

SMART Portal 3.29 User Guide

Document Version 1.0





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Welcome to the SMART Portal

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WebSend has been updated to be part of Bioclinica's SMART Services Suite and is now known as the SMART Portal.

SMART

The SMART Portal is Bioclinica's web-based system for communication management. Clinical sites use this Portal to access and reply to queries, upload completed forms, download documents provided by Bioclinica, and view or download submitted image files after they have completed the quality control process.

Depending on user role and trial configuration, the SMART Portal can also provide access to the SMART Submit system or the AG Mednet application to upload image files.

To learn more about SMART Submit, see:

SMART Submit Knowledge Base

For more information on AG Mednet see:

- <u>FAQ</u>
- Quick Reference
- User Manual

3.29 Release Updates

- The QC status is now visible in the History tab
- Upload of forms is now restricted to PDF format only

Getting Access

Welcome Email

Bioclinica sends each new SMART Portal user a "Welcome" email with their user id and password. This welcome email contains everything you need to get started.

SMART



Notification

Welcome to Bioclinica's SMART Portal; our web-based site portal. You are participating in one or more online trial(s) that will allow your site to quickly and easily complete all imaging activities as detailed below.

The following link will take you to the SMART Portal: https://smart.bioclinica.com/

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Below you will find your login credentials: Account Name: <Your Username>

Password: <Your Disernal Password>

Your credentials

Once you have successfully logged in, please select the trial you are working on.

Below is a list of the available tabs within the portal:

- TO-DO: displays a list of tasks organized by date

 SUBJECTS: displays a list of tasks by subject and allows you to access images

- QUERIES: displays a list of open queries and enables you to respond to queries

 DOCUMENTS: displays a list of documents uploaded by Bioclinica for sites to access (ex. Site Manual, Imaging Capabilities Questionnaire)

- HISTORY: displays a list of upload history and enables you to download images and attachments

- TRAINING: will re-direct you to the Smart START training portal (if applicable) - IMAGE/Video UPLOAD: launches Electronic Image/Video Transfer platform

You will receive a separate email containing your electronic image platform credentials (if applicable).

We are committed to providing you with the highest level of customer satisfaction possible. If you have any questions or require assistance, please contact Bioclinica Customer Support:

Toll-free from the US and Canada: +1-888-ASK- BIOC (1-888-275-2462) Direct dial worldwide: +1-484-928-6076** Fax: +1-267-757-3353 Support@bioclinica.com

Forgot Password

If you forget your password, click the Forgot Password on the login page, enter your email address and click **Send**.

Forgot your password?

Please enter the email address associated with your Bioclinica account. A new password will be emailed to you shortly.

someone@example.com				
	Send	Cancel		

If you've been expecting this information and it is not available to you, contact Bioclinica's help desk:

> US and Canada: 1-888-ASK-BIO2 (1-888-275-2462)

International: +1-484-928-6076

Email: support@bioclinica.com

Logging In

Once you have received the welcome email, you will be able to log into the SMART Portal - <u>https://smart.bioclinica.com</u>- and change your default password.



Sign in with your email address

some	one@example.o	com	
Pass	word		
Forgot Pass	word		Sign in
	Terms of Use	Privacy Policy	

Bioclinica helpdesk:

Phone:

US and Canada: 1-888-275-2462 International: +1-484-928-6076

Email:

support@bioclinica.com

- 1. Enter your email and password from the Welcome email.
- 2. Click Sign In.

If this is the first time that you are logging on, the <u>Change Password</u> box automatically displays.

If you have already changed your password, the <u>Select a Study</u> page displays.

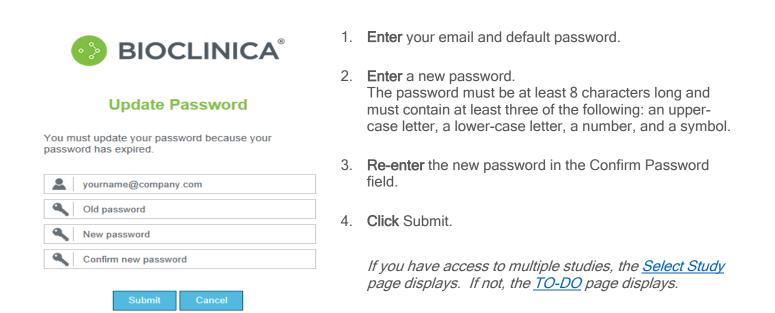


Changing Your Password

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To ensure that your password is secure, you will be required to change your default password before you will be able to log in a second time. The Change Password screen automatically displays.

