MI Portal user guide

# Contents

Chapter 1. MI Portal user guide	4
Dashboard Overview	5
Sign In	5
Sign Out	6
Forgotten Password Reset	6
Change Your Password	9
Password Policy	
Access to ServiceNow with Single Sign-On	
Access Site Services	
Access Help Guides and Training Videos	12
Study Attributes	13
User Roles and Permissions	13
View Outstanding Queries	14
View New Queries	15
My Queries Attributes	16
My Queries Overview	16
Filter Queries	16
Filter by Status Attributes	17
Search Queries	17
View Query Details	
View Query History	
Query Details Attributes	
Send Query Responses	20
Expedited Read Results	20
Types of Expedited Read Results	21
View Expedited Read Results	21
Expedited Read Results attributes	22

Reports	
View Reports	23
Interaction with Reports	
Subscribe to a report	60
Unsubscribe to a report	

# Chapter 1. MI Portal user guide



# **Dashboard Overview**

The Dashboard contains list of application and list of Studies. From Studies, you can access Queries, Expedited Read Results, and Reports. Once you sign into the MI Portal you see the Dashboard with Applications List and the Study List panes.

The applications that appear in the Applications List are dependent on your permissions and link to separate applications within Medical Imaging.

The Study List contains a list of Studies that contains Queries, Expedited Read Results, and Reports tab.

The Studies that appear in this list are dependent on the permissions you have. You can filter the Study List by the name of the Sponsor if required.

From the Dashboard you can access your user profile where you can change your password and logout.

The icon with the question mark has options to open up a pdf document of the help guide, the training videos and Quick start guides.

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Dashboard					
Applications List	Study List	×			Sourch for a chicky
CSM Portal - for access to Site Services	Sponsor	Program	Study Name	Study Id	
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				Nows per page.	V V I / / / J J J J J J J J J J J J J J J J
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# Sign In

Sign in to the portal when you require access. To Sign in to the portal:

- 1. Go to the MI Portal url : Login-Calyx MI Portal (b2clogin.com).
- 2. Type your Email Address.

3. Type your password. If you have forgotten your password see Forgotten Password Reset (on page 6).

perceptive	
Login Email Address Password	
Forgot Password?	

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The portal opens.

#### Sign Out

Sign out of your profile as necessary. To Sign out of your profile:

- 1. From the Dashboard, click the icon with your initials.
- 2. Click Logout.

A message appears: You have successfully logged out. Click here to login again.

#### Forgotten Password Reset

Reset your password if you have forgotten it. To reset your forgotten password:

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1. From the Login page Login-Calyx MI Portal (b2clogin.com) click Forgot Password.

Per al	perceptive	
	Login Email Address	•
	Password Forgot Password?	
8°	SIGN IN	

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- 2. Type your Email Address.
- 3. Click Send Verification Code.

CANCEL	perceptive 🔅	
Email A	ddress	
	SEND VERIFICATION CODE	
	CONTINUE	



- 5. Copy the verification code from that email.
- 6. Type the verification code in the *verification code* window of step 3.
- 7. Click Verify Code.

#### Note:

A message appears: The code has been verified. You can now continue.

- 8. Click Continue.
- 9. Type your New Password.
- 10. Type the same password again to confirm it.
- 11. Click Continue.

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New Password	
Confirm New Password	
CONTINUE	

A message appears: Password has been reset successfully. Please continue to login.

#### Change Your Password

Change your password as necessary. You must know your current password to do this. To change your password:

- 1. From the Dashboard, click the icon with your initials.
- 2. Click Change Password.

The customer portal login page opens.

3. Type your New Password. See Password Policy (on page 10) for New Password requirements.

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New Password	
Confirm New Password	
CONTINUE	

- 4. Confirm your new password.
- 5. Click Continue.

A message appears: Password has been changed successfully. Please continue to login.

# **Password Policy**

Name	Value	Description
Old Pass- word	8-16 characters of alphanumeric text that must contain 3 out of 4 of the following:	The Old Password you want to change.
	<ul> <li>Lowercase characters</li> <li>Uppercase characters</li> <li>Digits (0-9)</li> <li>One or more of the following symbols (@,#,\$,%,^,&amp;,*, -,_,</li> <li>+,=,[,],{,}, ,/:,', ~,(,); and .)</li> </ul>	

Name	Value	Description
New Pass- word	8-16 characters of alphanumeric text that must contain 3 out of 4 of the following:	The New Password being created.
	<ul> <li>Lowercase characters</li> <li>Uppercase characters</li> <li>Digits (0-9)</li> <li>One or more of the following symbols (@,#,\$,%,^,&amp;,*, -,_,</li> <li>+,=,[,],{,}, ,/:,', ~,(,); and .)</li> </ul>	
Confirm New Password	<ul> <li>8-16 characters of alphanumeric text that must contain 3 out of 4 of the following:</li> <li>I owercase characters</li> </ul>	Re-type the New Password to confirm it.
	<ul> <li>Uppercase characters</li> <li>Digits (0-9)</li> <li>One or more of the following symbols (@,#,\$,%,^,&amp;,*, -,_,</li> </ul>	
	+,=,[,],{,}, ,/:,',`,~,(,); and .)	

## Access to ServiceNow with Single Sign-On

Access ServiceNow with Single sign-on (SSO) from MI Portal application.

As an authenticated user of MI Portal application that has Azure Active Directory (AD) authentication enabled, you can access the ServiceNow portal with the Single sign-on capability from the Customer Service Portal link in the footer of the application. You are not required to enter the credentials again in the ServiceNow portal.

#### **Access Site Services**

Steps to access Site Services from Customer Service Management (CSM) portal. To access Site Services:

1. From the MI Portal Dashboard, in the Applications List pane, select CSM Portal - for access to Site Services.

The Perceptive Service Line page appears.

- 2. In the MI product pane, click View Catalogue. The *Medical Imaging* page appears.
- 3. In Site Services option, click View Requests.

The *Medical Imaging Site Services* page appears. You can select the required service.

You can access to ServiceNow with Single sign-on via the CSM Portal in the Applications List section of the Dashboard page or via the Customer Service Portal.

III perceptive MI Port	al					(	?) Help
Dashboard							
Applications List	Study List						
CSM Portal - for access to Site	All Sponsors	~				Search for a study	Q
Services	Sponsor	Program	Study Name	Study Id			
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	ences		ELI	E			
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#### Access Help Guides and Training Videos

Steps to access the User Help Guide and the Training Videos from the Dashboard page.

From the Dashboard click the Help icon and select the following options:



Options	Action/Description
User Help Guide	Opens the MI Portal .pdf a users help guide.
Training Videos and Quick Start Guides:	a. Training Videos:
	The following four Training Videos are available:

Options	Action/Description				
Using the Calyx MI Portal A database of the first of the	<ul> <li>MI Portal - Signing In for First Time</li> <li>MI Portal - The Dashboard</li> <li>MI Portal - Finding &amp; Downloading Reports (Sponsors)</li> <li>MI Portal - Viewing &amp; Responding to Queries (Sites)</li> </ul>				
	2. Opens the MI Portal Quick Start Guide: Study Co- ordinators v1.pdf				
	3. Opens the MI Portal Quick Start Guide: Sponsor Users v1.pdf				

# Study Attributes

Name	Туре	Description
Sponsor	Text	[Read-only] The name of the Sponsor.
Program	Text	[Read-only] The name of the program.
Study Name	Link	The name of the Study.
Study ID	Link	The unique identifier for the Study.

# **User Roles and Permissions**

Role	Study Access	Site Access	External Portal Permission/Access
Study Coordinator	Multiple Studies	1 Site per Study	View, reply to Queries and view Expedited Read Results only for their sites. View and download Expedited Read Results pdf reports only for their sites.
Sponsor	Multiple Studies	Multiple <b>Sites</b>	View and download Reports including Expe- dited Read Results report of the study. View and download Expedited Read Results pdf reports of all sites.

Role	Study Access	Site Access	External Portal Permission/Access
Site Monitor	Multiple Studies	Multiple Sites	View and download Reports.
MI Technical Support	Multiple Studies	Multiple Sites	View only for both - Reports and queries.
			View and download Expedited Read Results pdf reports of all sites.
MI Internal	Multiple Studies	Multiple Sites	View and download Reports.
Clinical Research As-	Multiple Studies	Multiple Sites	View and download Reports.
sociates (CRAs)			View and download Expedited Read Results
			pdf reports only for their sites.
Clinical Research Or-	Multiple Studies	Multiple Sites	View and download Reports.
ganizations (CROs)			View and download Expedited Read Results
			pdf reports of all sites.
Project Managers	Multiple Studies	Multiple Sites	View and download Reports.
(PMs)			View and download Expedited Read Results
			pdf reports of all sites.
Principal Investigator	Multiple Studies	Only for their	View and download Expedited Read Results
		sites	pdf reports only for their sites.

