Regulatory Inspector Quick Reference Guide

Logging in and Navigating to the Study Room

1. Log in with your Username and Password.
   a. *Warning: After five failed attempts, you will be temporarily locked out.*

2. On the Home Page you will see a list of rooms to which you have access. If no rooms appear, please select *All* from the menu at the top*.*
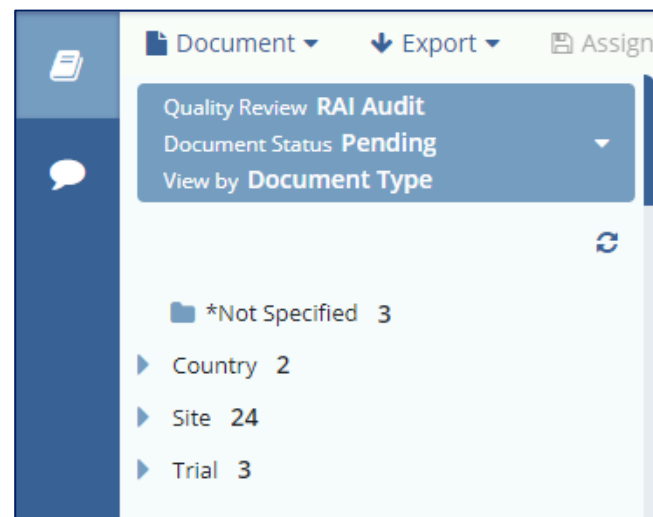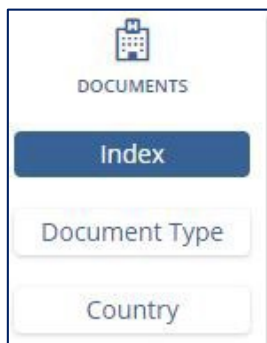
   All 8   Favorite 1   Recent 0

3. Click on the name of a room to enter.

How to Audit Documents

1. If necessary, click on the blue drop-down menu above the index to select the appropriate audit.

   (sample audit and folder names shown)

   Document ▼   ↓ Export ▼   🖫 Assign

   Quality Review **RAI Audit**
   Document Status **Pending**
   View by **Document Type**

   ↻

   📁 *Not Specified 3
   ▶ Country 2
   ▶ Site 24
   ▶ Trial 3

   DOCUMENTS
   Index
   Document Type
   Country

2. The documents can be displayed in several ways. Pick your preferred viewing options from the drop-down menu above the folders displayed.

TRIAL INTERACTIVE
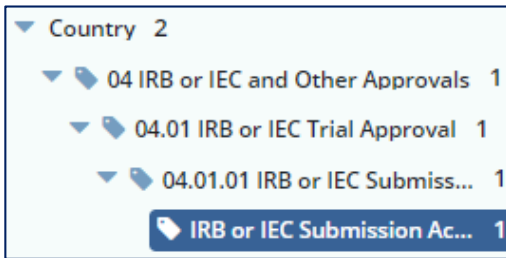
3. Click on a folder to expand it or to view documents in the grid.

4. Select a line item and click Document View to open a document and associated metadata from the grid.

5. Examine document to determine if it meets the audit criteria.

6. Choose a Status and other applicable options, e.g. Comments that will remain in the audit history. The fields available in the panel at the right may vary based on individual room configurations.

7. Click Save or Save and Next.