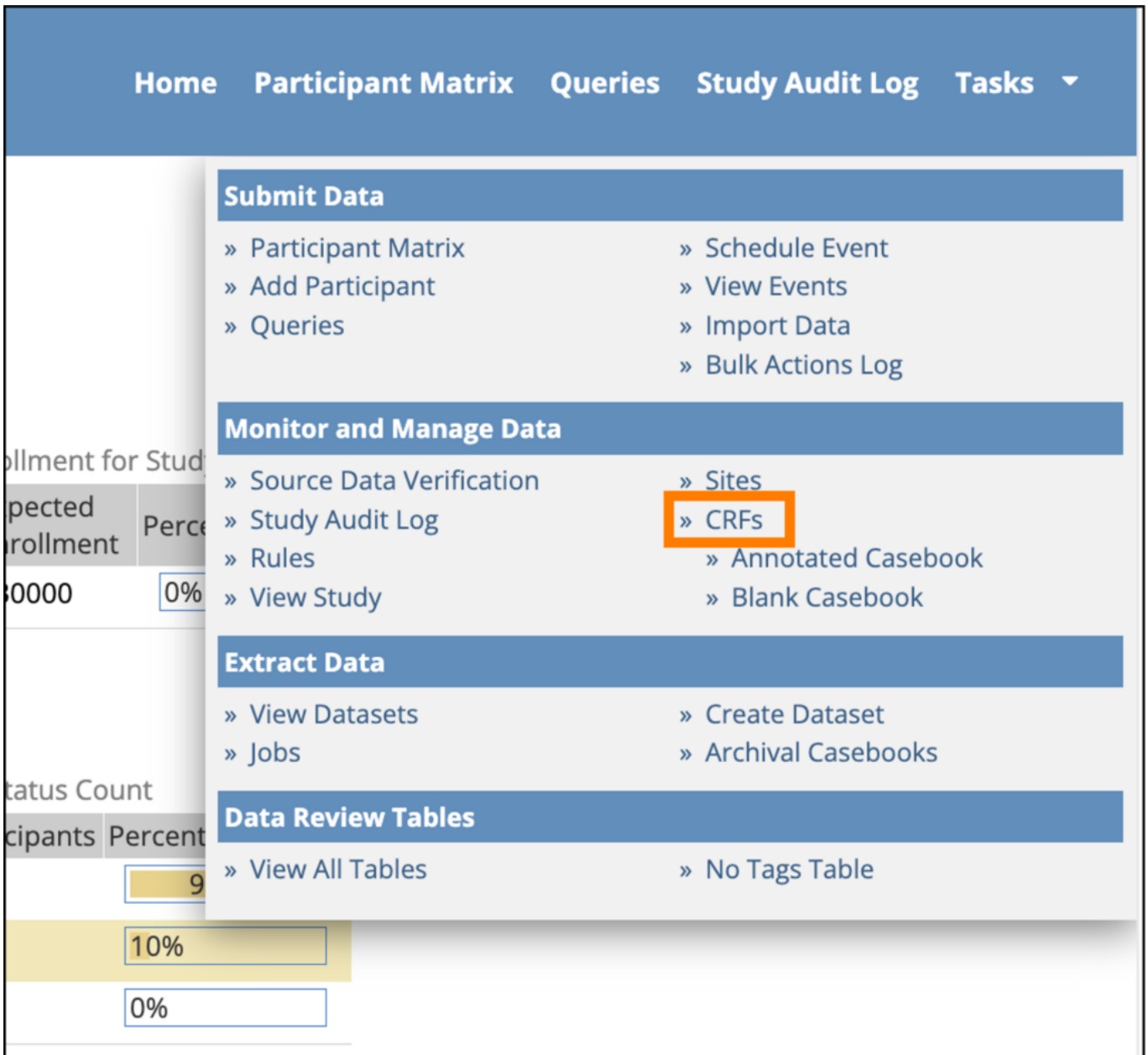


18.4 Generating Annotated eCRFs

This article describes a method for downloading annotated CRFs (aCRFs) which are automatically available for Data Manager roles within Study Runner. Annotated CRFs can be downloaded individually or an Annotated Casebook can be downloaded containing all CRFs for the entire study.

