

3.4.11 Remove, Restore, and Delete Defined CRFs

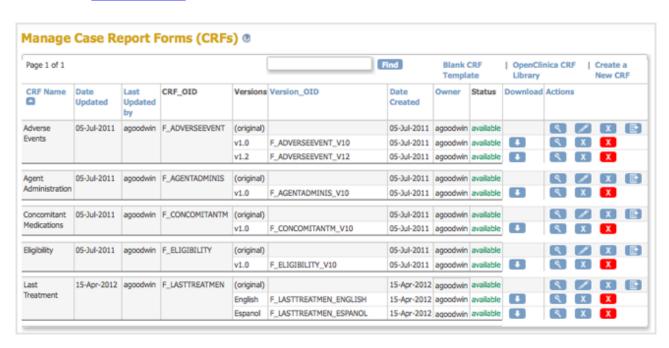
If your <u>User Type has appropriate permission</u>, you can perform the following actions on defined CRFs or versions you no longer want to use:

- Delete a version of a CRF if it has not been used for data entry for any Subjects and you no longer want the CRF in your OpenClinica system for potential use in any Studies. You cannot recover the CRF after its been deleted.
- Remove a version of the CRF if it has been used for data entry for Subjects, to prevent its use going forward. Data captured using this version of the CRF is not included in data extracts whose definition specifies that CRF. You can restore a version of the CRF that's been removed.
- Restore a version of the CRF that has previously been removed, which allows it to again be used for data entry for Subjects.
- Remove the "original" (parent) CRF to prevent any versions of that CRF to be used going forward, and to prevent the CRF from being assigned to any more Event Definitions. You can restore the parent CRF, and all versions, after it has been removed. Data captured using any versions of the CRF is not included in data extracts whose definition specifies that CRF.
- Restore an "original" CRF that has previously been removed, which allows any versions of that CRF to be used going forward, and allows the CRF to be assigned to Event Definitions.
- Archive a version of the CRF to prevent it from being added to any more Event Definitions. Data previously captured using that version of the CRF is included in data extracts whose definition specifies that CRF. Instructions to archive a CRF are in Administer CRFs.

Delete a CRF Version

Delete a version of a defined CRF if it has not been used for data entry for any Subjects. A deleted version of a CRF cannot be restored. To delete a version of a CRF:

1. Access the <u>Table of CRFs</u>.

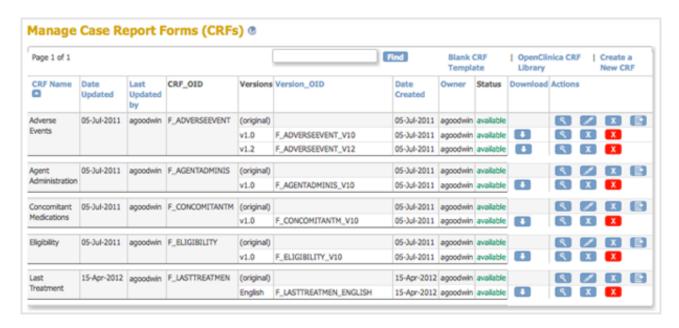


2. For the version of the CRF you want to delete, click the Delete icon ■. For the example, the Espanol version of the Last Treatment CRF is being deleted.

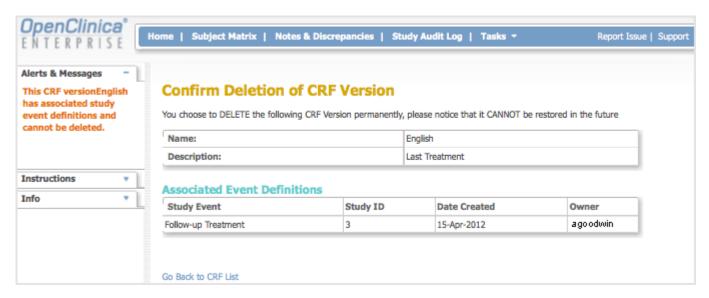
The Confirm Deletion of CRF Version page opens.

| Confirm Deletion of CRF V | ersion |
|--|---|
| You choose to DELETE the following CRF Version | n permanently, please notice that it CANNOT be restored in the future |
| Name: | Espanol |
| Description: | Last Treatment, Spanish |
| | |
| | |
| Delete CRF Version | Cancel |

Click Delete CRF Version, then click OK in the confirmation dialog box.The Manage CRFs page opens. The version of the CRF you deleted no longer appears in the table.



