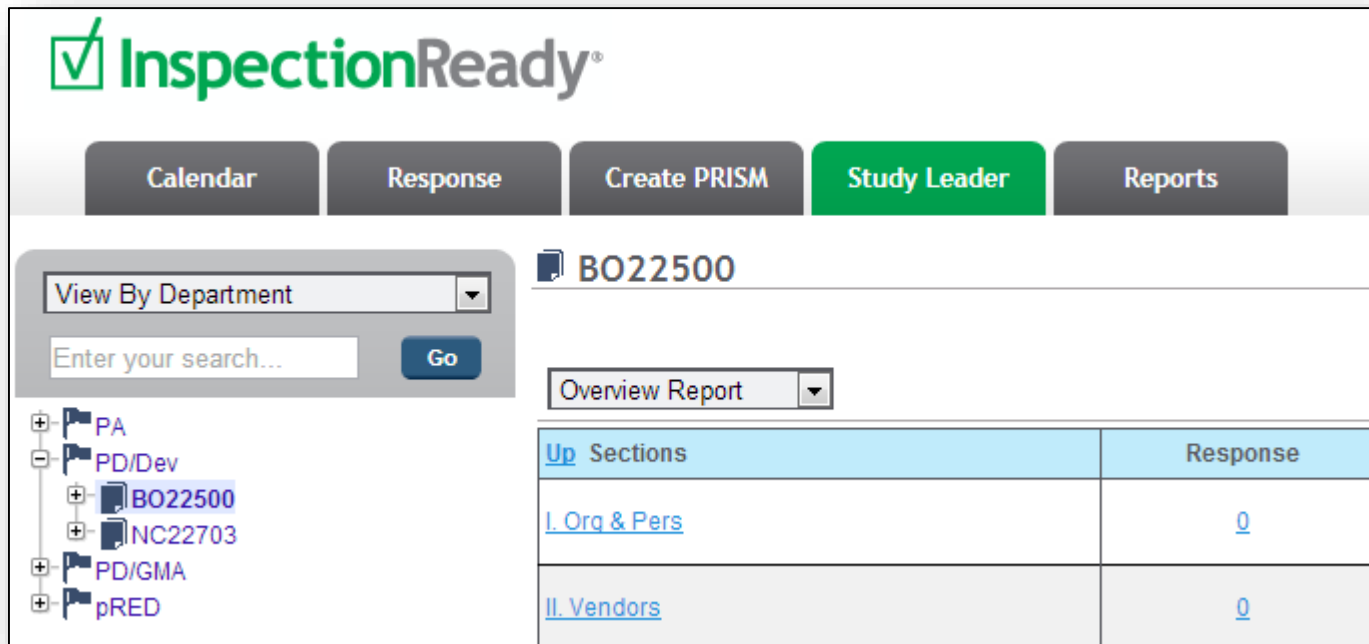


Study Leader Tab Reports

This reference guide is an overview of **Reports** within the **Study Leader Tab**. These reports are covered within this document:

- ✓ Overview Report
- ✓ Response Report
- ✓ Tasks Report
- ✓ Issues Report
- ✓ Action Items Report









The screenshot shows the InspectionReady interface. At the top, there are navigation tabs: Calendar, Response, Create PRISM, Study Leader (highlighted in green), and Reports. Below the tabs, there is a search area with a dropdown menu set to "View By Department", a search input field with the placeholder "Enter your search...", and a "Go" button. To the left of the search area is a tree view of departments: PA, PD/Dev (expanded), BO22500 (selected), NC22703, PD/GMA, and pRED. The main content area displays the title "BO22500" and a dropdown menu set to "Overview Report". Below this is a table with two columns: "Up Sections" and "Response".

Up Sections	Response
I. Org & Pers	0
II. Vendors	0

Overview Report















Overview Report

1. Select a [Section](#) to drill into the question level.

Overview Report Download Excel Report						
Up Sections	Response	Response Icon	Response Tasks	Issues	Action Items	Inspection Vulnerabilities
I.Org & Pers 	3		Open 8 Total 9	2	Open 1 Total 1	0
II.Vendors	0		Open 10 Total 10		Open 0 Total 0	0
III.Investigators	1		Open 9 Total 9		Open 0 Total 0	1

2. Click any values within the [Questions](#), [Responses](#), [Response Tasks](#), [Issues](#), [Action Items](#), and [Inspection Vulnerabilities](#) to open the Response Dialog.

