Reconcile SMF Documents

eTMF provides the ability to <u>Reconcile</u> Sponsor and Site documents directly in the eTMF. A record of who reconciled each document and when it was reconciled is stored in the Audit Trail and included when a Reconciliation report is generated.

How to Reconcile a Document

Users in the TMF Reconcile Documents group can reconcile (and unreconcile) documents by selecting Reconcile / Unreconcile Documents on the Actions Menu on the Study Items List page. This will display the Reconcile / Unreconcile Documents dialog.

If a Country and Site were already selected on the Study Items List page, they will be automatically populated and reconcilable documents for the Site will be displayed in the top grid. Otherwise, a Country and Site must be selected to begin reconciliation. The grid will show all reconcilable documents (Final, Obsolete and Superseded documents that have not yet been reconciled). The bottom grid, when expanded, shows documents not yet available for reconciliation (those that will need to be reconciled in the future but that do not yet have final content).

Finding a Document to Reconcile

To locate a specific document that you want to reconcile, search for it by entering keywords (complete words) in the Find Item field. When you locate a document that you want to reconcile, you can click on its hyperlink to view its contents in another browser tab. After you confirm that it has been reconciled, select the document's check box in the grid. Your name and the date will automatically be recorded. If you reconcile a document in error, de-select the box next to "Show Unreconciled Only". This will display reconciled documents so you can unreconcile them.

When you are done, close the screen or choose a different Country/Site combination to continue the reconciliation process.

Reconciliation information including all Study Items in the Study, Country, and Site that are part of SMF will be available in the Reconciliation Report.

Marking a Document as Not Applicable for Reconciliation

You have the option or marking documents as "Not Applicable" for reconciliation at a specific site. When a document is marked as "Not Applicable" it is removed from the list of reconcilable documents for the selected site in the dialog and can only be seen by selecting the **Show Not Applicable** check box. When displayed in the dialog, a Not Applicable document cannot be reconciled.

To mark a document as "Not Applicable," move the applicability toggle to the right, enter a comment, and select Save. The action and comment is recorded in the document's audit trail.

Reconcile / Un	reconcile	Document	S			2
Find Item	٩	Reconcilable Do	cuments			
Study Den Study Test	*	J.	IRB/IEC Approval (Country Level) - 19-Mar-2019			Not Applicable
Country United States			Ref Model ID: 04.01.02 Doc Type ID: 106.04 Level: Country - Den Study Test / United States	Organization: ClinOps Category: Central Trial Documents	Additional information:	You must enter a comment to make a document not applicable. Save
Site US-1008-??						

To mark a "Not Applicable" as "Applicable," move the applicability toggle to the left.

See Also: <u>What is Reconciliation?</u>