Download Individual Annotated CRFs

1. From the **Tasks** menu in Study Runner, select **CRFs**.



The screenshot shows the OpenClinica Study Runner interface. At the top, there is a navigation bar with the following items: Home, Participant Matrix, Queries, Study Audit Log, and Tasks (with a dropdown arrow). The 'Tasks' dropdown menu is open, displaying several categories of tasks:

- Submit Data**
 - » Participant Matrix
 - » Add Participant
 - » Queries
 - » Schedule Event
 - » View Events
 - » Import Data
 - » Bulk Actions Log
- Monitor and Manage Data**
 - » Source Data Verification
 - » Study Audit Log
 - » Rules
 - » View Study
 - » Sites
 - » CRFs (highlighted with an orange box)
 - » Annotated Casebook
 - » Blank Casebook
- Extract Data**
 - » View Datasets
 - » Jobs
 - » Create Dataset
 - » Archival Casebooks
- Data Review Tables**
 - » View All Tables
 - » No Tags Table









In the background, a table is partially visible with columns for 'Expected Enrollment' and 'Percentage'. The 'Expected Enrollment' column shows '0000' and the 'Percentage' column shows '0%'. Below the table, there are several progress bars or status indicators, one of which shows '10%'.

2. The *Manage Case Report Forms (CRFs)* page opens. Click the **Download** icon to download an individual Annotated CRF for the form version on that row.

Manage Case Report Forms (CRFs)

[Annotated Casebook](#)

Page 1 of 1

CRF Name	Date Updated	Last Updated by	CRF_OID	Version(s)	Date Created	Owner	Status	Download	Actions
Demographics	27-Feb-2023	rbianchi@openclinica.com	F_DEMOGRAPHICS	(original)	21-Feb-2023	rbianchi@openclinica.com	Available		 
				1	21-Feb-2023	rbianchi@openclinica.com	Available	N/A	 
Vital Signs	27-Feb-2023	rbianchi@openclinica.com	F_VITALSIGNS	(original)	21-Feb-2023	rbianchi@openclinica.com	Available		 
				1	21-Feb-2023	rbianchi@openclinica.com	Available	N/A	 

The downloaded PDF document will include a cover page with Study Name, Study OID, Form Name, Form OID, Form Version, and Form Version Initial Publish Date. It also includes the generated date and time in the footer.

While there are labels for the Event Name/OID and SDV Configuration for individual CRFs, the values are not displayed because the form could be in more than one event. Download the Annotated Casebook for the study to view these values. From the *Manage Case Report Forms (CRFs)* page, you can use the **Annotated Casebook** link to get all Annotated CRFs for the study, or follow the steps in the next section.

Download the Annotated Casebook for the Study

The Annotated Casebook compiles the default versions of active forms in the study, collates them by event, and creates a PDF you can download. Each item includes annotations that describe the form's configuration. This option is only available to Study Data Manager roles and is only available when accessing the study at the Study level (the option is not available when logged in at the Site level).

1. From the **Tasks** menu in Study Runner, select **Annotated Casebook**.

Home Participant Matrix Queries Study Audit Log Tasks ▾

Submit Data

- » Participant Matrix
- » Add Participant
- » Queries
- » Schedule Event
- » View Events
- » Import Data
- » Bulk Actions Log

Monitor and Manage Data

- » Source Data Verification
- » Study Audit Log
- » Rules
- » View Study
- » Sites
- » CRFs
- » **Annotated Casebook**
- » Blank Casebook

Extract Data

- » View Datasets
- » Jobs
- » Create Dataset
- » Archival Casebooks

Data Review Tables

- » View All Tables
- » No Tags Table

Note: The Annotated Casebook page can also be accessed by clicking the **Annotated Casebook** link on the *Manage Case Report Forms (CRFs)* page.

2. Select the *Include archived events and forms* checkbox if you want to include these in the PDF, otherwise only Active forms will be included by default. Click **Get PDF**.

Annotated Casebook

The Annotated Casebook compiles the default versions of active forms, collates them by event, and creates a PDF you can download. Each item includes annotations that describe the form's configuration.

Include archived events and forms

Get PDF

3. A green message bar will appear letting you know that the PDF is being generated. This may

take some time if it is a large study. Click the **Bulk Actions Log** link to navigate to the *Bulk Actions Log* and view the status of the job.

Annotated Casebook

The Annotated Casebook compiles the default versions of active forms, collates them by event, and creates a PDF you can download. Each item includes annotations that describe the form's configuration.

Include archived events and forms

Get PDF



The PDF is being created. Once it is ready, you can access it from the [Bulk Actions Log](#)

4. Click the **Download** icon to download the Annotated Casebook PDF that was generated.

Bulk Actions Log

Bulk actions log displays logfiles that are generated by executing the bulk APIs. [Click here](#) to access API documentation. Reload this page to update job statuses.