Note: for information about the **Response Dialog** menu, please review the training tutorials on the **Response Dialog**.

Overview Report				
Up Questions	Response	Response Icon	Tasks	Issues
I.1	0		Open 1 Total 1	
I.2	0		Open 1 Total 1	
I.3	0		Open 1 Total 1	
I.4	0		Open 1 Total 1	
I.5	0		Open 1 Total 1	
I.6	0		Open 1 Total 1	
I.7	0		Open 1 Total 1	

Response Report

Response Report

1. Select **Response Report**.

Note: Question rows are color coordinated to indicate the amount of preparation that should take place before an inspection:

- **Red:** at all times
- **White:** regularly updated
- **Blue:** at time of inspection

Response Report				
	Questions	Response Owners	Anticipated Inspector Questions / Request for Information	Supporting Documentation
Search	<input type="text" value="Question"/>	<input type="text" value="Owner"/>	<input type="text" value="Inspector"/>	<input type="text" value="Documentation"/>
	<i>I, Org & Pers I.1</i>	Jared Sol, Jason Snead, Jered Myers	Summary of clinical development plan/program for inspected molecule List of all trials for the molecule (Development, IST, Registry, Partner/Collaborator trials) Trial Monitoring Plans (TMP) for selected study(ies)	Determine the overall organization of the clinical research activities and monitoring of the selected studies.
	<i>I, Org & Pers I.2</i>	Jered Myers, Russell Rottach	Roche Group and Development organizational charts - PDLT and SMT level organization chart including Hal Barron	Obtain relevant organizational charts that document structure and responsibilities for all activities involving investigational products
	<i>I, Org & Pers I.3</i>	Jered Myers, Nancy Janzen, Russell Rottach	Comprehensive Study Management Team Contact List including - past/present members and service provider personnel and - handover documentation per gcp_sop001778 / PDO Project and Study Handover Procedure JD, qualifications and training of the	(1) Identify all departments, functions, and key individuals responsible for areas of sponsor activities such as protocol development, selection of investigators, statistical analysis, clinical supplies, monitoring, and quality assurance

2. Select the **Status** menu to filter the **Response Report**.

Status

All

✓ Complete

✓ Complete

Tasks Report

Tasks Report

1. Select **Tasks Report**.

Tasks Report			
	Questions	Response Owners	Anticipated Inspector Questions / Request for Information
<input type="button" value="Search"/>	<input type="text" value="Question"/>	<input type="text" value="Owner"/>	<input type="text" value="Inspector"/>
	<i>I. Org & Pers I.1</i>	Jared Sol, Jason Snead, Jered Myers	Summary of clinical development plan/program for inspected molecule List of molecule (Development, IST, Registry, Partner/Collaborator trials) Trial Monitoring (TMP) for selected study(ies)
	<i>I. Org & Pers I.2</i>	Jered Myers, Russell Rottach	Roche Group and Development organizational charts - PDLT and SMT level chart including Hal Barron
	<i>I. Org & Pers I.3</i>	Jered Myers, Nancy Janzen, Russell Rottach	Comprehensive Study Management Team Contact List including - past/present and service provider personnel and - handover documentation per gcp_sop0 Project and Study Handover Procedure JD, qualifications and training of the individuals involved at any stage of the clinical trial process Roles and responsibilities: t gcp_for000794 RO-GNE: Inspection Contact list should be used to document Inspection Contacts per field of expertise, if involved the GIG also prepares a RO-GNE: GCP/PV Inspection Subject Matter Expert (SME) List

2. Select the **Tasks** menu to filter the **Tasks Report**.

Tasks
All
Open 1 Total 2
Open 2 Total 3


Issues Report

Issues Report


1. Select **Tasks Report**.


Issues Report			
	Questions	Response Owners	Anticipated Inspector Questions / Request for Information
Search	<input type="text" value="Question"/>	<input type="text" value="Owner"/>	<input type="text" value="Inspector"/>
	<i>I. Org & Pers I.1</i>	Jared Sol, Jason Snead, Jered Myers	Summary of clinical development plan/program for inspected molecule List of all trials molecule (Development, IST, Registry, Partner/Collaborator trials) Trial Monitoring Plan (TMP) for selected study(ies)
	<i>I. Org & Pers I.2</i>	Jered Myers, Russell Rottach	Roche Group and Development organizational charts - PDLT and SMT level organizational chart including Hal Barron
	<i>I. Org & Pers I.3</i>	Jered Myers, Nancy Janzen, Russell Rottach	Comprehensive Study Management Team Contact List including - past/present member and service provider personnel and - handover documentation per gcp_sop001778 / Project and Study Handover Procedure JD, qualifications and training of the individuals involved at any stage of the clinical trial process Roles and responsibilities: the gcp_for000794 RO-GNE: Inspection Contact list should be used to document all available Inspection Contacts per field of expertise, if involved the GIG also prepares a gcp_for000794 RO-GNE: GCP/PV Inspection Subject Matter Expert (SME) List

