

5.4.10 Create a New Version of a Defined CRF

You can make changes to a defined CRF that is already in your OpenClinica system.

Start by downloading the existing defined CRF from OpenClinica: see Download an Existing Defined CRF in <u>Create a CRF</u>. Then make changes to defined CRF using Excel: see <u>Providing Content for a Defined CRF</u>. Finally, upload the new version to OpenClinica. When you upload it, you can either:

- Replace the existing version (under certain conditions), or
- Add the modified CRF as a new version

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5.4.10.1 Replace a Defined CRF

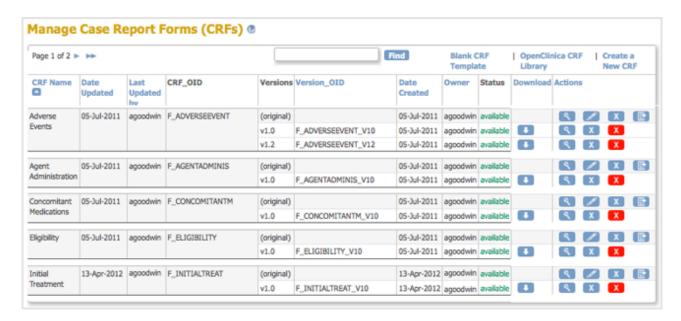
You can replace an existing version of a defined CRF under the following conditions:

- You must be the CRF's Owner, as listed in the Table of CRFs. The Owner is the user who uploaded the CRF you are replacing.
- The CRF cannot be assigned to any Event Definitions in any Studies.
- The values for CRF_NAME and VERSION for the CRF already in OpenClinica and the CRF you are replacing it with must match exactly.

If these conditions are not met, OpenClinica prevents you from replacing the CRF, but you can instead Add it as a New Version of the CRF.

To replace a CRF:

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



2. For the CRF you are replacing, click the Create New Version icon ... The Create a CRF Version for ... page opens. In the example shown here, the CRF being replaced is Initial Treatment.

Create a CRF Version for Initial Treatment
You can download a blank OpenClinica CRF Excel spreadsheet template here.
OpenClinica is tested and supported with the use of Microsoft Excel 97-2003. If you are using a more recent version of Excel, please use the options to "save as 97-2003 version". MS Excel File To Upload: Browse
Preview CRF Version Exit

- 3. Click Browse, then navigate to the CRF you want to upload. Select the file and click Open.
- 4. Click Preview CRF Version.

The Create a New CRF Version - Confirm Delete Previous Same Version page opens. In the example, the v1.0 version of the Initial Treatment CRF is being replaced: the CRF you are uploading has the value v1.0 for VERSION, and Initial Treatment for CRF_NAME.



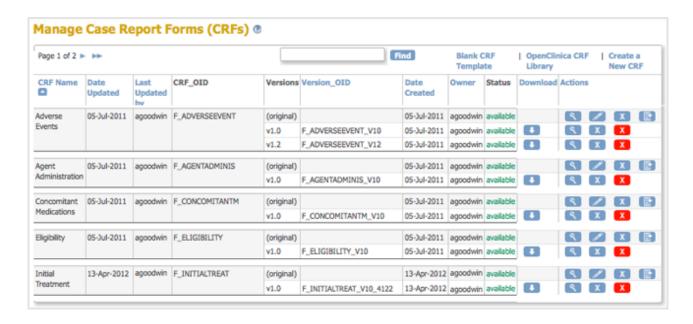
5. Click Yes, Remove Previous Version.

The Check CRF Version Data page opens, presenting a preview of the CRF in the OpenClinica web interface.

- 6. Correct any errors as described in <u>Upload a Defined CRF</u> (step 6).
- 7. After previewing the CRF and completing any changes, click Continue. The Create a New CRF Version - Data Committed Successfully page opens.
- 8. Click Go back to the CRF List.

The Manage CRFs page opens.

