

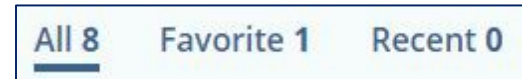


Regulatory Inspector Quick Reference Guide

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.*

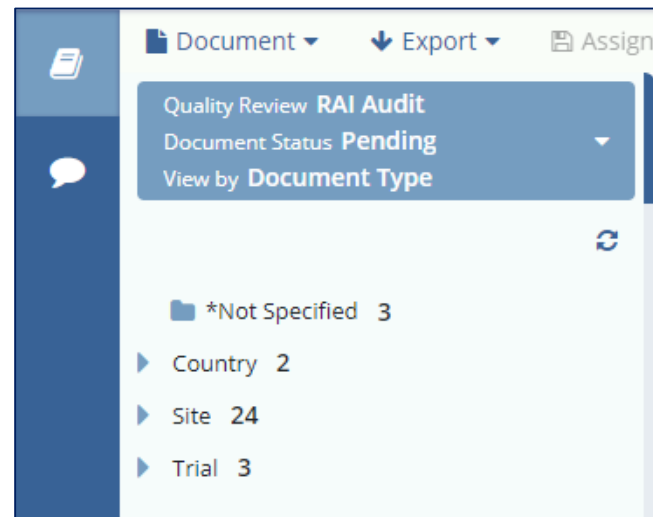
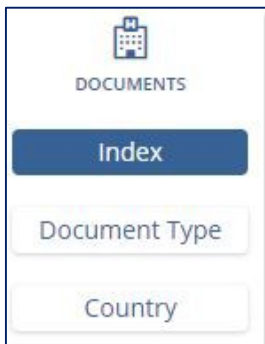
2. On the Home Page you will see a list of rooms to which you have access. If no rooms appear, please select *All* from the menu at the top.



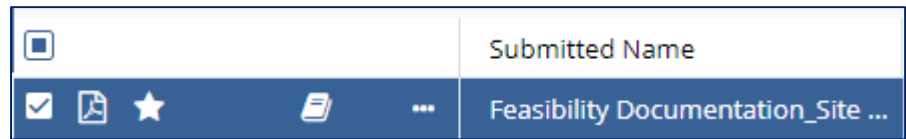
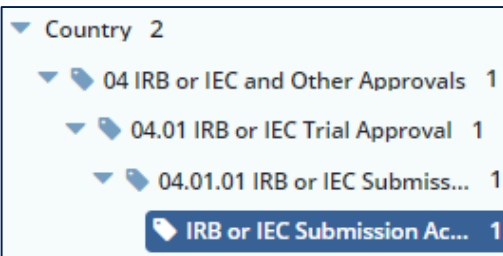
3. Click on the name of a room to enter.

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)



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



3. Click to expand a folder 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 to determine if it meets the audit criteria.

PATIENT INVESTIGATIONAL PRODUCT ACCOUNTABILITY RECORD
BETRIXABAN / PLACEBO

Acute Medically Ill VTE Prevention with Extended Duration [REDACTED] Trial
Pharmaceuticals, Inc. Protocol: 11-019

Patient #: 800041001 Patient Initials: VC Site #: 04T
Country: LATVIA Investigator Name: [REDACTED]
Site name: [REDACTED]

Kit #	Quantity Dispensed (# capsules)	Date Dispensed (dd/mm/yyyy)	Dispensed to Patient By (Initials)	Quantity Returned by Patient (# capsules)	Quantity Returned by Patient (# capsules)	Date Returned (dd/mm/yyyy)	Received by (Initials)
100433	50	24 Oct 2012	L.S.	14	36	27 NOV 2012	J.S.
	50						
	50						
	50						
	50						

Audit Panel:

- Status * (This field is required)
- Comments
- Contains PHI?
- Grading/Finding: Critical, Major, Minor
- Responsible Party
- Responder
- Buttons: Cancel, Save, Save & Next
- Navigation: Previous Document, 1 of 1, Next Document

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**