2. Select the **Issues** menu to filter the **Issues Report**.

Note: The  icon indicates all issues are complete. The numeral in the **Issues** column represents the number of incomplete issues.

Issues

All 



2

Action Items Report

Action Items Report

1. Select **Action Items Report**.

Action Items Report			
	Questions	Response Owners	Anticipated Inspector Questions / Request for Information
<input type="button" value="Search"/>	<input type="text" value="Question"/>	<input type="text" value="Owner"/>	<input type="text" value="Inspector"/>
	<i>I. Org & Pers I.1</i>	Jared Sol, Jason Snead, Jered Myers	Summary of clinical development plan/program for inspected molecule L molecule (Development, IST, Registry, Partner/Collaborator trials) Trial M (TMP) for selected study(ies)
	<i>I. Org & Pers I.2</i>	Jered Myers, Russell Rottach	Roche Group and Development organizational charts - PDLT and SMT le chart including Hal Barron
	<i>I. Org & Pers I.3</i>	Jered Myers, Nancy Janzen, Russell Rottach	Comprehensive Study Management Team Contact List including - past/p and service provider personnel and - handover documentation per gcp_s Project and Study Handover Procedure JD, qualifications and training of t involved at any stage of the clinical trial process Roles and responsibility gcp_for000794 RO-GNE: Inspection Contact list should be used to docu Inspection Contacts per field of expertise, if involved the GIG also prepare RO-GNE: GCP/PV Inspection Subject Matter Expert (SME) List

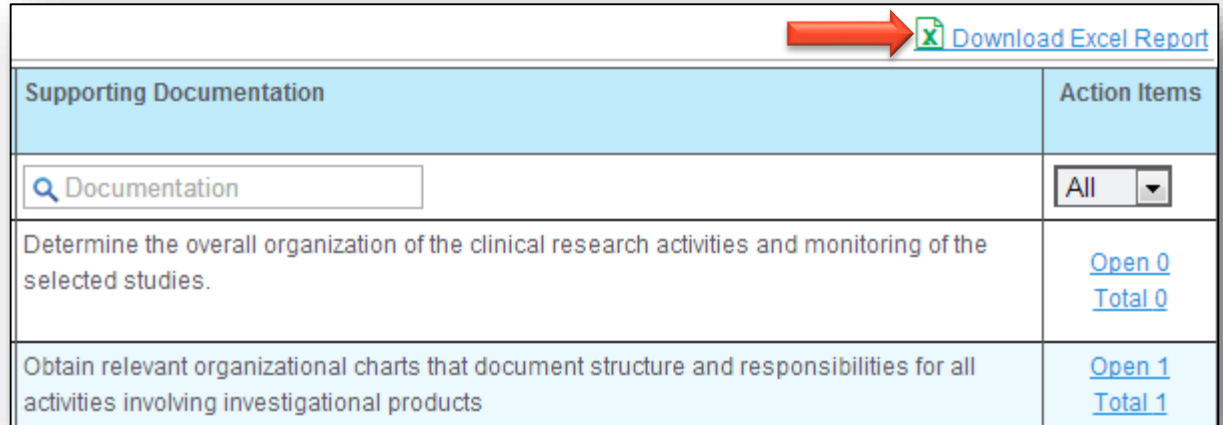
2. Select the **Action Items** menu to filter the **Action Items Report**.

Action Items
All
Open 0 Total 0
Open 1 Total 1

Export Report

Export Report

1. Select [Download Excel Report](#) in the upper right-hand corner of any report.



The screenshot shows a report interface. At the top right, there is a link labeled "Download Excel Report" with a green Excel icon. A red arrow points to this link. Below the link is a table with the following structure:

Supporting Documentation	Action Items
<input type="text" value="Documentation"/>	All ▾
Determine the overall organization of the clinical research activities and monitoring of the selected studies.	Open 0 Total 0
Obtain relevant organizational charts that document structure and responsibilities for all activities involving investigational products	Open 1 Total 1