

17 Knowledge Articles

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17.1 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**.

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

Extract Data

» View Datasets
» Jobs
» Create Dataset

Data Review Tables

» View All Tables
» Medical History









- 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

Find

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	 

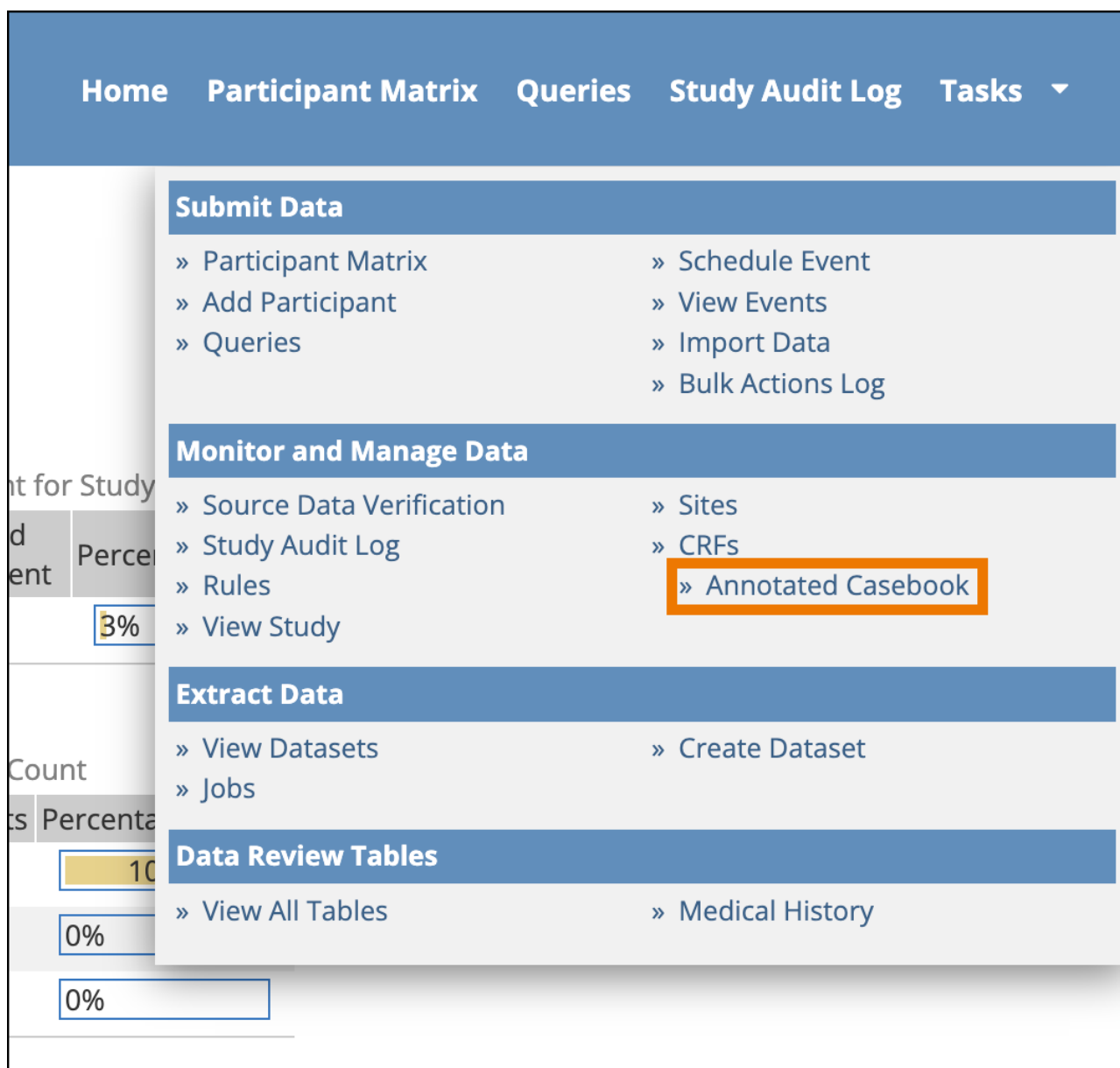
The downloaded PDF document will include a cover page with Study Name, Study OID, Form Name, Form OID, Form Version, and Form Version Initial Publish. It also includes the generated date and time in the footer. While there are labels for the Event Name/OID and SDV Configuration for individual CRFs, the 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**.



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, 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, 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, Event Name, Event OID, Form Name, Form OID, Form Version, Form Version Initial Publish 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

The Annotated values occasionally need to have some symbols changed from their value on the Form Definition to their value on the Annotated CRF. 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
}]	Default, Calculation, Label, Required, Constraint, Trigger, Item Group, Choice Name, Choice Label, Show When
>	gt	Default, Calculation, Required, Constraint, Trigger, Item Group, Show When
<	lt	Default, Calculation, Required, Constraint, Trigger, Item Group, Show When

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 loading opening a form to edit on screen. This only applies to the labels and hints defined for the form. Annotations 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.*

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17.2 Suggested SOPs

List of Suggested Data Management Standard Operating Procedures for Electronic Data Capture The following list of Standard Operating Procedures (SOPs) is a suggested set of SOPs for users of electronic data capture (EDC) systems. This is in no way meant as an exhaustive list, but is instead presented as a recommended minimum set of data management procedures. For a complete list of required SOPs, please consult the current regulations and guidelines applicable to your business and/or study(ies). OpenClinica's professional services team can help you develop SOPs, or review your existing SOPs. In addition to this list, organizations that use electronic systems for clinical trials should audit the vendor(s) of the software system(s) used to ensure the appropriate development SOPs were in place and followed appropriately throughout the development of the software.