SMART



Select Study

If you have access to more than one study, or multiple sites within a study, the System displays a study selection dialog after login:

BIOCLINICA [®]		your.name@company.com	🔦 Change Password	➡ Logout
We	elcome to Bioclinica's SMAR Submit Manage Analyze Report Transf			
	Please select from the following worklist ite	ems:		
	DEMO-9999			
	Forms - DEMO-9999 - 002			
	DEMO-312-0115			
	DEMO312-0117			
	Image Submission DEMO 9999 001			

 Click the study or study/site combination you wish to work with from the list. The <u>TO-DO</u> page displays.

Site Portal - DEMO-9999 - 001 Site Portal - DEMO-9999 - 002

Logout

To logout of the SMART Portal, click **Logout** in the upper right corner of the screen. The system confirms that you have successfully logged out.

SMART



Sign out You have successfully signed out.

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Forgotten password, please contact the Bioclinica helpdesk at:

Phone:	US and Canada: 1-888-275-2462 International: +1-484-928-6076

Email: support@bioclinica.com

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Welcome, ws user2

Contact

Using the SMART Portal

BIOCLINICA

BIOCLINICA[®]

Logou

SMART Portal

V3212-Build-2010/00/00 PSUBJECTS | QUERIES | QUALITY-NOTIFICATIONS | SURVEYS | DOCUMENTS | HISTORY | FORM-UPLOAD | TRAINING | IMAGE UPLOAD

SMART

Link Menu

The link menu displays in the upper right corner of SMART Portal scree	ens.
--	------

- **Contact** Displays phone, fax and email information.
- Help Displays online help.
- **SMART Portal** Returns to the study selection dialog for the SMART Portal.

Main Menu

- <u>TO-DO</u> list of tasks and processing options organized by date
- <u>SUBJECTS</u>- list of tasks and processing options organized by subject
- <u>QUERIES</u> list of queries and processing options (Only open queries are listed by default, but there is an option to include closed queries.)
- <u>QUALITY NOTIFICATIONS</u> list of image quality notifications and processing options (Similar to queries, but do not require a response.)
- <u>SURVEYS</u> list of surveys and processing options (Only published surveys are listed by default, but there is an option to include All queries.)
- <u>DOCUMENTS</u> list of trial and site level documents uploaded by Bioclinica and available for you to download
- <u>HISTORY</u> on-screen report that displays a list of files uploaded to Bioclinica for trials for which you are authorized
- FORM UPLOAD tool for uploading PDF forms to Bioclinica
- <u>TRAINING</u> provides access to the SmartStart training site
- IMAGE UPLOAD launches the file upload application in a separate browser tab

Screen Panels

- 1. Left Panel: Filters selections to narrow down what is shown in the center panel See <u>Working with Filters</u> for more information.
- 2. Center Panel: List contains rows that can be selected for processing
- 3. Right Panel: Details displays data for selected row (first row selected by default

Action Icons

Action icons link to other pages for you to take a specific action. They display, where applicable, on list rows. They also display as buttons the bottom of any given list. The action buttons at the button may apply to the entire list (such as Export to Excel).

Filters

The Filters panel allows you to make selections to narrow down what is shown in the center panel. The parameters of the filters are depended on the columns and items that are displayed in the center panel.

SMART

Filters
Protocol
all
BSIL Test - BI 00001 BSIL - 123334323
BioClinica Test Client – iVAL 99-90 BioClinica Test Client – iVAL 99-99
Subject
all 💌
Due On
02-Sep-2016
Туре
Survey Response
Image Upload
Query Reply
Filter
Reset

Working with Filters

1. Select the parameters that you wish to use to filter the contents of the center panel.

Filter

- 2. When you are finished, click
- 3. To reset the filters at any time, click

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Export to Excel

The Export to Excel button is available on most of the pages in the SMART Portal. This button allows you to export the displayed list to Excel.

Export to Excel



1. Click Export to Excel from any page.

A message box displays at the bottom of the page asking if you want to open or save the list.

2. Click Open to open the list in Excel, click Save to save the file.





Contact Information

We hope that this guide is helpful. If you have additional questions, feel free to contact us:

SMART

- Address: Bioclinica, Inc. 211 Carnegie Center Drive Princeton, NJ 08540
- Phone: US and Canada: 1-888-ASK-BIO2 (1-888-275-2462)

International: +1-484-928-6076

Email: support@bioclinica.com



To-do List

1

The List of Tasks

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The To-do list contains your imaging related tasks that are coming due or are overdue.