# View Outstanding Queries

View Outstanding Queries that have not been resolved. To view an outstanding query:

1. From the Study List, select a Study. The My Queries tab opens.

perceptive		MI Portal						? Help
Dashboard My C	Queries Ex	xpedited Read Re	sults Reports					
Mar 5 / My Q	lueries							
⊞ New Queries 5	\Xi Outstan	nding Queries 92	C Refresh Queries	Filter by status:	New	~	Search	Q
Query ID	Site ID	Subject ID	Visit ID	Last Sent Date	Closed Date	Age		Status
6709	'A	7A	те	13-Nov-2024		0 day	/S	Outstanding
6708	'A	7A	eduled Visit-1	13-Nov-2024		0 day	/S	Outstanding
6707	'A	7E	up2	13-Nov-2024		0 day	/S	Outstanding
6706	'A	7 G	up1	13-Nov-2024		0 day	/S	Outstanding
6705	'A	7G	up2	13-Nov-2024		0 day	/S	Outstanding
				Rows per	r page: 10 🗸	« ‹	1 > >	5 items in 1 pages

- 2. Click Outstanding Queries.
- 3. Select the query you want to view.

The Query Details page opens.

# **View New Queries**

View Queries to see specific details of the query. To view a query:

1. From the Study List, select a Study. The My Queries tab opens.

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Dashboard My Queries Expedited Read Results Reports										
Manui / My Queries										
E New Queries 5	⊡ Outstar	nding Queries 92	$oldsymbol{\mathcal{C}}$ Refresh Queries	Filter by status:	Outstanding	✓ Search		Q		
Query ID	Site ID	Subject ID	Visit ID	Last Sent Date	Closed Date	Age	Status			
5531	7A			03-Jul-2024		139 days	Outstanding			
5532	7A			04-Sep-2024		133 days	Outstanding			
6709	7A	)7A	e	13-Nov-2024		0 days	Outstanding			
5545	7A	17A	p1	04-Sep-2024		133 days	Outstanding			
5550	7A	17A	p2	04-Sep-2024		132 days	Outstanding			
5546	7A	17A	p3	04-Sep-2024		133 days	Outstanding			
5534	7A	17A	duled Visit-1	03-Jul-2024		139 days	Outstanding			
5525	7.4	17.6	dulad Visit 1	04-500 2024		122 dave	Outstanding			

- 2. Click New Queries.
- 3. Select the query you want to view.

The Query Details page opens.

# My Queries Attributes

Name	Value	Description
Query ID	Link	Unique query identifier.
Site ID	Link	Unique Site identifier.
Subject ID	Link	Unique subject identifier.
Visit ID	Link	Unique visit identifier.
Last Sent Date	[Read-only]	The last date a query was sent.
Closed Date	[Read-only]	The date a query was closed.
Age	[Read-only]	The Age of the query in days.
Status	[Read-only]	Status of the query. See Status Attributes ( <i>on page 17</i> ) for more details.

# My Queries Overview

Queries are opened to request further information as required.

My Queries contains a list of all Queries related to a Study received from the tracking system. You can respond to Queries opened/created by MI Portal team when additional information is required from the Site regarding an image, subject, visit or generally about the Site.

A query can be opened for data clarification to request missing images, image quality issues, or for any information necessary for the subject's data to be adequately reviewed.

There are New Queries and Outstanding Queries for each Study.

The New Queries list contains Queries for the last 30 days. Any Queries older than 30 days appear in the Outstanding Queries list.

You can filter the Queries by status, for example closed, Outstanding and so on. You can also search for Queries by entering a term into the search field.

# **Filter Queries**

You can filter Queries based on the status. To filter Queries:

- 1. From the Study List, select a Study. The My Queries tab opens.
- 2. Select a status from the Filter by Status drop-down. See Filter by Status Attributes (on page 17) for a description of the options.

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IE New Queries 5	0utstar	nding Queries 92	C Refresh Queries	Filter by status:	Outstanding	✓ Search	Q			
Query ID	Site ID	Subject ID	Visit ID	Last Sent Date	All		Status			
5531	7A			03-Jul-2024	Outstanding New	ays	Outstanding			
5532	7A			04-Sep-2024	Responded	ays	Outstanding			
6709	7A	07A		13-Nov-2024		0 days	Outstanding			
5545	7A	07A	o1	04-Sep-2024		133 days	Outstanding			
5550	7A	07A	52	04-Sep-2024		132 days	Outstanding			
5546	7A	07A	53	04-Sep-2024		133 days	Outstanding			
5534	7A	07A	uled Visit-1	03-Jul-2024		139 days	Outstanding			
5525	7.٨	07.6	ulad Visit 1	04 500 2024		122 dave	Outstanding			

The filtered results appear.

# Filter by Status Attributes

Name	Description
All	Queries in all statuses.
Closed	Queries that have been closed by the Perceptive team.
Outstanding	Queries that have not been resolved or closed.
New	Queries that have not been opened/viewed by the Site user.
Responded	Queries that Sites responded to but are not closed.
Overdue	Queries that have not been responded to within the defined turnaround time of the study.

# Search Queries

You can search Queries by using a specific term as required. To search Queries:

1. From the Study List, select a Study. The My Queries tab opens.

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E New Queries 5	i⊟ Outsta	nding Queries 92	2 Refresh Queries	Filter by status:	Outstanding	~	Search D			
Query ID	Site ID	Subject ID	Visit ID	Last Sent Date	Closed Date	Age	Status			
5531	'A			03-Jul-2024		139 days	Outstanding			
5532	2 A			04-Sep-2024	04-Sep-2024		Outstanding			
6709	'A	)7A	ne	13-Nov-2024		0 days	Outstanding			
5545	'A	)7A	/up1	04-Sep-2024		133 days	Outstanding			

- 2. Type a search term in the search field.
- 3. Click Enter on your keyboard. The search results appear.

# **View Query Details**

View the Query Details as necessary. To view Query Details:

- 1. From the Study List, select a Study. The My Queries tab opens.
- 2. Select the Query.

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Dashboard My Queries Expedited Read Results Reports											
Manu / My Queries / 5329											
Query Deta	ails										
Query ID	Site ID	Subject ID	Visit ID	Query Category	Age	Closed Date	То		сс	Query Originator	Status
5329	S1	Sub1406A	Followup1	Required Scan Missing	153 days			idam@ ng22@outlook.com ng23@outlook.com		MIBIntegration@calyx.ai	Outstanding
Query History: Show											
Query Com	Query Comments										
Please subm	it the scan reque	sted in the query	for the Subject I	Number: "Sub1406A" to the Sit	e ID: "S11	Visit Name: "Follov	vup1"				

The Query Details tab opens.

View the Query Details in the table.

#### **View Query History**

You can view the Query History to see previous Query activity. To view the Query History:

- 1. From the Study List, select a Study. The My Queries tab opens.
- 2. Select the Query.

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Dashboard	l My Que	eries Expe	dited Read R	esults Reports							
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Query Det	ails										
Query ID	Site ID	Subject ID	Visit ID	Query Category	Age	Closed Date	То		сс	Query Originator	Status
5329	S	Sub1406A	Followup1	Required Scan Missing	153 days			am@calyx.ai 22@outlook.com 23@outlook.com		MIBIntegration@calyx.ai	Outstanding
Query Hist	t <b>ory:</b> Hide										
Date			From		Query Comn	nents					
14-Jun-2024 MIBIntegration@calyx.ai			Please submit the scan requested in the query for the Subject Number: "Sub" to the Site ID: "S11j" Visit Name: "Followup1"								
Query Con	nments										
Please subm	nit the scan requ	ested in the quer	y for the Subject	Number: "Sub1406A" to the S	ite ID: "S1	Visit Name: "Follo	wup1"				

3. In the Query History field, click Show.

The Query History displays.

## **Query Details Attributes**

Name	Value	Description
Query ID	[Read-only]	Unique query identifier.
Site ID	[Read-only]	Unique Site identifier.
Subject ID	[Read-only]	Unique subject identifier.
Visit ID	[Read-only]	Unique visit identifier.
Query Category	[Read-only]	The category of the Query defined in the Perceptive system.
Age	[Read-only]	Age of the Query in days.
Closed Date	[Read-only]	The date the Query was closed.
То	[Read-only]	Receiver of the Query.
СС	[Read-only]	The copied receiver of the Query.
Query Originator	[Read-only]	The Query sender.
Status	[Read-only]	The status of the Query. See Status Attributes <i>(on page 17)</i> for more details.

# Send Query Responses

Send Query Response as required. To send a Query Response:

- 1. From the Study List, select a Study. The My Queries tab opens.
- 2. Select the Query you want to respond to. The Query Details page opens.
- 3. Type the Query Response.

III perceptive	MI Portal					? Неір СК
5329 S11 Sub1406	iA Followup1	Required Scan Missing	153 days	i@c ∶alyx.ai utlook.com utlook.com	MIBIntegration@calyx.ai	Outstanding
Query History: Show						
Query Comments						
Please submit the scan requested in the	query for the Subject	: Number: "Sub1406A" to the Si	te ID: "S11 Visit Name: "Follo	wup1"		
Query Response *						
Submitted the requested scan for the Su	ibject Number: "Sub1	406A" to the Site ID: "S11	" Visit Name: "Followup1" on 12-No	ov-2024.		
Maximum limit is 2000 characters						
			< >			

end Respo

4. Click Send Response.

A message appears: Your response sent successfully.

# **Expedited Read Results**

Once Site or Sponsor users are provisioned in MIB, by MIB admin user, MIB Project Manager or MIB Site Management user, they can view appropriate Expedited Read Results of their study within the MI Portal.

Site users can view a list of all results report for subjects at their site within the MI Portal:

- · Sorted with the most recent at the top
- View Site, Subject, Visit, Date Report Generated

Sponsor users can view a list of all results report for all subjects across all sites within the MI Portal:

- · Sorted with the most recent at the top
- View Site, Subject, Visit, Date Report Generated

Site and Sponsor users can:

• Open and Download pdf results report on-screen in real-time (that is, user clicks the report and can view it immediately in a separate window).

### Types of Expedited Read Results

There are two types of Expedited Read Results:

- Eligibility Cases: Results of the independent central imaging review for the eligibility visit used to help determine a subjects' inclusion or exclusion in a trial.
- Verification of Progressive Desease (VOPD): Progressive Disease results from the independent central imaging review for Visits where VOPD was requested.

#### **View Expedited Read Results**

To view Expedited Read Results at MI Portal:

- 1. Login to the MI Portal.
- 2. From the Dashboard page, click a **Study ID**.

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Dashboard					
Applications List	Study List				
O CSM Portal - for access to Site	All Sponsors	~			Search for a study ${\cal O}$
Services	Sponsor	Program	_		
	nics		mg09( <sup>&gt;</sup> tN	ıl_mg0	
	nics		1000	O	-
	ciences			lity Study Den	no - DO NOT DELETE
	nics			8	
	nics	Test Programme	estStudy	o	
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- 3. Click Expedited Read Results tab.
- 4. Click **View** icon against the desired **Site ID** to view the detailed report.

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Dashboard	Expedite	d Read Results	Reports							
manua	manue / Expedited Read Results									
Expedited Rea	d Results			Search By	Site	Subject	Visit	Report(s) Type	V Clear /	All Q
View	Site	Subject			Visit	Report(s) Type		Date Report Generated		
0	82	VEMSL			FU1	Progressive Disease	Report	08-Apr-2024		
0	82	Subhy			Unscheduled Visit-1	Progressive Disease	Report	22-Mar-2024		
0	82	TESTU:			FU1	Progressive Disease	Report	22-Mar-2024		
0	82	TESTU			FU1	Progressive Disease	Report	15-Mar-2024		
						Rov	vs per page: 10 🗸	« < 1 > »	4 items in	1 pages

#### A reports pdf opens.

5. Scroll to View or click Download to save the report as required.



#### Expedited Read Results attributes

Name	Value	Description				
Site	[Read-only]	Unique Site identifier.				
View	[Read-only]	Opens the pdf result report in new window.				
Subject	[Read-only]	Unique Subject identifier.				
Visit	[Read-only]	Unique Visit identifier.				
Reports Type	[Read-only]	There are two types of report:				

Name	Value	Description
		<ul> <li>Progressive Disease Report: Progressive Disease Report is a result from the independent central imaging review for Visits where verification of Progressive Disease was re- quested.</li> <li>Eligibility Report: Eligibility Report is a result of the inde- pendent central imaging review for Visits used to deter- mine a subjects' inclusion in a trial.</li> </ul>
Date Report Gener- ated	[Read-only]	The date of report generation.

# Reports

Study-level reports are available to end users via the MI Portal. The reports and visualizations provide information on the operational processing of Medical Imaging data for a particular clinical trial study.

## **View Reports**

Depending on the study platform whether it is Gen 1 or Gen 2, you can view different types of reports in the Reports section.

## View Gen 1 Studies Reports

For studies belonging to the Gen 1 platform, you can view the below report:

- 1. Study Performance Monitoring
  - Image QC Monitor
  - Read Monitor
  - Sites
  - Subjects
  - ∘ Visits
  - Images
  - Queries
- 2. MI Portal User Access

To view Reports related to Gen 1 **Studies**:

1. From the Study List, select a Study. The Reports tab opens.

# perceptive	MI Portal						🥐 Help
Dashboard My Queries Exp	pedited Read Results	Reports					
22 / Reports							
Report Name							
Study Performance Monitoring							
MI Portal User Access							
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2. Click the report name: Study Performance Monitoring.

The Reports page displays. This page contains seven sections having various metrics and graphical charts with buttons to drill down to tabular Reports of the underlying data.

3. Click each tab to view the different Reports.

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Pages			Image QC Monitor		<b>∓</b> Filters »
Image QC Monitor Read Monitor Sites Subjects Visits	Country Pro	oject Shapshot 7,774 Iotal Image Groups B(lank) PIA 17 Imports Last 7 Days (B(lank) PIA Age Average 2 WP Processable	PIA and WIP by Month	Monthly Actions vs imports	International Constraints of the search sear
mages Queries		15 WIP Blocked by Query 24 Open Visit Queries (Blank) Overdue Visit Queries 1 nitial Action vs Import* 2 inal Action vs Import*	Daily Actions vs Imports Last 7 Days User Onto Action Of Field Action 2	Backlap B Week         WD           223-0-23         01           223-0-23         01           223-0-24         01           223-0-24         01           223-0-23         01           223-0-24         01           223-0-24         01           223-0-24         01           223-0-24         01           223-0-24         01	

## Study Performance Monitoring

#### Image QC Monitor

This tab provides an overview of the high-level metrics associated with image quality checks (QC) processing. Image QC Monitor section displays:

- Project Snapshot: a set of summary metrics for the Study. The description of each matric is as follows:
  - Total Image Groups: total count of image groups received, where image group is defined as unique Modalities per visit.
  - PIA: count of Pending Initial Action image groups, meaning at least one image in the image group has had no action taken on it yet. PIA is a subset of WIP.
  - WIP: count of image groups Work In Progress, meaning at least one image in the image group has not had QC completed.
  - Imports Last 7 Days: count of image groups imported in the last 7 calendar days.
  - PIA Age Average: Average age of image groups Pending Initial Action in business days from date received to date report is viewed.
  - WIP Processable: count of image groups that do not have any queries blocking processing.
  - WIP Blocked by Query: the count of image groups that are blocked for processing by an unresolved query.
  - Open Visit Queries: the count of unresolved visit queries.
  - $\circ\,$  Overdue Visit Queries: the count of unresolved required scan missing visit queries.
  - Initial Action vs Import: shows the rate of change to PIA in the last 7 days by taking the difference between the number of initial actions performed and imports.
  - Final Action vs Import: shows the rate of change to WIP in the last 7 days by taking the difference between the number of final actions performed and imports.
- PIA and WIP by Month: graph by month displays the count of image groups in Pending Initial Action and Work In Progress status, and the average age of image groups Pending Initial Action in business days.
- Monthly Actions vs Imports: graph by month displays the count of image groups imported, image groups with Initial Action performed, and image groups with Final Action performed, with lines showing the ratio of Initial Action to Import and Final Action to Import to help gauge rate of change to the study backlog.
- Daily Actions vs Imports Last 7 Days: graph displays the counts of image groups imported, image groups with Initial Action performed, and image groups with Final Action performed. Note that if this chart is not displayed, there were no actions taken in the last 7 days.
- Backlog By Week: displays a snapshot of image groups in Pending Initial Action and Work In Progress by week. A heat map color gradient calls attention to weeks with highest counts (darker color).

To view the Images in the QC backlog, click the PIA List button below the Slicers on the left to view Images Pending Initial Action or WIP List button to view Images that are Work In Progress. To return to the Image QC Monitor tab from the PIA List or WIP List, click the Back to Report button above the Slicers in the upper left.



#### **Read Monitor**

The Read Monitor tab provides an overview of the number and status of available cases. The Read Monitor section display the following data:

- Pending Cases by Date Category: displays the count and average age in business days of pending cases by Month, Work Week, or Day, with date category with the selectable buttons next to the visual.
- Case Actions by Date Category: displays the count of cases assigned and completed by Month, work Week, or Day, with date category selectable with the same buttons next to Pending Cases by Date Category visual.
- Project Summary: displays case metrics for the project (study). This view is selectable by clicking the Project Summary button left of the visual.
  - Cases Created: total cases created to date.
  - Cases Completed: total cases completed to date.
  - Cases Incomplete: total cases incomplete to date, inclusive of pending and unassigned cases.
  - Pending Cases: total cases that have been assigned to a reviewer but not completed.
  - Average Pending Case Age: average age of pending cases in business days between date assigned and date report viewed.
  - Pending Cases > 5 Days: count of pending cases that have aged more than 5 business days.
  - Pending Cases > 10 Days: count of pending cases that have aged more than 10 business days.
  - Completed Cases Current Month: count of cases completed in the current month.

- Completed Cases Last Month: count of cases completed in the prior month.
- Completed Cases Last 6 Months: count of cases completed in the prior 6 months (excludes current month).
- Reviewer Summary: Displays case metrics by anonymized Reviewer. This view is selectable by clicking the Reviewer Summary button left of the visual.
  - Pending Cases: total cases that have been assigned to a reviewer but not completed.
  - Average Pending Case Age: average age of pending cases in business days between date assigned and date report viewed.
  - Pending Cases > 5 Days: count of pending cases that have aged more than 5 business days.
  - Pending Cases> 10 Days: count of pending cases that have aged more than 10 business days.
  - Completed Cases Current Month: count of cases completed in the current month.
  - Completed Cases Last Month: count of cases completed in the prior month.
  - Completed Cases Last 6 Months: count of cases completed in the prior 6 months (excludes current month).

To view the full list of cases, click the Case List button below the Slicers on the left. To return to the Read Monitor tab from the Case List, click the Back to Report button above the Slicers in the upper left.



Age based calculations are in business days

#### Sites

The Sites tab provides an overview of the Site initiation process. The Sites section displays the following data:

- Total Sites: count of all Sites in the Study to date.
- Pending Sites: count and percent of total Sites that are pending initiation to date.
- Initiated Sites: count and percent of total Sites that have been initiated to date.
- Terminated Sites: count and percent of total Sites that have been terminated to date.
- Avg Days to Initiate: Average business days from Site identification to initiation.
- Median Days to Initiate: Median business days from Site identification to initiation.
- Avg Days to First Image Received: Average business days from Site initiation to first Designated for Review (DFR) image received by the Site.
- Median Days to First Image Received: Median business days from Site initiation to first Designated for Review (DFR) image received by the Site.
- Total Non-Terminated Sites vs Initiated Sites: displays counts of non-terminated Sites and initiated Sites per month for the last 12 months.
- Site Status Change Actions: displays counts of initiated and terminated Sites per month for the last 12 months.
- Sites by Country: displays the following metrics by Site country:
  - $\circ\,$  Total Sites count to date.
  - Pending sites count to date.
  - Initiated sites count to date.
  - Terminated count sites to date.
  - $\circ$  Avg Days to Initiate: Average business days from Site identification to initiation.
  - Avg Days to First Image: Average business days from Site initiation to first Designated for Review (DFR) image received by the Site.

To view the full list of Sites, click the Site List button below the Slicers on the left. To return to the Sites tab from the Site List, click the Back to Report button above the Slicers in the upper left.



#### **Subjects**

The Subjects tab shows a breakdown of subject status and provides a quick look at how the processing for Images is going at a subject level.

Subjects section displays:

- Total Subjects: count to date.
- Screen Fail Subjects: count to date.
- Randomized Subjects: count to date.
- Off Study Subjects: count to date.
- Randomized Subjects and Off Study Subjects counts with the following segmentation:
  - $\circ$  With 1+ Read: one or more reviewer cases associated with the subject.
  - With 1+ Read Complete: one or more of the reviewer cases associated with the subject have been completed.
  - With All Available Reads Complete: all reviewer cases associated to the subject to date have been read (subject would be removed from this segment if additional incomplete cases are associated to the subject).
  - $\circ$  With Missing Images: Subjects with at least one visit where all Images are missing.
- Subject Status Changes: displays the counts of Randomized and off Study subjects by month for the last 12 months

- Subjects by Country and Site: two tables with ability to toggle the grouping using buttons above the visual. Both tables contain the following metrics as counts to date with the same definitions outlined above:
  - Total Subjects
  - Screen Fail
  - Randomized
  - Off Study
  - Randomized w/ 1+ Read
  - Randomized w/ 1+ Read Complete
  - Randomized w/ All Available Reads Complete
  - Randomized w/ Missing Images
  - Off Study w/ 1+ Read
  - Off Study w/ 1+ Read Complete
  - Off Study w/ All Available Reads Complete
  - Off Study w/ Missing Images

To view the full list of Subjects, click the Subject List button below the Slicers on the left. To return to the Subjects tab from the Subject List, click the Back to Report icon above the Slicers in the upper left.



#### Visits

The Visits tab provides a high-level look at Visits that have been received and how many of them have made it through the QC process.

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The Visits section display the following data:

- A banner of summary metrics:
  - Received Visits: count of Visits received to date.
  - Unscheduled Visits: count of unscheduled Visits received to date.
  - Overdue Visits: count of unresolved required scan missing Queries.
  - Missing Visits: count of Visits where site has confirmed we are not expected to receive any imaging.
  - Avg Modalities Per visit: average number of Modalities imaged per visit.
  - % Visits Queried After Receipt: percentage of total Visits that have had a Query issued after the image was received
  - Visits w/ 1+ Read: count of Visits where at least one reviewer case associated with the visit has been completed.
  - Visits w/ All Direct Reads Complete: count of Visits where all reviewer cases associated to the visit are completed.
- Visit Summary: displays a table of the following metrics by visit
  - Expected Visits: count of Visits received + count of unresolved overdue visit Queries.
  - $\circ\,$  Received Visits: count of Visits received to date.
  - $\circ\,$  Overdue Visits: count of unresolved required scan missing Queries.
  - Overdue Visits > 30 days: count of unresolved required scan missing Queries that have been open for more than 30 calendar days.
  - All DFR Images QCed: count of Visits where all Designated for Review (DFR) Images received have had QC completed.
  - All Direct Cases Complete: count of Visits where all reader cases associated to the visit have been completed.
- Visit Case Summary: displays a table of the following reader case metrics by visit:
  - $\circ\,$  Cases: count of total reader cases created for the visit
  - $\circ$  Completed: count of reader cases created for the visit that are completed
  - Assigned: count of reader cases created for the visit that are assigned to a reader, inclusive of completed cases
  - Unassigned Not Blocked by Case Rule: count of cases that have not been assigned to a reader that are ready for assignment.
  - Unassigned Cases Blocked by Case Rule: count of cases that cannot be assigned to a reader due to one or more operational checks preventing assignment.
- Visits By Country and Visits by Site: table displays the following visit metrics grouped by Country or Site, selectable using the buttons above the visual:
  - Received Visits: count of Visits received to date.
  - Unscheduled Visits: count of unscheduled Visits received to date.
  - Overdue Visits: count of unresolved required scan missing Queries.

- Missing Visits: count of Visits where Site has confirmed we are not expected to receive any imaging.
- Avg Modalities Per visit: average number of Modalities imaged per visit.
- % Visits Queried After Receipt: percentage of Visits that have had a Query issued after the image was received.
- Received Visits: displays the count of Visits total Visits received within a month, total Visits received to date, and unscheduled Visits received to date, for the last 12 months.

To view the full list of Visits, click the Visit List button below the Slicers on the left. To return to the Visits tab from the Visit List, click the Back to Report icon above the Slicers in the upper left

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4.0		222222: Repeat Screening	145	145			722	112				2	2.3	44.6%		
All	$\sim$	222222: Treatment Day 1	137	137			727	13					2.9	7.7%		
Reset Slicers		222222: Treatment Month 6	351	351			728	4					2.5	25.0%		
		222222: Treatment Month 12	280	280			729	81		1		7	2.5	51.9%		
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		222222: Treatment Month 24	177	177			734	24					2.3	12.5%		
		222222: Treatment Month 30	145	145			736	24					2.6	12.5%		
		222222: Treatment Month 36	135	135			737	22		1			2.7	40.9%		
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#### Images

The Images tab provides an overview of Images received for the Study and metrics for Image Processing . The Images section displays the following data:

- Image Receipt: displays count of Images received, Images received via ETransfer, and average business days from exam date to image received date by month for the last 12 months.
- Image QC Actions And Turn Around Times: displays counts and days to action for QC actions:

- Site Contact: count site notification, and average business days from image receipt to site notification, where Site notification is image acceptance or image quality-related Query.
- Initial Action: count of Images where QC actions were started, and average business days from image receipt to QC action started.
- Final Action: count of Images where QC actions were completed, and average business days from image receipt to QC action completed.
- Images By Country and Images By Site: table displays the following image metrics grouped by Country or Site, selectable using the buttons above the visual:
  - Total Images: count of Images received to date.
  - Average Days To Receipt: average business days between exam date and received date.
  - % Received via ETransfer: percentage of total Images received via ETransfer.
  - $\circ$  QC Complete: count of Images received to date that have completed QC.
  - $\circ$  QC Incomplete: count of Images received to date that have not completed QC.
  - Avg Days To First Site Contact\*: average business days from image receipt to Site notification, where Site notification is image acceptance or image quality-related Query.
  - Median Days To First Site Contact\*: median business days from image receipt to Site notification, where Site notification is image acceptance or image quality-related Query.
  - Avg Days To Initial Action\*: average business days from image receipt to QC action started.
  - Median Days To Initial Action\*: median business days from image receipt to QC action started.
  - Avg Days To Final Action\*\*: average business days from image received to QC completion.
  - Median Days To Final Action\*\*: median business days from image received to QC completion.

Metrics marked with single and double asterisk are calculated based on last 12 months of QC processing actions only. Metrics marked with double asterisk exclude days where an open Query blocked image processing.

To view the full list of Images, click the Image List icon below the Slicers on the left. To return to the Images tab from the Image List, click the Back to Report button above the Slicers in the upper left.



#### Queries

The Queries tab provides overview metrics and trends for all Queries for the Study. The Queries section displays the following data:

- Total Queries: count of Queries opened for Study to date.
- Closed Queries: count of resolved and closed Queries for Study to date.
- Open Queries: count of unresolved Queries for Study to date.
- Average Days To Close: average days in calendar days from date Query opened to date Query resolved.
- Avg Age Open Queries: average age in calendar days for unresolved Queries from date Query opened to date report viewed.
- % Open Queries > 30 Days: percentage of total unresolved Queries that were opened greater than 30 days before the date report viewed.
- Query status: displays pie chart of open and closed Query counts to date.
- Open Query Age: displays pie chart of unresolved Query counts in segments of 0 to 14 calendar days, 15 to 30 calendar days, and greater than 30 calendar days since Query was opened.
- Open vs Closed By Month: displays counts of opened and closed Queries to date by month and counts of opened and closed Queries in each month, for the last 12 months. This visual is selectable with a button to the left of the visual.

- Open Queries: displays count of open Queries, count of Queries open for greater than 30 calendar days, and average age of open Queries in calendar days by month for the last 12 months. This visual is selectable with a button to the left of the visual.
- Query Category: displays a pie chart of Query counts by Query Category; visit, Site, and Subject Queries.
- Site, Subject, and visit Query Types: displays a table of Query counts and percentages by Query type for each Query Category; visit, Site, and Subject Queries. The Query Category is selectable with buttons below the visual.
- Queries by Country and Queries by Site: table displays the following Query metrics grouped by Country or Site, selectable using the buttons above the visual:
  - Total Queries: count of Queries opened to date.
  - $\circ\,$  Closed: count of resolved and closed Queries to date.
  - Open: count of unresolved Queries to date.
  - Avg Age: average age in calendar days
  - Open 0-14 Days: count of unresolved Queries that have been open between 0 and 14 calendar days as of date report viewed.
  - Open 15-30 Days: count of unresolved Queries that have been open between 15 and 30 calendar days as of date report viewed.
  - Open >30 Days: count of unresolved Queries that have been open greater than 30 calendar days as of date report viewed.
  - % Open >30 Days: percentage of total unresolved Queries that were opened greater than 30 calendar days before the date report viewed.
  - Avg Days To Close: average calendar days between date Query opened and date Query resolved.

To view the full list of Queries, click the Query List icon below the Slicers on the left. To return to the Queries tab from the Query List, click the Back to Report button above the Slicers in the upper left.



#### **MI Portal User Access**

To access this functionality in MI Portal:

- 1. Login to the MI Portal.
- 2. Click on a Study Name or Study ID.

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- 3. Click on Reports tab.
- 4. Click MI Portal User Access.

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5. Hover over on the top right corner of the table to view the **More options** icon (three dots).

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6. Click **Export data** to export the data in spreadsheet format.

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7. [Optional] Sort the data in ascending or descending order to view as required.

## MI Portal User Access Attributes

Name	Value	Description
Trial Identifier	[Read-only]	Unique Trial identifier
First Name	[Read-only]	First Name of the User

Name	Value	Description
Last Name	[Read-only]	Last Name of the User
Email Address	[Read-only]	Unique Email Address of the User
User Role	[Read-only]	Role of the User in MI Portal
Site Number	[Read-only]	Unique Site Identifier
Study Association Date	[Read-only]	Date when the User is added to the Study/Trial
Study De-associa- tion Date	[Read-only]	Date when the User is removed from the Study/Trial
Last Accessed Date	[Read-only]	Date when the User last accessed the Study/Trial on MI Portal Dashboard

## View Gen 2 Studies Reports

For studies belonging to Gen 2 platform, below reports will be available:

- 1. Status of Visits
- 2. All Queries
- 3. Breakdown Report
- 4. Status of Sites
- 5. Expedited Read Results
- 6. Ambra User Status Report
- 7. MI Portal User Access

To view Reports related to Gen 2 **Studies**:

- 1. Login to the MI Portal.
- 2. From the Dashboard page, click a **Study ID**.

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- 3. Click **Reports** tab.
- 4. Click a **Report Name** as required to view.

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#### Status of Visits

List of visits with details used from the Image Collect stage to the Image Assessment stage. Useful for all, particularly the Case Management team in looking at 'How many Visits/ Reads are impacted by query holdups' Also useful during the Data Management/ Reconciliation stage.

To view the Status of Visits:

1. From the Reports tab, click **Status of Visits**.

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Fastpath:	
A list of Status of Visits with related attributes appears.	
	5

2. View or Export the **Status of Visits** report by clicking on the three dots.

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#### 3. Status of Visits Attributes

Name	Value	Description
Trial Identifier	[Read-only]	Unique Trial identifier.
TIMS	[Read-only]	Unique TIMS code
Site Name	[Read-only]	Unique Site Name
Site Number	[Read-only]	Unique Site number
Subject	[Read-only]	A person taking part in a study
Subject Arm	[Read-only]	
Visit	[Read-only]	Visit of a subject to the site for examination purpos-
		es
Modality	[Read-only]	The medium of test performed

Name	Value	Description
Date of Exam	[Read-only]	The date when test was performed
Upload date	[Read-only]	The date when image was uploaded to Ambra
Date of Acceptance	[Read-only]	The date of image acceptance
Image Status	[Read-only]	The status of image acceptance
Any open queries against image	[Read-only]	Status of open queries against each image
Image ID	[Read-only]	Unique image identifier

#### All Queries

List of queries with details used from the Image Collection & Quality Check stages up until the stage where a case is assigned to a reader. Also used in the Data Management stage i.e. Queries might be issued during Data Reconciliation.

To view the All Queries report:

1. From the Reports tab, click **All Queries**.

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Expedited Read Results	
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2. View or Export the **All Queries** report by clicking on the three dots.

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	Query Details Trial Identifier Big Bott Big Ber Ber Ber Ber Ber Ber Ber Ber Ber Ber	<b>by Query</b> Protocol Number Que 56 56 56 56 56 56 56 56 56 56 56 56 56 5	ry ID Site Nan Main Testing Site Main Testing Main Testing Site Main Testing Main Testing Main Testing Main Testing Main Testing Main Testing Main Testing Main Main Testing Main	All Queri e Site Number Subject 501 E0404002 501 TAS115-11-0380 501 0100001 501 E1004008 501 860-15-005 501 860-15-005 501 46000401 501 621.014	Vat Vat Folowp2 Folowp1 Folowp2 Folowp2 Folowp2 Folowp2 Folowp1 Folowp	Modality Espedited Date of Exam Upload Date No No No No No No No No No No	Query Status Requery Requery Requery Requery Requery Requery Requery Requery	<ul> <li>Filters</li> </ul>

3. All Queries Attributes

Name	Value	Description
Query details by query ∘ Trial Identifier ∘ TIMS	[Read-only]	Unique query identifier.
Query ID	[Read-only]	Unique query identifier.
Site Name	[Read-only]	Unique Site identifier.
Site Number	[Read-only]	Unique Subject identifier.
Subject	[Read-only]	Subject is a patient to visits to the site
Visit	[Read-only]	Subject visit to the site to monitor disease pro- gression
Modality	[Read-only]	Imaging Type
Expedited Visit	[Read-only]	Visits treated on fast-track mode with addi- tional agreed upon charges
Date of Exam	[Read-only]	The date when test was performed
Upload date	[Read-only]	The date when image was uploaded to Ambra
Query status	[Read-only]	Status of query
Query Type	[Read-only]	Type of query
Query Text	[Read-only]	Body part of query

Name	Value	Description
Last Action Date	[Read-only]	Latest activity date
Last Action Comment	[Read-only]	Latest activity message
Query Created Date	[Read-only]	The date of query creation
Query Resolved Date	[Read-only]	The date of query resolution
Query Closed Date	[Read-only]	The date when query was closed
Opened By	[Read-only]	Name of the person who opened the query
Resolved By	[Read-only]	Name of the person who resolved the query
Turnaround Time from Query Created to Query Re- solved (in Business Days)	[Read-only]	Total time from query creation to resolution days
Days Since Original Query Sent (in Calendar Days)	[Read-only]	The day when original query was posted
Image ID	[Read-only]	Unique image identifier.

## Breakdown Report

List of Images for a study with high-level details of sites, visits, and queries against each. Used throughout the entire study as a starting point for an overview of data associated with each image.

To view the Breakdown Report:

1. From the Reports tab, click **Breakdown Report**.

III perceptive 💮 MI Portal		⑦ Help
Dashboard Expedited Read Results Reports		
manual( / Reports		
Report Name		
All Queries		
Status of Sites		
Status of Visits		
Breakdown Report		
Expedited Read Results		
Ambra User Status Report		
MI Portal User Access		
	Rows per page: 10 🗸	> >> 7 items in 1 pages



2. View or Export the Breakdown Report by clicking on the three dots.

	percep	otive 🚫	MI Po	rtal												🥐 Help	
Das	nboard	My Queries	Expedited I	Read Res	ults	Reports											
Eligit	ility Study		/ Reports / mage Status Al Caseprated for Review Al V	Breakdown Images by I New QC in Progress	n Report mage Stat	us		Breako	lown Repo	ort				18			⋇ ᆕ Filters
				Breakdown Trial Identifier El St Di Di El St Di Di El	by Image Project Manager(s)	Country	Site Number ES01 ES01	Subject 0016-280203 0100001	Subject Date of Birth 01 Jan 1900 01 Jan 1900	Visit Baseline Baseline	Modality MR CT	Anatomy	ARD IDEL Same	Date of Exam 30 May 2014 13 Aug 2011	Upload Date Image Stat 24 Oct 2024 New 24 Oct 2024 New 24 Oct 2024 New		
				El St			ES01	11371015	01 Jan 1900	) Baseline	CT	CT ABD PELV W	ABD/PEL 5mm, CORONAL,	28 Jul 2014	24 Oct 2024 New		

3. Breakdown Report Attributes

Name	Value	Description
Trial Identifier	[Read-only]	Unique Trial identifier.
project manager	[Read-only]	A Project Managers (PMs) responsible for man- aging a project
Country	[Read-only]	Unique Country identifier
Site Number	[Read-only]	Unique Site number
Subject	[Read-only]	A human participating in clinical trial or Study
Subject date of birth	[Read-only]	Date of birth of a human participating in a Study
Visit	[Read-only]	Visit of a subject to site for the examination purposes
Modality	[Read-only]	Imaging Type
Anatomy	[Read-only]	Body parts
Sequence	[Read-only]	Order of the test performed
Date of Exam	[Read-only]	Date of examination

Name	Value	Description
Upload date	[Read-only]	Date of image upload to Ambra
Image Status	[Read-only]	Status of image
Date of QC complete	[Read-only]	Date of quality check completion
Acceptance	[Read-only]	Image acceptance status
Date of Acceptance	[Read-only]	Date of Image acceptance
Designated for Review (DFR)	[Read-only]	A person authorized to perform the image re- view
Any Open Query against Image	[Read-only]	Open queries against the image
Query Type(s) of Open Queries	[Read-only]	Type of query
Image ID	[Read-only]	Unique image identifier.

#### Status of Sites

List of sites with details used throughout the entire study; at Site Qualification, at Registration of Sites/ Subjects, and during the Image Processing stage.

#### To view the Status of Sites:

1. From the Reports tab, click **Status of Sites**.

III perceptive 💮 🔰 MI Portal	(?) Help
Dashboard Expedited Read Results Reports	
manual( / Reports	
Report Name	
All Queries	
Status of Sites	
Status of Visits	
Breakdown Report	
Expedited Read Results	
Ambra User Status Report	
MI Portal User Access	
Rows per page: 10 $\checkmark$ $\ll$ $<$ 1 $>$ $>$	7 items in 1 pages
Fastpath:	
A list of status of Sites with related attributes appears.	

2. View or Export the **Status of Sites** report by clicking on the three dots.

perce	ptive 💧	MI Portal							(?) Help	
Dashboard	My Queries	Expedited Read Results	Reports							
Eligibility Stu		/ Reports / Status of Sites								
				Status	of Sites			More optio	ons	ू ब मः
		Status of Site by Sit Trial Identifier	Protocol Number	Country	Site Name	Site Number	Principal Investigator(s)	Site Qualificat		Iters

#### 3. Status of Sites Attributes

Name	Value	Description
Trial Identifier	[Read-only]	Unique Trial identifier.
TIMS	[Read-only]	Unique TIMS code
Country	[Read-only]	Unique Country identifier
Site Name	[Read-only]	Unique Site Name
Site Number	[Read-only]	Unique Site number
Principal Investigator(s)	[Read-only]	A head member who performs investigation
Site Qualitfication status	[Read-only]	Status of site eligibility to perform the test
Date created	[Read-only]	Original date of site creation
Date Qualified	[Read-only]	The date when site was qualified
Date Terminated	[Read-only]	The date when site was terminated

#### **Expedited Read Results**

A cumulative view of Expedited Read Results reports generated for a study for sponsor users. Includes tabs **Eligibility Cases** and **Verification of Progressive Desease (VOPD)** Cases depending on whether the study is an Eligibility Study or VOPD study or both.

To view the Expedited Read Results report:

1. From the Reports tab, click **Expedited Read Results**.

III perceptive 🌑 🔰 MI Portal	🥐 Help
Dashboard Expedited Read Results Reports	
manu / Reports	
Report Name	
All Queries	
Status of Sites	
Status of Visits	
Breakdown Report	
Expedited Read Results	
Ambra User Status Report	
Rows per page: 10 $\checkmark$ ( 1 $\checkmark$ )	6 items in 1 pages

A list of Expedited Read Results with related attributes appears.

2. View the Eligibility Cases report.

III perceptive	MI Portal									? Hel	p
Dashboard Expedited Rea	d Results Reports	]									
manua / Reports / R	Expedited Read Results										
Pages	Site Number	# with Measurable Disease	# without Measura	Elig able Disease	ibility Case	s					» بال
Eligibility Cases	All 🗸	0	0								Filters
VOPD Cases	All 🗸								Ξ	63	
		EIGIDIIITY Cases Detail ERR Report ID Trial Identifier Site Number	Subject	Visit	Date ERR Report Request Received	Date Case Review Completed	Date ERR Report Generated	Date ERR Report Provided to Site	Issues Preventing Assignment	Responsi Measural	

3. Eligibility cases Attributes

Name	Value	Description
With Measurable Disease	[Read-only]	Test that indicates eligibility of a subject for clinical trial with measurable disease
Without Measurable Dis- ease	[Read-only]	Test that indicates eligibility of a subject for clinical trial without measurable disease

4. View the Verification of Progressive Desease (VOPD) report.

perceptive	MI Portal									🥐 Helj
Dashboard Expedited	Read Results Reports									
nanu / Repor	ts / Expedited Read Results									
Pages				Verificat	ion of Progre	ssive Disea	ase Cases			
	Site Number	# Confirmed PD Case	s # V	OPD Requeste	d					
Flinibility Course	Al V									
Eligibility Cases	Issues Preventing	2		4						
noner e	Assignment									
VOPD Cases	All V									
		VOPD Cases Detail								
		ERR Report ID	Trial Identifier	Site Number	Subject	Visit	Date ERR Report Request Received	Date Case Review Completed	Date ERR Report Generated	Date ERR Report Provided to Site
		Assessment-Workflow-Report-1626	manualUS121890DRp	82648	VEMSUB2603202501	FU1	08 Apr 2024	08 Apr 2024	08 Apr 2024	31 May 200
		Assessment-Workflow-Report-1511	manualUS121890DRp	n 82648	Subhyd2020bl31	Unscheduled Visit-	22 Mar 2024	19 Mar 2024	22 Mar 2024	28 Mar 20
		Assessment-Workflow-Report-1508	manualUS121890DRp	1 82648	TESTUS121890DR03	FU1	22 Mar 2024	15 Mar 2024	22 Mar 2024	31 May 200
						-				

5. VOPD cases Attributes

Name	Value	Description
Confirmed PD Cases	[Read-only]	Number of cases where progressive disease was confirmed
VOPD Requested	[Read-only]	Number of requests for verification of progres- sive disease received

#### Ambra User Status Report

The Ambra User Status report shows a list of Pending and Active users of Ambra.

#### To view the Ambra User Status Report:

1. From the Reports tab, click **Ambra User Status Report**.

? Help
> >> 7 items in 1 pages

**Fastpath:** A list of Ambra User Status Report with related attributes appears.

- m perceptive MI Portal Dashboard Expedited Read Results Reports manualU / Reports / Ambra User Status Report Ambra User Status Report ₹ Filters Site Number Q Search 
   Image: Second state

   Image: User Status All There aren't any filters to display Date Access Provided Group User Status 29 Jan 2024 manual/US121890DRptn-82648 Active Trial Identifier Site Number Full Name Email Address User Role Enal Address User Pilo ctest, o CF -ctest, o CF manualUS12 82648 ctestu co Pr manualUS12 82648 ctestu 29 Jan 2024 manualUS121890DRptn-82648 Active manualUS12 82648 DVTQ sok. Pr 29 Mar 2024 manualUS121890DRptn-82648 Pending 28 Mar 2024 manualUS121890DRptn-82648 Active manualUS12 82648 qates gates 29 Mar 2024 manualUS121890DRptn-82648 Pending manualUS12 82648 03 Apr 2024 manualUS121890DRptn-82648 Active manualUS12 82648 gates 82648 qates 03 Apr 2024 manualUS121890DRptn-82648 Active manualUS12 manualUS12 03 Apr 2024 manualUS121890DRptn-82648 Pending 82648 qates!
- 2. View or Export the Ambra User Status Report by clicking on the three dots.

#### 3. Ambra User Status Report Attributes

Name	Value	Description		
Trial Identifier	[Read-only]	Unique Trial identifier.		
Site Number	[Read-only]	Unique Site number		
Full Name	[Read-only]	Full name of the Ambra user.		
Email Address	[Read-only]	Email address of the Ambra user.		
User Role	[Read-only]	User assigned role of Ambra user.		
Data Access Provided Group	[Read-only]	User group who has access to data in Ambra.		
User Status	[Read-only]	User status indicating user is active or inac- tive.		

#### MI Portal User Access

To access this functionality in MI Portal:

- 1. Login to the MI Portal.
- 2. Click on a Study Name or Study ID.

m perceptive MI Port	tal				(?) Hel	p
Dashboard						
Applications List	Study List					
CSM Portal - for access to Site	All Sponsors	~			Search for a study	Q
Services	Sponsor	Program	Study Name	Study Id		
	mics		Man	Manu		
	mics				-	
	Sciences					
	mics					
	mics	Test Programme				
	ıa					

- 3. Click on Reports tab.
- 4. Click MI Portal User Access.

III perceptive 🛞 🔰 MI Portal	⑦ Нер
Dashboard Expedited Read Results Reports	
manuali / Reports	
Report Name	
All Queries	
Status of Sites	
Status of Visits	
Breakdown Report	
Expedited Read Results	
Ambra User Status Report	
MI Portal User Access	
Rows per page:	10 🗸 < < 1 > >> 7 items in 1 pages

5. Hover over on the top right corner of the table to view the **More options** icon (three dots).

III perceptive	MI Portal									⑦ Help	
Dashboard My Queries	Expedited Read Resul	lts Repo	rts								
22 / Reports / MI Portal User	Access										
			Г	MI Portal U	User A	lecess					«
Las	Name Bortal Usor A								- 63		ч
Al	Trial Identifier	First Name U	last Name	Email Address		User Role	Site Number	Study Association Date	Study De-association		<u>.</u>
									Date More options		₹
	2	CID 0	32	1	ok.com	Mi Internal	-	26 Jun 2023 17:35:04			8
	2	CID 0	04		sk.com	CRO		26 Jun 2023 16:56:22			8
	2:	CID 0	05		ok.com	Sponsor		26 Jun 2023 16:56:22			
	2;	CID (	07		ok.com	MI Internal		26 Jun 2023 16:56:22			
	21	CID (	38		sk.com	Study Coordinator	10	26 Jun 2023 16:56:22			
	2:	CID 0	38		sk.com	Study Coordinator	AL	26 Jun 2023 16:56:22			
	2;	CID 0	29		ok.com	Study Coordinator	AL	26 Jun 2023 17:35:04			
	2:	CID 1	10		sk.com	Study Coordinator	10	26 Jun 2023 17:53:41			
	21	CID 1	10		sk.com	Study Coordinator	AL	26 Jun 2023 17:53:41			
	2:	MIB 1	1029		tlook.com	Study Coordinator	10	26 Jun 2023 17:53:41			
	2:	MIB 1	1029		tlook.com	Study Coordinator	10	26 Jun 2023 18:12:50			
	22	MIB 1	1029		tlook.com	Study Coordinator	AL	26 Jun 2023 17:53:41			
	2:	MIB 2	20		ok.com	Study Coordinator	10	26 Jun 2023 16:56:22			
	22	User@!#\$%&r* L	Last!@#\$%^&**		ok.com	Study Coordinator	10	02 Aug 2024 06:08:55	11 Sep.		
		()withSplChar ( acter~+_() [ ()::\"?/	]_+-=0 ][\\\":;"?/.,`~Name								
	222340	MIB F	Perf01	perfmigration01@out	look.com	MI Technical Support		26 Jun 2023 14:46:06			

6. Click Export data.

perceptive	MI Po	ortal										(?) Hel	р
Dashboard Expedited	Read Results	Reports											
30 / Reports / MI Portal I	Jser Access												
					MI Porta	al User A	ccess						«
	Last Name	Portal User Acc	155								6	Export data	
	Al	Trial Identifier	First Name	Last Name	Email Address		User Role	Site Number	Study Association Date	Study De-association La Date	st Æ	Show Export data	1 Fit
		90	db2cuser7	; ount	v-0.00	count@tst.com	MI Technical Support		13 Nov 2023 06:27:2		ß	Spotlight	S16
		90		t tuser1.4	c u	itlook.com	MI Technical Support		14 Nov 2023 05:48:40	)	0	Get insights	
		90	inal	l er	F d	tlook.com	MI Technical Support		10 Nov 2023 04:55:15	5	Ã↓	Sort descending	
		90	est	l er	C )	outlook.com	CRO		13 Jun 2023 09:24:48	3	2 41	Cort opponding	
		90	est	l er	c þ	outlook.com	MI Technical Support		10 Nov 2023 04:53:54	1	v z↓	Sort by	>

7. Select the required file format to export the data.

perceptive	MI P	ortal				? Help	
Eligibility Study D	/ Reports Last Name Ail	/ MI Portal User Access Which data do you v Export your data in the forma	want to export? t that suits your needs. If you ha	Xve a lot of data, the number of	ciation Last Acces		× ∓ Filter
		rows you export might be lim <u>exporting data</u> Data with current layout Export this data in the same layout you see now, but without any icons, colors, or other formatting you added. File format:	ited depending on the file type : Summarized data Export the summarized data used to create your visual (for example, sums, averages, and medians).	you select. Learn more about → ⊕ ⊕ Underlying data () Visual does not have aggregates or measures			S

8. [Optional] Sort the data in ascending or descending order to view as required.

## MI Portal User Access Reports Attributes

Name	Value	Description
Trial Identifier	[Read-only]	Unique Trial identifier
First Name	[Read-only]	First Name of the User
Last Name	[Read-only]	Last Name of the User
Email Address	[Read-only]	Unique Email Address of the User
User Role	[Read-only]	Role of the User in MI Portal
Site Number	[Read-only]	Unique Site Identifier
Study Association Date	[Read-only]	Date when the User is added to the Study/Trial

Name	Value	Description
Study De-associa- tion Date	[Read-only]	Date when the User is removed from the Study/Trial
Last Accessed Date	[Read-only]	Date when the User last accessed the Study/Trial on MI Portal Dashboard

#### Interaction with Reports

Instructions to view the report data using multiple options in the user interface.

You can view the image processing data in different Reports like bar charts, pie charts, tables and graphs. There are various filters and Slicers and hover over options to view the data points by specific time lines, durations and by Site or Country and other variables.

Upon selecting any report, you can find the following features depending upon the study platform:

- Summary KPIs
- Graphical trends
- Legends to explain the graphical data
- Change visuals to different aggregations
- Navigational aid
- List reports for detailed data supporting the KPIs and graphs
- Slicers (filters) enabling end-users to select subsets of data for analysis

The different options are explained below:

## **Slicers for Filtering**

The Slicers apply across all the tabs (except for a few Slicers that are tab-specific) and to the list Reports.

Country	
All	$\sim$
Site ID	
All	$\sim$
Reset Slicers	
D PIA List	WIP List

You can select the required options from the drop-down list for fields. The charts then display the corresponding data in various charts of the report. To return to the original display, click Reset Slicers.

#### **Lists Reports**

Each tab contains links to List report below the Slicers to view the underlying data in tabular format. For example, selecting PIA List on the Image QC Monitor tab opens up a Pending Initial Action List report for the Images in this QC step, as shown below.

								PIA List							
Back to report		PIA List Work ID	Project	Protocol	Project Manager	Site ID	Subject ID	Visit	Visit Qualifier	Modality	Exam Date	Date Received	Days Since Receipt	Active Query	Processing Stat
All	$\sim$	7654321	222345	BBB222233334	John II Doe	825	779015	Treatment Month 12		DXA	10-Jul-2023	10-Jul-2023	3	1	Processing.Imp
Site ID		7654321	222345	BBB222233334	John II Doe	729	729070	Treatment Month 42		DXA	06-Jul-2023	06-Jul-2023	5	1	Processing.Imp
All		7654321	222345	BBB222233334	John II Doe	774	774003	Premature Discontinuation		Ultrasound (trans-vaginal)	02-Jun-2021	04-Jul-2023	7	1	Processing.lmp
All	~	7654321	222345	BBB222233334	John II Doe	774	774015	Treatment Day 1		Ultrasound (trans-vaginal)	03-Jun-2020	04-Jul-2023	7	1	Processing.Imp
Subject ID		7654321	222345	BBB222233334	John II Doe	776	776031	Treatment Month 42		DXA	17-Jun-2023	03-Jul-2023	8	T	Processing.lmp
		7654321	222345	BBB222233334	John II Doe	729	729070	Treatment Month 42		DXA	20-Jun-2023	29-Jun-2023	10	1	Processing.Imp
All	~	7654321	222345	BBB222233334	John II Doe	774	774040	Treatment Month 36		Ultrasound (trans-vaginal)	07-Mar-2023	29-Jun-2023	10	T	Processing.Imp
Visit		7654321	222345	BBB222233334	John II Doe	808	808079	Treatment Month 36		DXA	28-Jun-2023	28-Jun-2023	11	1	Processing.Imp
		7654321	222345	BBB222233334	John II Doe	907	907028	Treatment Month 36		DXA	21-Jun-2023	26-Jun-2023	13	1	Processing.lmp
All	~	7654321	2223.45	RRR222233334	John II Doe	83.4	834018	Treatment Month //8		DYA	23. Jun. 2023	23-Jun-2023	1.4		Processing Imp

To get back to the Reports, select Back to Report in the left side of tabular List report.