If you try to delete a version of a CRF that has already been used to enter Subject data, OpenClinica prevents you and displays the following:



Remove a CRF Version

If a version of a defined CRF has been used for data entry for Subjects, you can prevent its use going forward by removing it. A version of a CRF that has been removed can be restored. To remove a version of the CRF:

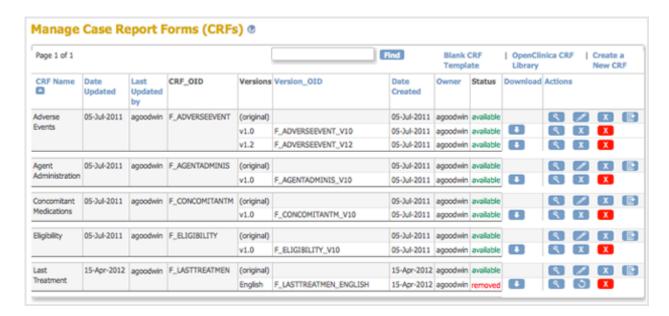
- 1. Access the Table of CRFs.
- 2. For the version of the CRF you want to remove, click the Remove icon . For the example shown here, the Last Treatment CRF, English version, is being removed.

 The Confirm Removal of CRF Version page opens. It lists the Event CRFs and Subjects who have had data entered using that version of the CRF.

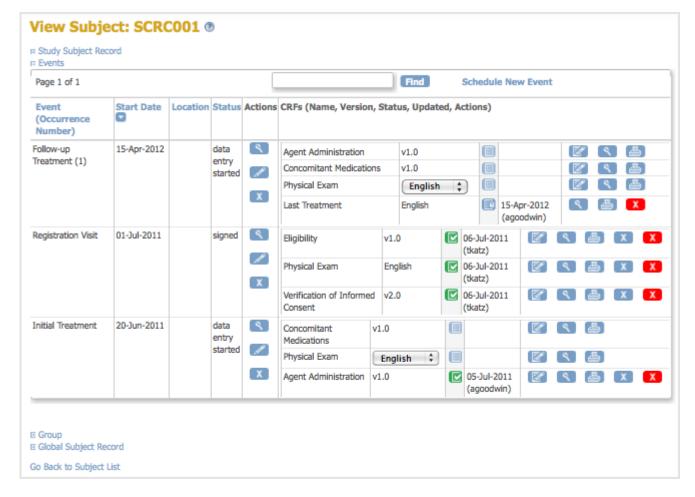


3. Click Remove CRF Version, and then click OK in the confirmation dialog box.

The Manage CRFs page opens. The version of the CRF you removed is listed, but with a Restore icon instead of a Remove icon in the Actions column and a Status of "removed".



After removing the version of the CRF, you can still view the CRF and can still view Subject data for that version of the CRF, as shown below, however you cannot change any of the data. The status of the CRF for the Subject is "locked":



After removing a version of the CRF, it is no longer available for you to choose from when you enter data for any other Subjects for that CRF.

Restore a CRF Version

After removing a version of a defined CRF, you can restore it to make it available for use for entering Subject data. To restore a version of the CRF:

- 1. Access the Table of CRFs.
- 2. For the version of the CRF you want to restore, click the Restore icon . For the example shown here, the Last Treatment CRF, English version, is being restored.

 The Confirm Restore of CRF Version page opens. It lists the Event CRFs and Subjects who have had data entered using that version of the CRF.



3. Click Restore CRF Version, then click OK in the confirmation dialog box.

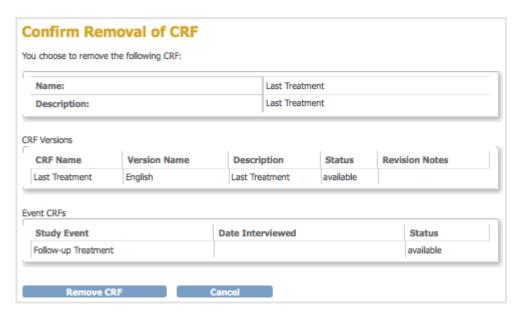
The Manage CRFs page opens. The CRF you restored is listed with a status of "available."

