

APPLICABLE TO:

- ☐ Admin
- ☐ Manager
- ☒ Editor
- ☒ Reader
- ☒ eTMF
- ☐ eISF

This job aid guides CRA users in how to mark documents as **Verified**, **Not Required**, or **Missing in Investigator Site File (ISF)** while they carry out site monitoring tasks (“Visit”).

Reconciling any differences between site and eTMF documentation reduces compliance risk, enhances discoverability of information, and contributes to a healthy and timely eTMF.

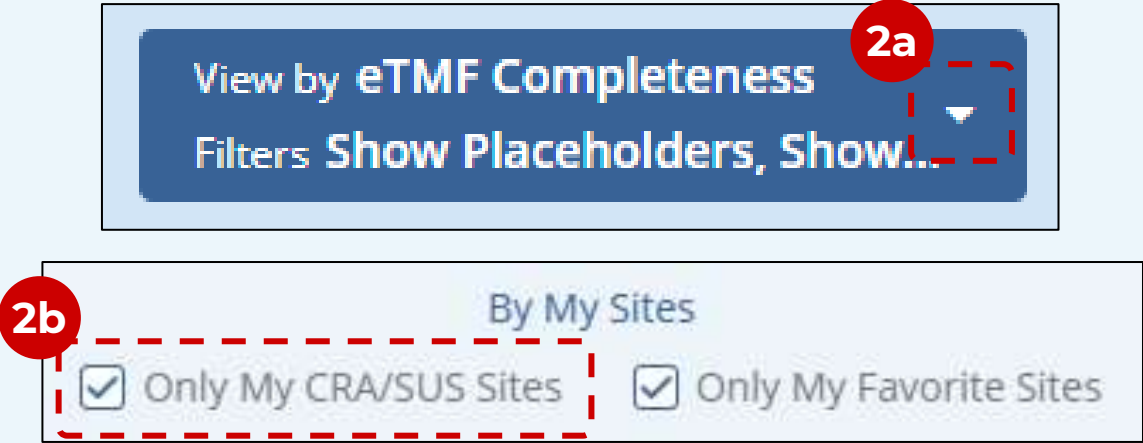
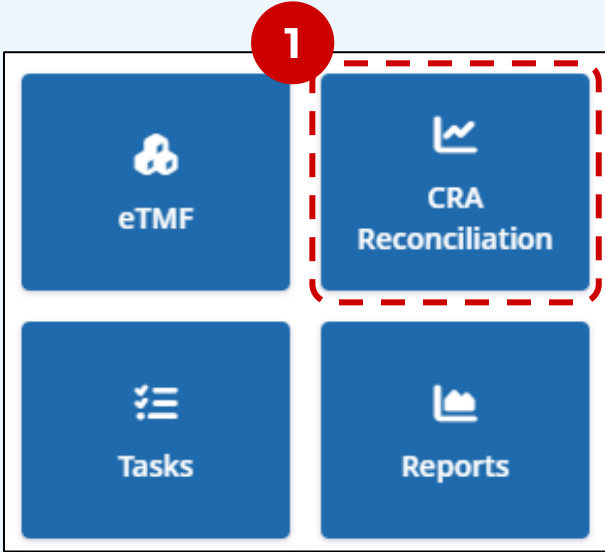


Users can perform this process only when their profile setup fulfills two conditions:

1. the user has the CRA attribute, managed in Site Details.
2. the user has been endowed with the **CRA Reconciliation** action.

Admins and Managers are not eligible for receiving the CRA attribute.

- 1 Access the **CRA Reconciliation** module.
- 2 By default, the view is filtered for sites where the user is a CRA only. You may sometimes need to **lift** that restriction (see images).



- 3 **Select** the site to review. The grid will populate with associated records.



4 Review the contents of the Site. This will likely include both documents and placeholders.



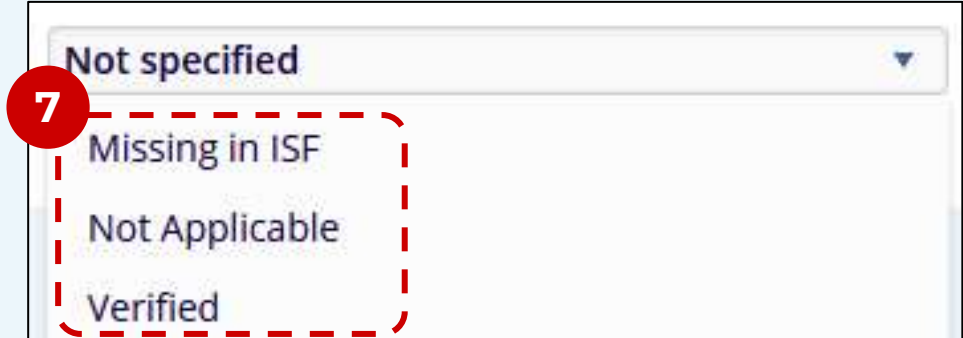
5 If you need to replace a placeholder with an available document, use **Add Document**.



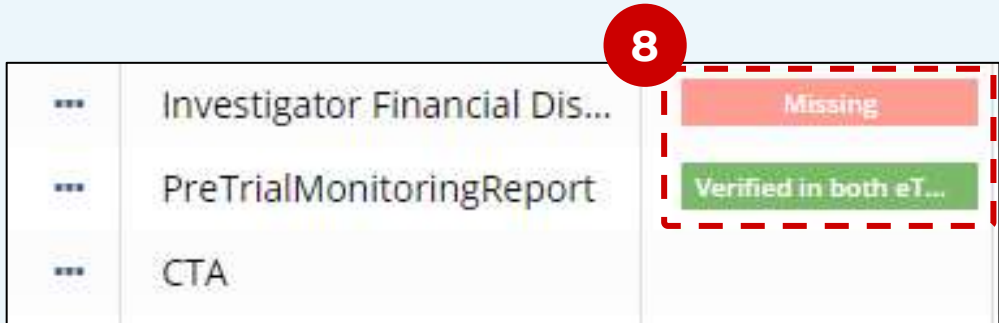
6 Once you have reviewed documents, select one or more documents that you determine are of the same status, and click **Reconcile**.



7 Set one of the statuses: **Verified**, **Not Applicable**, or **Missing**. (Small variations in the exact wording are common)



8 Assigned statuses are shown as labels in the column 'Visit Status'.



9 Repeat steps as needed to complete your visit. A report can be generated for all activity performed here. See related Job Aid: "How to Run a TMF Reconciliation Report".