



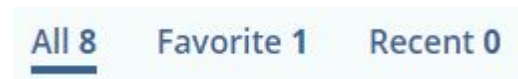
Regulatory Inspector Quick Reference Guide

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.*

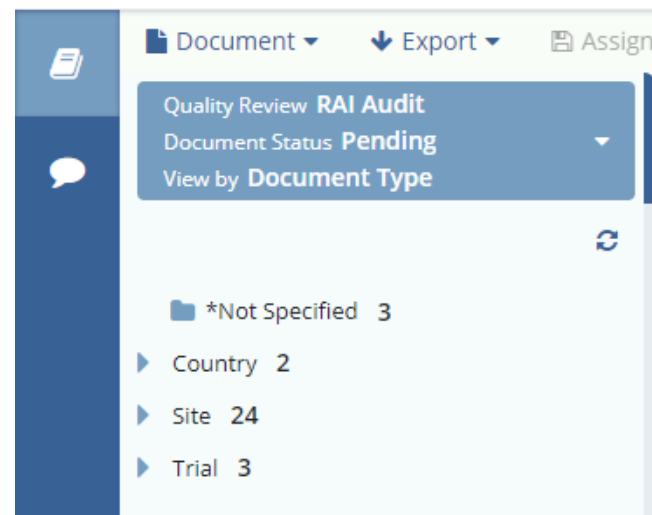
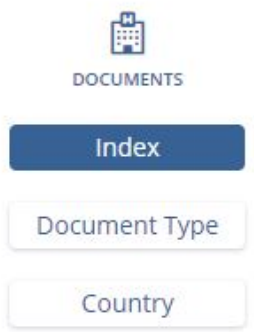
2. On the Home Page you will see a list of rooms to which you have access. If no rooms appear, please select *All* from the menu at the top.

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 index.

- Customize your Index name
- 01 Trial Management 21
 - 01.01 Trial Oversight 13
 - 01.01.01 Trial Master File Pl... 1
 - 01.01.02 Trial Management... 2
 - 01.01.03 Quality Plan 2

<input type="checkbox"/>	Document Type	Docume...	Index	Document Id
<input type="checkbox"/>		Recruitment Plan		01 Trial Management\01.01 Trial... 577944
<input type="checkbox"/>		Recruitment Plan		01 Trial Management\01.01 Trial... 907952
<input type="checkbox"/>		Recruitment Plan		01 Trial Management\01.01 Trial... 917027

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.

The screenshot shows a document viewer with a document titled "Acute Medically Ill VTE Prevention with Extended Duration [redacted] Trial" by "Pharmaceuticals, Inc." The document is a "PATIENT INVESTIGATIONAL PRODUCT ACCOUNTABILITY RECORD" for "BETRIXABAN / PLACEBO".

Key document details include:

- Patient #: 900041001
- Patient Initials: VC
- Site #: 045
- Country: LATVIA
- Investigator Name: [redacted]
- Site name: [redacted]

The document contains a table with the following data:

Kit #	Quantity Dispensed (# capsules)	Date Dispensed (dd/mm/yyyy)	Dispensed to Patient By (Initials)	Quantity Returned by Patient (# capsules)	Quantity Used by Patient (# capsules)	Date Returned (dd/mm/yyyy)	Received by (Initials)	Verified by (Initials)
100433	50	26 Oct 2012	L.S.	11	36	27 NOV 2012	J.S.	[redacted]
	50							
	50							
	50							
	50							

An audit panel is open on the right side of the screen, containing the following fields:

- Status * (dropdown menu, with a red message "This field is required")
- Comments (text area)
- Contains PHI? (checkbox)
- Grading/Finding (radio buttons for Critical, Major, Minor)
- Responsible Party (dropdown menu)
- Responder (dropdown menu)
- Buttons: Cancel, Save, Save & Next
- Navigation: Previous Document, 1 of 1, Next Document

At the bottom of the document viewer, the "Document View" button is highlighted with a red box.

6. Choose a **Status** and other applicable options, e.g. Comments that will remain with the audit history.

7. click **Save** or **Save and Next**