How to Use the CRA Reconciliation Module TI v 10.4

APPLICABLE TO:

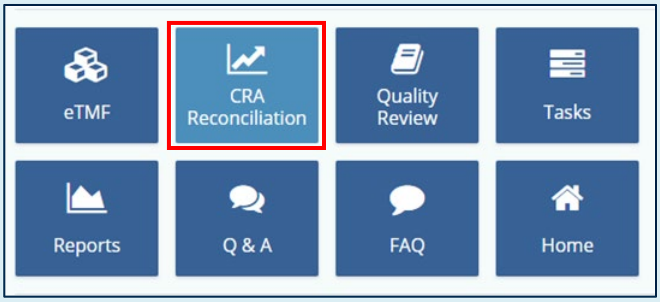
- ○ Administrators
- ● Managers
- ● Editors
- ● Readers
- ● eTMF
- ○ Study Start-Up
- ○ Collaborate

This job aid shows the CRA user how to mark documents as **Verified**, **Missing in eTMF**, or **Missing in Investigator Site File (ISF)**.

The user must first:

1. Be added within the **CRA** field under the site profile.
2. Have the **Action: CRA Reconciliation** enabled under their User Profile.

eTMF Admins cannot be CRAs in TI. Therefore, Admins cannot perform this task.



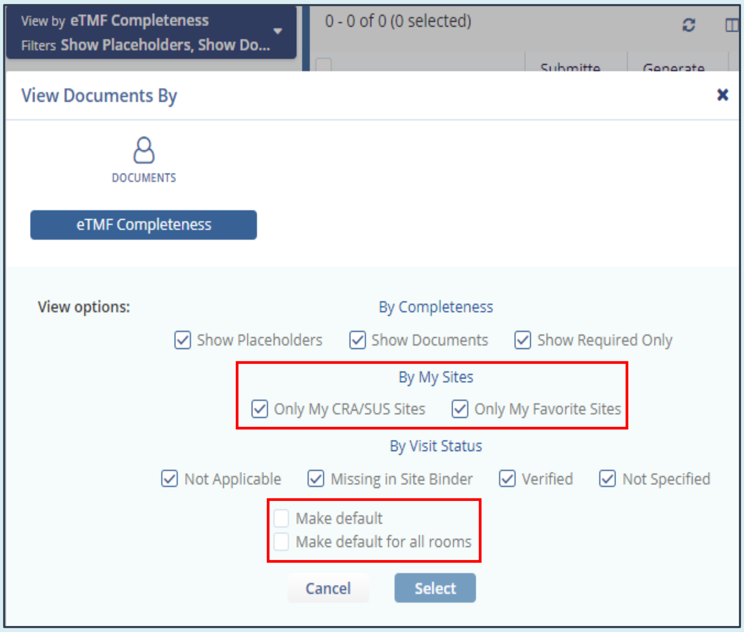
1. Access the **CRA Reconciliation** module via the Navigation Grid.

2. By default, the user will see only those sites to which they have been added as a CRA. This setting can be changed by the user.

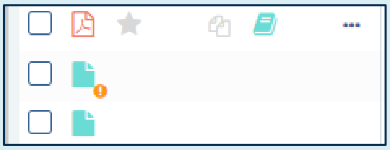
<u>**Optional:**</u>

2b. Disable the "By My Sites" filters to see more investigative sites.

2c. Enable the "Make default" or "Make default for all rooms" options to change the default view to the current settings.



3. Select the site to reconcile with the ISF. The grid will populate with associated records.

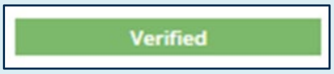


- **Missing Required Documents** are indicated by a teal pageicon with an ! placed inside an orange circle.
- **Placeholders** are indicated by a teal page icon.
- **Collected** documents are represented by their corresponding file-type icon (e.g. PDF).

4. When performing reconciliation, each document will fall into 1 of 3 statuses.

4a. A document that is in the ISF but not showing in the eTMF will be marked "Missing".

4b. If a document isn't required for inclusion in the eTMF, use status "Not Applicable".



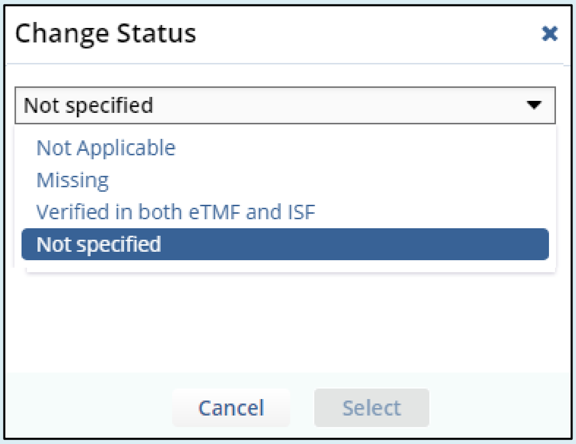
4c. When a document is present in both the eTMF and the ISF, mark it as "Verified".

While there are three basic statuses, status names are customizable per room and thus can vary from those shown.

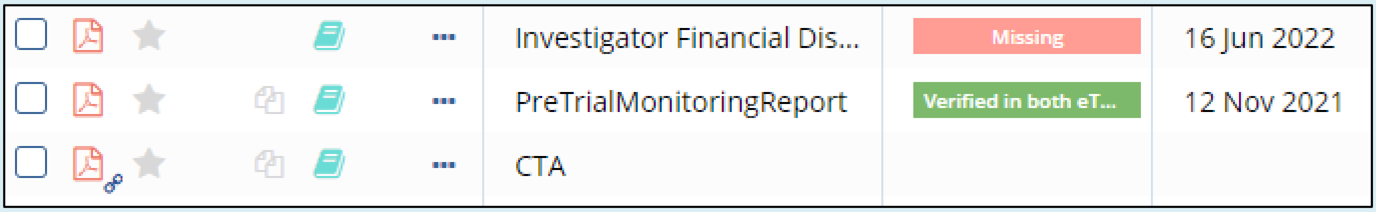
5. With one or multiple documents selected, click **Reconcile**.

6. In the popup window, choose the correct status for the document(s) and click **Select**.

7. Repeat steps 5 and 6 for all documents pending reconciliation.



8. The document reconciliation status and date will update in the grid.



For additional assistance, please refer to the User Guide or to the related job aid **How to Run a TMF Reconciliation Report.**