SOP	Description
1. Development and maintenance of SOPs	Define the SOP template and the development, review/approval process for all SOPs, including roles/responsibilities, SOP release/distribution requirements, SOP version control, etc.

2. SOP Deviations	Describe the process for reporting and documenting any deviations from the SOPs. Be sure to address planned as well as unplanned deviations.
3. Data Privacy and Protection	Describe the process for ensuring data privacy and protection within your organization as well as via your software solution/service (if applicable).
4. Document/File/Study Binder Management	Describe the process for managing all documents related to study conduct. Include details on any differences between in-house vs. CRO-conducted studies. What is the version control process for the Study Binder?
5. Data Management Roles and Responsibilities	Clearly define the roles and responsibilities for all users participating in study data management.
6. Data Management Plan (DMP)	Describe the DMP template. Be sure to include a list of the SOPs to be followed, the clinical data management system to be used, descriptions of data sources, data handling processes, data transfer formats and process, and quality control procedures to be applied. Define the process for developing, approving, and maintaining the Data Management Plan. Include details on version control.
7. Data Monitoring Plan	Describe the Data Monitoring Plan template. The Data Monitoring Plan should ensure: <ul style="list-style-type: none"> • The rights and well-being of participants are protected • The reported data are accurate, complete, and verifiable from source documents. • The trial is conducted in compliance with currently approved protocol and other applicable regulatory requirements If partial data monitoring is used, be sure to specify exactly what "partial data monitoring" means for the study in question (e.g., 100% monitoring for a list of critical data values, 100% verification of 20% of the subjects, etc.) Define the process for developing, approving, and maintaining the Data Monitoring Plan. Include details on version control.
8. Statistical Analysis Plan	Describe the Statistical Analysis Plan template and define the process for developing, approving, and maintaining the Statistical Analysis Plan; include details on version control.
9. e-CRF Design and Development	Define the process for design, development, and standardization of eCRFs. Be sure to include details for the design, development, approval, and version control process.

10. Study-Specific Database Design	Describe the process for setting up any study-specific attributes (anything outside of your standard eCRFs). This may include annotated CRFs or design documents.
11. Edit Check/Data Validation Programming	Document the process for creating edit check specifications, as well as edit check development, review and approval, testing, documentation, and version control.
12. Study User Acceptance Testing (UAT)	Define what testing is required and what documentation is required to demonstrate that the study passed validation. Specify who gives approval for use of the system. Testing should not be performed by the person who built the study database.
13. Data Entry	Define the process for entering and editing data. Data entry should address general guidelines (inputting scientific symbols (if applicable), use of UI features, etc.) as well as how/where to document study-specific guidelines.
14. Data Receipt and Handling	Define the different means by which data may be received. Be sure to address all types of data receipt □ EDC, ePRO, imports, web services, paper, etc.
15. Discrepancy Management	Define the process for reviewing and resolving data discrepancies, and define roles and responsibilities associated with discrepancy management.
16. Coding	Define the process for coding adverse events and medications, any review process involved, and the change control or re-coding process.
17. Serious Adverse Event Reconciliation	Define the process for handling serious adverse events and the reconciliation process between data management and safety surveillance. Define any review timeframes and sign-off procedures that may be required prior to locking the database.
18. Lab Data Management	Define the process for handling laboratory data. If necessary, differentiate between local vs. central labs and the data import and discrepancy resolution process.
19. Data Extraction and Validation	Define the process for extracting data and the method for verifying that the data that was extracted matches the data that was entered into the system.
20. Data Transfer and Validation	Define the process for transferring data to other systems and the method for verifying that the data that was transferred matches the data that was entered into the original system.

21. Database Security	Describe the requirements, methods, and tests that ensure your database is secure. This should include username/password requirements, password expiration, means for resetting passwords, how system/study access is granted/revoked, roles and role-based access, etc.
22. Database Lock/Unlock/Closure	Define the process for locking, unlocking, and closing a database. Include details on lower-level (e.g., event-level locking) if lower-level locking methods are used. Address investigator signature requirements prior to locking.
23. Data Retention and Archival	Define the data retention, archival, and retrieval process. For databases managed by external sources (CRO, hosting service provider), define the process for accessing the database throughout your defined retention period. This should include the clinical data, eCRFs, and discrepancies/resolutions.
24. CRO and Vendor Management	Detail the CRO / vendor selection and management process. Address sign-off procedures, meeting frequency, metrics, etc. Also address the auditing process and schedule.
25. Training <ul style="list-style-type: none"> • SOPs • HIPAA • GDPR • 21 CFR Part 11 • System(s) • Study-specific issues/practices • Internal (e.g. sponsor) • External (e.g. site) 	Define how the data management staff and site staff are trained on the topics listed at left (and any other topics as you see fit), how training is documented, re-training requirements, and how training records are maintained.

References and Additional Resources

21 CFR Part 11, US Department of Health and Human Services, Food and Drug Administration, March 1997

Guidance for Industry Part 11, Electronic Records; Electronic Signatures □ Scope and Application, US Department of Health and Human Services, Food and Drug Administration, August 2003

Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance, US Department of Health and Human Services, Food and Drug Administration, April 1996

Guidance for Industry □ Computerized Systems Used in Clinical Trials, US Department of Health and Human Services, Food and Drug Administration, May 2007

PIC/S Guidance □ Good Practices for Computerised systems in Regulated □GXP□ Environments, PIC/S, September 2007

Susanne Prokscha, Practical Guide to Clinical Data Management, Third Edition, CRC Press, Oct 26, 2011

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