Note: Overdue and expedited tasks are highlighted in red and require immediate attention.

SMART

5-Build-2020-11-19.10.		TO-DO SUBJECTS	QUERIES QUALITY-N	OTIFICATIONS SURVEYS DOCUMENTS HISTORY FORM-UPLOA	Conta	IMAGE UPLOA	
ilters				Tip: The following tasks require your attention.			Details
otocol							Protocol numbe
all	~	PROTOCOL	SITE	TITLE	DUE ON	ACTION	Demo
		Demo	AU10001	Images are missing for Subject 260103, Week 54	08-Mar-2021		Site number 101
all	~	Demo	AU10001	Images are missing for Subject 260106, Week 30	04-Mar-2021		Subject number
ali	Ť	Demo	AU10001	Query 10009068-Q00531 needs response.	01-Mar-2021	EC.	55555
		Demo	AU10001	Images are missing for Subject 260104, Week 42	18-Feb-2021		Timepoint
all	~	Demo	AU10001	Query 10009068-Q00371 needs response.	15-Feb-2021	≣ Ø	Week 5
le On		Demo	AU10001	Images are missing for Subject 260103, Week 48	25-Jan-2021		Business moda
17-Mar-2021		Demo	AU10001	Images are missing for Subject 260104, Week 36	07-Jan-2021		
ре		Demo	AU10001	Images are missing for Subject 260103, Week 42	14-Dec-2020		
Survey Respons	se	Demo	AU10001	Images are missing for Subject 260106, Week 18	10-Dec-2020		
Image Upload		Demo	AU10001	Images are missing for Subject 260104, Week 30	26-Nov-2020		
Query Reply		Demo	AU10001	Images are missing for Subject 260103, Week 36	02-Nov-2020		
Filter		Demo	AU10001	Images are missing for Subject 100/000/0000, Week 24	18-Jun-2018		
		Demo	AU10001	Images are missing for Subject 359158022, Week 20	21-May-2018		
Reset		Demo	AU10001	Images are missing for Subject 100/000/0000, Week 16	23-Apr-2018	11	

Left Panel (Filters)

To filter the list, select filters and click Filter button. To clear filters, click Reset button.

Center Panel: The List

- Protocol ID or # of the protocol with which the task is associated
- Due On date by which the task must be completed
- Site clinical site with which the task is associated
- Title description of the task
- Action symbols that link to specific processing options related to the task
 - Upload Images
 - E
 Reply to Query
 - Complete Survey

Right Panel: Details

This panel displays details (some also on the row and some additional) related to the currently selected row.

List Menu (Options vary based on the selected row.)



Export to Excel - See Export to Excel



Reply to Query See Reply to Queries (available for query tasks)

Response To Survey - See Response to Survey

(available for survey tasks)



Subjects

The Subject List

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The Subject list contains a list of tasks organized by subject. To add a subject, you must filter by site.

Iters			Tip: Select and proce	ess each subject requiring your action.		Details
tocol oClinica - Demo 🗸	PROTOCOL	SITE	SUBJECTNUMBER	RANDOMIZATION DATE	ACTION	Subject Number 999992
	Demo	999	999992		\checkmark	Subject Initials
	Demo	999	999994		 	XXX Secondary ID
9 🗸	Demo	999	999999		v	N/A
Filter	Demo	999	100/000/0000	01-Jan-2018		Date Of Birth
Reset	Demo	999	999991		 V 	XX-XX-XXXX
	Demo	999	123456		✓	Randomization Date
						Enrollment Date N/A
						Discontinuation Date N/A
						Discontinuation Rea
						Status Active

SMART

Left Panel (Filters)

To filter the list, select filters and click Filter. To clear filters, click Reset.

Center Panel: The List

- Protocol ID or # of the protocol with which the task is associated
- Site clinical site with which the task is associated
- Subject Number ID or # of the trial subject
- Randomization Date date on which the subject was randomized for the study
- Action processing symbols and the completed task symbol
 - Upload Images
 - Q <u>View Query</u>
 - V There are no outstanding items for this subject

Right Panel: Details

CLARIO.

THE BEST OF ERT & BIOCLINICA

This panel displays details (some also on the row and some additional) related to the currently selected row.

List Menu (Options vary based on the selected row.)



Export to Excel - See Export to Excel

View Image List - See View Image List

Upload Image _See Image Upload





View Queries - See Query List



Add a Subject

The Add Subject page allows you to add new subjects to the protocol.

