



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.*

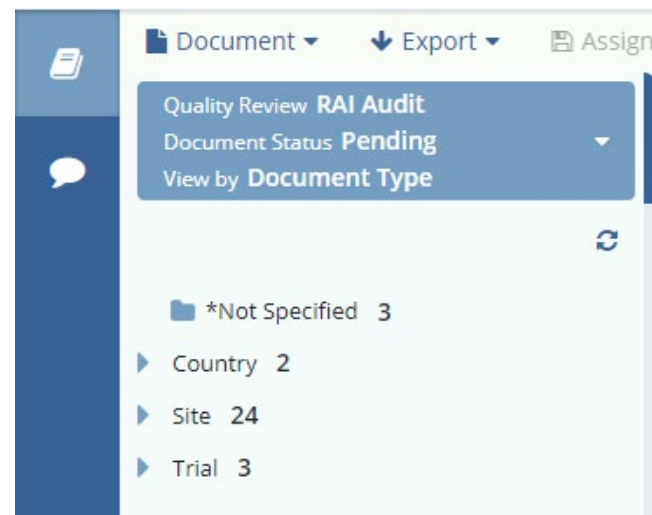
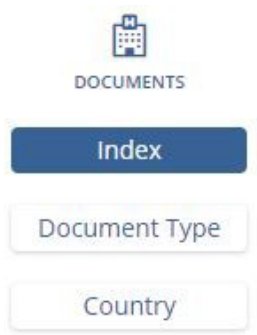
2. On the Home Page you will see a list of rooms to which you have access. If no rooms appear, please select *All* from the menu at the top.

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.

- Country 2
 - 04 IRB or IEC and Other Approvals 1
 - 04.01 IRB or IEC Trial Approval 1
 - 04.01.01 IRB or IEC Submiss... 1
 - IRB or IEC Submission Ac... 1

1 - 1 of 1 (0 selected)

	Document Id	Submitted Name
<input type="checkbox"/>	85103	Acknowledgement IB Signature Page_pd...

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" by "Pharmaceuticals, Inc." The document is a "PATIENT INVESTIGATIONAL PRODUCT ACCOUNTABILITY RECORD" for "BETRIXABAN / PLACEBO".

Key document details include:

- 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 (# capsules)	Date Returned (dd/mm/yyyy)	Received by (Initials)
100433	50	29 Oct 2012	L.S.	14	36	27 NOV 2012	J.S.
	50						
	50						
	50						
	50						

The "Audit" panel on the right contains the following fields:

- Status * (Dropdown menu, with a red note "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

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**