
TC_adv_primary_(	1_TESTTC_ADV_PRIMARY_03	Date of Birth:	date	1,2.fields added.5	ок	

From the View CRF Details page or from the Manage CRFs table, you can view a CRF version as it appears in the OpenClinica web interface. To view it, click the View icon for the version you want to view. The form opens, showing the first section. To see another section, click the tab for it. Note that when the CRF is viewed in this manner all hidden fields in the CRF are displayed.

Adverse Events v1.0
CRF Header Info
Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started
Exit
AE 1 (0/9) AE 2 (0/9) AE 3 (0/9)
Title: Adverse Event
Were any Adverse  Events experienced?
Adverse Event:
Start Date of AE:
End Date of AE:
Severity:
Is the AE serious:
Relationship:
Action taken:
Outcome: