

Study Export

You can export content and metadata for an ongoing or final study to a secure FTP site using the “Study Export” option, which is available only to Business Administrators within the Actions menu of the Study Home page or study item list.

Note: Since Study Export is a resource-consuming process, only one study export can be requested per day per study.

1. Click on the Actions menu icon for the study item list or on the Study Home page for the study you want to export and select “Study Export”. The Export Study screen appears, displaying a notice about the sensitivity of the documents to be exported.
2. Click in the **Document Statuses** field and select the statuses of the documents you want to export. Available statuses include *InQC*, *Final*, *Superseded*, and *Obsolete*.
3. In the **Export Only Final Submission Documents** field, select “Yes” if you want to include only documents that have been marked to be included in a regulatory submission (as defined by the document type). To see which documents fall into this category, you can filter the study item list by the Export For Regulatory Submissions facet.
4. In the **Content to Export** field, select whether to export only PDF renditions, native content (if not PDF), or both.
5. In the **Export Unblinded Documents** field, select “No” if you do not want to export documents containing information that could unblind the trial.
6. In the **Export Restricted Documents** field, select “No” if you do not want to export documents marked as restricted.
7. In the **Export Audit Trail** field, select “Yes” if you want to export audit trail entries for the study items being exported.

8. In the **Export Business Documents** field, select “No” if you do not want to export business documents. Note: This field appears only if you have permission to view business documents in the system.
9. If you want to export only study items finalized after a specific date, enter that date in the **Export Date Range Start** field.
10. If you want to export only study items finalized before a specific date, enter that date in the **Export Date Range End** field.
11. In the **Export Format** field, select the desired format from the drop-down list. Note that if you choose the TMF Exchange Mechanism format, you will be prevented from exported documents with a status of *InQC*.
12. Click **Export**.

If the study export was successful, you will find it on the [Downloads List Page](#). Click on the zip file for the study to download the file.

If you exported to the Wingspan eTMF format, the files are organized into a study/country/site folder structure. The following files are included:

- an Excel manifest file containing a row for each study item exported and the folder path for each study item
- an xml file containing the audit trail (if the audit trail was exported)
- a HIPAA notice
- An xml file for each study item exported
- A content file for each rendition of content exported
- xml files containing study information, country information, and site information

If you exported to TMF Exchange Mechanism format, the files are organized into a TMF Reference Model folder structure. The following files are included:

- an exchange.xml file containing metadata for all content exported, as well as audit records (if included in the export)
- a content file for each rendition of content exported

Possible reasons for an unsuccessful export include network connectivity issues or a database connectivity issue. Additionally, Exports over 2 gigabytes in size will not be successful.