- There will be a new value for Date Updated if you the version you replaced was last uploaded on a previous date.
- There is a new Version_OID for the CRF you replaced. This is not the same as the value you specified for VERSION for the CRF, but is an internal identifier that OpenClinica uses to manage CRF versions.



5.4.10.2 Add a New Version of a Defined CRF

For background information, see About CRF Versions.

You can add a new version of a CRF to OpenClinica under the following conditions:

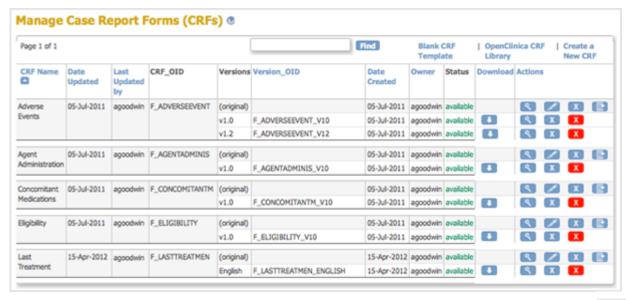
- The CRF_NAME in the new version of the defined CRF must match the CRF Name already in OpenClinica, but the value for VERSION must be different.
- For each ITEM_NAME, the DESCRIPTION, GROUP LABEL, and DATA_TYPE must exactly match the DESCRIPTION, GROUP LABEL, and DATA_TYPE already in OpenClinica. Changes to response sets are limited.

For more information, see CRF Versioning in the OpenClinica Technical Documentation.

When you add a new version of a CRF, the version already in OpenClinica remains. If you want to, you can <u>remove the previous version</u> from OpenClinica after adding the new version, or you can keep the previous version if you want users to be able to complete either versions going forward.

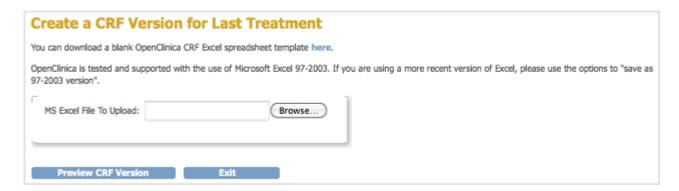
To add a new version:

1. Access the Table of CRFs.



2. For the CRF to which you are adding a new version, click the Create New Version icon

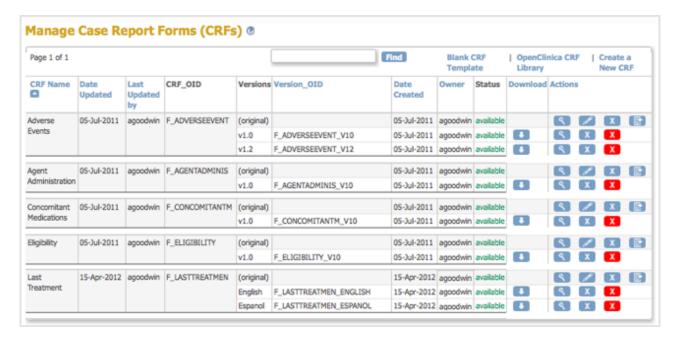
The Create a CRF Version for ... page opens. In the example shown here, a new version
(Espanol) is being added for the Last Treatment CRF.



- 3. Click Browse, then navigate to the CRF you want to upload. Select the file and click Open.
- 4. Click Preview CRF Version.
 The Check CRF Version Data page opens, presenting a preview of the defined CRF in the OpenClinica web interface.
- 5. Correct any errors as described in <u>Upload a Defined CRF</u> (step 6).
- 6. After previewing the CRF and making changes, click Continue.

 The Create a New CRF Version Data Committed Successfully page opens.
- 7. Click Go back to the CRF List.

 The Manage CRFs page opens. The version of the CRF you added is listed in the table.



Now, when a user <u>enters Event Data for a Subject</u>, they can choose which version of the defined CRF to use. For the example, Last Treatment, the user can choose the English or Espanol version.