#### Filters and Advanced Filters

In addition to Slicers, the filter menu on the right side of the page is available to use the different types of additional filters to view specific data points.

You can select a Visual element to apply these filters, it is best to click title of the visual. You can then select the various options in the filters available to view a specific data as required.

∓ Filters		>
Q, Search		
Døy is (All)	v	4
Work Week Start is (All)	Ŷ	q
Month is (All)	^	Q.
Filter type		
Advanced filtering		¥
Show items when the	value	
contains		~
● And ○ Or		
		~

Advanced Filtering: Certain additional filter options appear with respect to the data of the particular chart you select. You can select the Advanced Filtering options to drilled down to the required data point.

Once you apply certain filters, the filters needs to be cleared using the Clear Filter icon as shown below. Or else it will be reset the next time the Study Performance Management report is loaded.

Q Search	
Month contains '50%' Filter type	Clear filter
Advanced filtering	×
Show items when the v	alue
contains	~
50%	
● And ○ Or	

The Reset Slicers button will not clear these filters.

#### **Buttons**

Some charts and visuals have buttons to show different grouping of data for example: By Country, Site, Week, Month or Day.



# Read Monitor

Select the required button to view the data in the charts. To get back to the original data select the default option button.

## **Interactive Visuals**

Some report elements can be clicked which affects other applicable visuals on the page. For example clicking a date value in a bar chart can filter other metrics on the page. Click the same element again to clear that filter.

For example in the image below, upon selecting the blue bar (completed cases for a time period), the adjacent bar chart (Pending cases by category) and the tabular data (Reviewer Summary) accordingly display the changed data.



#### Hover Over Data

You can view the data value for a particular section of a visual by hovering your cursor over that section.



### Focus Mode

The Focus mode allows you to view a visual to full size of the window, where the other charts are not visible and only the selected chart appears.

For example in the below Site Status Change Actions, when we apply the Focus mode for the Site Status Change Actions chart (Figure 1), it is expanded to full screen (Figure 2).





Click on Back to Report to get back to the original view.

#### Show as a Table

This option is useful to quickly see the data points for a given visual.

In the report section for a particular chart, click the three dots More options icon and select Show as a table.



The selected bar chart appears as a full screen with tabular data below it as shown.

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Click Back to Report at the top to get back to the Reports section.

#### **Download Reports**

You can download Reports as necessary. To download a selected report:

1. Hover over a report and click More options.



2. Click Export data.

The Which data do you want to export? page displays.

- 3. Make the selections as appropriate.
- 4. Click Export.

Export your data in the format that suits your needs. If you have a lot of data, the number of rows you export might be limited depending on the file type you select. Learn more about exporting data



ne ionnat.

.xlsx (Excel 150,000-row max)~

Export

Cancel

The *Downloads* window displays.

5. Click Open file. The report displays.

The underlying data option is disabled, but you can view and download underlying data by clicking the list link on each tab below the slicers and following the same steps above to download.

#### Subscribe to a report

Anybody (Internal to perceptive or external user) who wants to keep receiving the specific report for themselves, can subscribe to a report.



To Subscribe to a report in MI Portal:

- 1. Login to the MI Portal.
- 2. Click on a study from the dashboard page.

III perceptive 🌑 MI Portal				() не	p
Dashboard					
Applications List	Study List				
O CSM Portal - for access to Site Services	All Sponsors	~		Search for a study	Q
-	Sponsor	Program	Study Name	Study Id	
	10x Genomics		Man	Mar	
	10x Genomics		2225	222	
	180 Life Sciences		ELDI	Elig	
	10x Genomics		2225	222	
	10x Genomics	Test Programme	555;	249	
	2A Pharma		ABC101001	UARGen1	
	10x Genomics		man	mant	
	3B Pharmaceuticals		Dem	Spr3	
				Rows per page: 10 V	is in 1 pages

3. Click on a Report Name.

III perceptive () MI Portal	⑦ Неір
Dashboard Reports Expedited Read Results	
UARGen1 / Reports	
Report Name	
Study Performance Monitoring	
MI Portal User Access	
	Rows per page: 10 V 《 < 1 > 》 2 items in 1 pages

- 4. Click on a page name to subscribe for the report.
- 5. Click Subscribe.

perceptive 🍏	MI Portal	-	() Help
Dashboard Reports	Expedited Read Resu	s	
222344 / Reports / Study Perfor	mance Monitoring		Subscribe
Pages		Read I	Monitor
Image QC Monitor	Country All V	Pending Cases by Date Category	Case Actions by Date Category
Read Monitor	Site ID	Month	
Sites	Subject ID	Work Week Start	
Subjects	All V	Day	
Visits	All V		
Images	Reviewer ID		
Queries	Case Type	Project Summary	
	All ~	Project Summary Created Completed Incomplete Cases Pending Average Pendi Created Completed Incomplete Cases Pending Case Case Age Days	ng Pending Completed Completed Completed > 5 Cases - Cases Cases Lat Gases Lat Gase Lat 6 Days Current Month Months
		Reviewer Summary	Month

6. Select a day of the week and click **Confirm**.

abscribe to Report Page - Read i	wonitor	
Subscription successful!		
Frequency		
Day of Week Day of Month		
Select All		
🗌 Sunday 🛛 🗹 Monday 🗌 Tuesday	,	
🗌 Wednesday 🗌 Thursday 🗌 Friday		
Saturday		
	CLOSE	CONFIRM
<b>Note:</b> You may select as many days as possible of a week y	ou want to receive the	updates on your

The selected report is subscribed for you.

## Unsubscribe to a report

An external user can unsubscribe from MI Portal.

To stop receiving the report updates:

- 1. Login to the MI Portal.
- 2. Click on a desired study from the dashboard page.

III perceptive MI Portal					⑦ Help		
Dashboard							
Applications List	Study List						
O CSM Portal - for access to Site Services	All Sponsors	All Sponsors 🗸					
	Sponsor	Program	Study Name	Study Id			
	10x Genomics		Man	Mar			
	10x Genomics		222:	222			
	180 Life Sciences		ELDI	Elig			
	10x Genomics		222:	222			
	10x Genomics	Test Programme	555;	249			
	2A Pharma		ABC101001	UARGen1			
	10x Genomics		man	mant			
	3B Pharmaceuticals		Dem	Spr3			
				Rows per page: 10 V	1     >     8 items in 1 pages		

3. Click on a Report Name.

III perceptive 💮 🔰 MI Portal	(?) Неір
Dashboard Reports Expedited Read Results	
UARGen1 / Reports	
Report Name	
Study Performance Monitoring	
MI Portal User Access	
	Rows per page: 10 V 《 〈 1 〉 》 2 items in 1 pages

- 4. Click on a page name to unsubscribe for the report.
- 5. Click Unsubscribe.

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Dashboard Reports	Expedited Read	d Resu	ılts														
222344 / Reports / Study Perform	mance Monitoring																
												At 09:3	0 (UTC) on N	fonday and Thursd	lay Unsubscril	be	
Pages								Rea	d Mo	onitor							
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Read Monitor	AI	$\sim$	_														
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Sites	Subject ID		Work Week Start														
Subjects	All	$\sim$	Berr	Days													
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Images	All	$\sim$															
Queries	Case Type			_	Project Summary	,											
	All	$\sim$	Project Summa	ry -	Cases Cases Created Completed	Cases Pi Incomplete C	lending Jases	Average Pending	Pending Cases > 5	Pending Cases > 10	Completed Cases	Completed Cases Last	Completed Cases Last 6				
	Reset Silcers Case List		Reviewer Summ	ary	0			Case Age	Days	Days	Current Month	Month	Months				

6. A confirmation message appears, click **CONFIRM**.

	Expedited field field		
222344 / Reports / Study Per	formance Monitoring	Unsubscribe to Report Page - Read Monitor	×
		By unsubscribing, you will no longer receive the report page you subscribed to.	0 (UTC) on Monday and Thursday Unsubscribe
Pages		-	
Image QC Monitor	Country	Subscription Created Date	late Category
Read Monitor	Site ID Month	Time (UTC)	
Sites	All V Work W	09:30 am	
Subjects	Al	Frequency	
Visits	All V	Day of Week Day of Month	
Images	Reviewer ID	Select All	
Queries	Case Type	🗌 Sunday 🛛 Viesday	Constant
	Reset Sicers	🗌 Wednesday 🗧 Thursday 📄 Friday	Cases Last 6 Months
	Case List	Saturday	
		CLOSE CONFI	RM

The Page is Unsubscribed.