Search:

Source	Job Type	Site Name	Job Status	Start Time	Submitted By	Completion Time	Actions
RGB22	ANNOTATED_CASEBOOK	S_RGB22(TEST)	COMPLETED	22-Feb-2023 10:23	rbianchi@openclinica.com	22-Feb-2023 10:23	 

The Annotated Casebook includes the date and time it was generated and the page number on each page. It also includes:

- A cover page with the name of the study, Site Name (if run at the site level), the date and time it was generated, and the page numbers.
- A Table of Contents that includes the name of the study and the study OID, Site Name and Site OID (if run at the site level), a heading for each event and a page number for each CRF below the associated event.
- A title sheet for each aCRF which includes Study Name, Study OID, Site Name and Site OID (if run at the site level), Event Name, Event OID, Form Name, Form OID, Form Version, Form Version Publish Date, and SDV Configuration.
- An annotated CRF for each CRF included in the download.

Reviewing Annotated CRFs

When reviewing Annotated CRFs, text will appear in different colors to help differentiate the annotations. Each annotation is based off the form definition with similar names. Below is a list of the Annotation Labels, their associated names on the Form Definition, the color and the order which they will appear.

Order in aCRF	Annotation Label	Form Definition Name	Color
1	Label	label	black
2	Name	name	orangered
3	Type	type	black
4	Item Group	bind::oc:itemgroup	blue
5	Show When	relevant	green
6	Required	required	red
7	Required Type	bind::oc:required-type	cornflowerblue
8	Constraint	constraint	magenta
9	Default	default	deepskyblue
10	Calculation	calculation	maroon
11	Trigger	trigger	darkgreen
12	Read-Only	readonly	chocolate
13	Image	image	darkviolet
14	Repeat Count	repeat_count	lime
15	External	bind::oc:external	indigo
16	Choice Filter	choice_filter	dodgerblue
17	Contact Data	instance::oc:contactdata	tomato
18	Video	video	darkviolet
19	Audio	audio	darkviolet
20	Identifier	instance::oc:identifier	tomato

21	Constraint Type	bind::oc:constraint-type	darkolivegreen
22	[Custom Annotation]	bind::oc:oc_annotation_[Custom Annotation]	black

Notes:

- Items with relevant logic will have a Show When annotation, but will always be displayed within the annotated form.
- Select_one or select_multiple item using choice filters will have a Choice Filter annotation, but will display all possible Choice values.
- Custom annotations are designed by the study designer in the Form Definition. To learn more about how to define custom annotations, see [Using the Form Template](#).
- All items with type "calculate" will appear at the end of the annotated form.

The Annotated values occasionally need to have some symbols changed from their value on the Form Definition to their value on the Annotated CRF for technical compatibility. Below is a list of the original values from the Form Definition to the replacement value that will appear on the Annotated CRF along with each Annotated Label which may have that symbol change.

Original Symbol	Annotation Replacement Symbol	Annotation Label
{	[Default, Calculation, Label, Required, Constraint, Trigger, Item Group, Choice Name, Choice Label, Show When, Choice Filter, Custom Annotation
}]	Default, Calculation, Label, Required, Constraint, Trigger, Item Group, Choice Name, Choice Label, Show When, Choice Filter, Custom Annotation

>	gt	Default, Calculation, Required, Constraint, Trigger, Item Group, Show When, Choice Filter, Custom Annotation
<	lt	Default, Calculation, Required, Constraint, Trigger, Item Group, Show When, Choice Filter, Custom Annotation
-	_	Choice Filter, Video, Audio, Custom Annotation
*	*	Custom Annotation

Note: Any label formatting done in the form definition will carry over to the annotated CRF. For example, if the label includes **label** then the label will be **bolded**.

Languages

Annotated CRFs and Casebooks can be displayed in different languages (only for studies configured to support this). When a form has multiple languages configured, the annotated CRF or Casebook will display in the same language that would appear for the user when opening a form to edit on screen.

This only applies to the user-defined labels and hints defined for the form. System-generated annotation labels are always in English as described above.

Note: OpenClinica does not yet have every language configured and tested. New languages are added to the system by request. If your preferred language is not currently set up in OpenClinica, please reach out to our Support Team to discuss getting it added.

Functional approval by Paul Bowen. Signed on 2024-07-02 1:30AM

Approved for publication by Kate Lambert. Signed on 2024-07-02 9:27AM

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