| Page 1 of 1 | | | | | | Find | Blank CRF Template | | OpenClinica CRF Library | | - 1 | 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 | | 9 | 1 | X | E |
| | | | | v1.0 | F_ADVERSEEVENT_V10 | 05-Jul-2011 | agoodwin | available | | (9) | (X) | X | |
| | | | | v1.2 | F_ADVERSEEVENT_V12 | 05-Jul-2011 | agoodwin | available | | 9 | X | X | |
| Agent Administration | 05-Jul-2011 | agoodwin | F_AGENTADMINIS | (original) | | 05-Jul-2011 | agoodwin | available | | (٩) | 1 | X | E |
| | | | | v1.0 | F_AGENTADMINIS_V10 | 05-Jul-2011 | agoodwin | available | | (9) | X | X | |
| Concomitant Medications | 05-Jul-2011 | agoodwin | F_CONCOMITANTM | (original) | | 05-Jul-2011 | agoodwin | available | | 9 | 1 | X | 1 |
| | | | | v1.0 | F_CONCOMITANTM_V10 | 05-Jul-2011 | agoodwin | available | | (९) | X | X | |
| Eligibility | 05-Jul-2011 | agoodwin | F_ELIGIBILITY | (original) | | 05-Jul-2011 | agoodwin | available | | 8 | 1 | X | |
| | | | | v1.0 | F_ELIGIBILITY_V10 | 05-Jul-2011 | agoodwin | available | | (9) | X | X | |
| Last Treatment | 15-Apr-2012 | agoodwin | F_LASTTREATMEN | (original) | | 15-Apr-2012 | agoodwin | available | | 3 | 1 | X | E |
| | | | | English | F_LASTTREATMEN_ENGLISH | 15-Apr-2012 | agoodwin | available | | 9 | X | _ | |

Remove the Original Version of a CRF

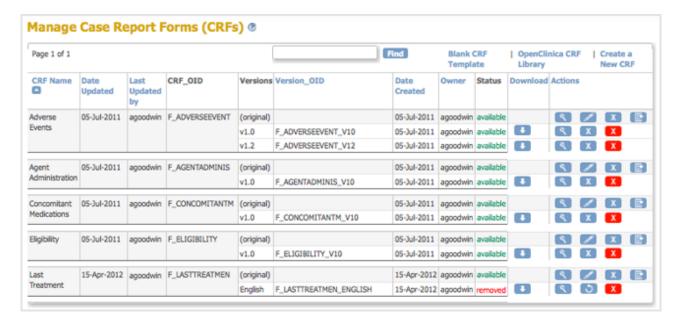
You can remove the original (parent) version of a defined CRF, which automatically removes all versions of the CRF. To remove the original version of a CRF:

- 1. Access the Table of CRFs.
- 2. For the CRF you want to remove, click the Remove icon in the row for the version "original". For the example shown, the Last Treatment CRF is being removed. The Confirm Removal of CRF page opens. It lists all versions of that CRF and all Event Definitions to which the CRF has been assigned.



3. Click Remove CRF, then click OK in the confirmation dialog box.

The Manage CRFs page opens. The CRF you removed is listed, but with a Restore icon instead of a Remove icon in the Actions column and a Status of "removed." All versions of the CRF are listed, but with a status of "auto-removed."



After removing the original version of a defined CRF, any Event Definitions to which the CRF was assigned list the CRF, but show the status as auto-removed. When you are adding CRFs to Event Definitions, the removed CRF is not listed for you to choose from.

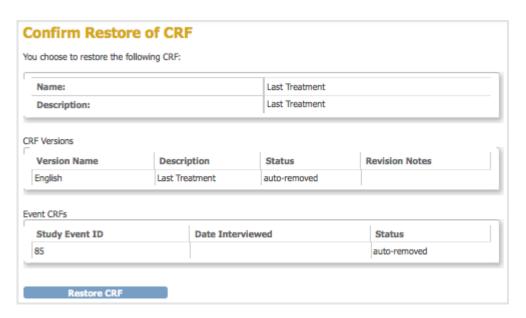
Note: you cannot delete the original version of a defined CRF.

Restore the Original Version of a CRF

After removing the original version of a CRF, you can restore it. Restoring the original CRF restores all versions of it to all Event Definitions in all Studies to which the CRF was assigned. To restore the original version of a CRF:

- 1. Access the Table of CRFs.
- 2. For the CRF you want to restore, click the Restore icon in the row for the version "original." For the example shown, the Last Treatment CRF is being restored.

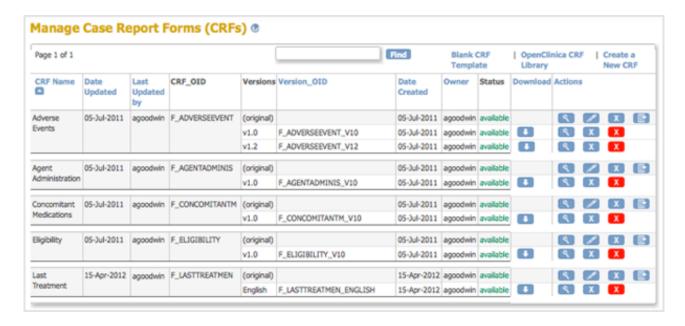
 The Confirm Restore of CRF page opens. It lists CRF versions for that CRF and all Event Definitions to which the CRF has been assigned.



3. Click Restore CRF, then click OK in the confirmation dialog box.

The Manage CRFs page opens. It lists the CRF you restored and all versions of it with a status

of "available."



This page is not approved for publication.