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	Tip: Add new study subject information.
Add Subject	Information
Protocol: BioClinic	a Test Client - BioDemo17
Site: N/A	
Subject Number:	# # # # # # # # # #
Subject Initials: the middle box.)	# # (First/Middle/Last Initial; if no middle initial, blank out
Visit Schedule: De	fault Schedule ▼

SMART

- 1. **Type** the subject number (one number per box).
- 2. **Type** the First/Middle/Last Initials of the subject. If the subject has no middle initial leave the middle box blank.
- 3. Select the Visit Schedule.



4. Click Add

The subject is added to the list.

Welcome, ws_user2@biopacstest.domain

Logout

Subject Image List

BIOCLINICA[®]

BIOCLINICA				Contact	Help SMART Por
V3.25-Build-2020-11-19.10.00	TO-DO I SUBJECTS I QUERI	ES QUALITY-NOTIFICATIONS SURVEYS	DOCUMENTS HISTORY FORM-UPLOA	D TRAINING IMAGE UPLO	AD
🕞 Subjects		Tip: Select subjects to view a	and/or process their images.		Details
234567					Timepoint Name
59158034AB	SITE NUMBER	SUBJECT NUMBE	R	ACTION	Week 15
59158022	101	359158022EE			Business modality
	101	359158022EE		(11)	Expected sequence name
59158034s	101	359158022EE			(Unknown) Locator
5555	101	359158022EE		(11)	Study date
59201015					13-Aug-2013
59349008					Received date 25-Oct-2013
2352					
59158022EE					
		View eDTF View Sequence	Export to Excel Export Sequence		

SMART

Left Panel (Subject)

Click one of the other Subject Numbers listed to display the image list for the selected subject.

Center Panel: The List

- Site Number clinical site with which the subject is associated
- Subject Number the current subject number

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- Action symbols that link to specific processing options related to the images
 - <u>View eDTF</u>
 - Q View Sequence

Right Panel: Details

This panel displays details (some also on the row and some additional) related to the currently selected row.

List Menu (Options vary based on the selected row.)

Export to Excel - See Export to Excel

View eDTF - See View eDTF





eDTF

View eDTF

The View eDTF button and icon allow you to view the eDTFs created when the images were uploaded.

SMART

1. Select the row in the Subject Image List and click either III or View eDTF.

The View eDTF page displays with the file or files associated with the image upload.



2. Highlight a row and click View eDTF

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The eDTF displays.

- 3. Click to save the file or click to print the eDTF.
- 4. When you are finished, click Subjects

View Sequence

The View Sequence button and icon allow you to view the sequences that were uploaded.

1. Select the row in the Subject Image List and click either in view Sequence.

The Image Viewer page displays with the thumbnail of the image in the left pane and the sequence grid on the right.

2. Double-click the thumbnail you wish to view.

The sequence displays in the grid.

3. Click to display a single image in the grid.

The thumbnail panel expands and displays all the images in the sequence. The image displayed in the grid is highlighted in green in the thumbnail panel.

4. Double-click a thumbnail to change to another image.



Note: For more grid toolbar instructions, see Image Grid Toolbar.

BIOCLINICA® SMART	SMART Portal 3.29 User Guide
Image Grid	
€ BIOCLINICA	==
V3.12.2 Build 20161208.10.10	
series: Unidentified	
#files: 1	Q,
30	< ≡¢∹
sories: Unidentified #files: 1	
	T
	 O

The left panel displays a thumbnail for each sequence. By default, the first (in this case only) sequence is selected.

Each image within the selected sequence is displayed within a square on the center panel.

The narrow panel to the right contains the toolbar for working with the images. (See next page for details.)

The Image Grid Toolbar

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lcon	Description
	Display Mode enables you to toggle between showing all sequences and showing only the currently selected image within the sequence.
Ó.	Window/Level is available for a selected image in any of the available panels. When active, you can hold the left mouse button and drag to change the amount of contrast.
Ø	Stacking, in a virtual sense, places one image (slice) beneath the next so that you can scroll back and forth through the slices (to scroll, use the left mouse button and drag.
₩,	Pan allows you to move the entire image within the center panel. Hold the middle mouse button and shift key and drag in any direction.
Q	Zoom allows you to magnify or shrink the image. Hold the middle mouse button; drag up to magnify and down to shrink.
4	Color Table brings up a sub-menu of color schemes for you to apply to the image.
	B2R BWR CBY CT HM R2B Rainbow1 Rainbow2 SUV2 Thermal
	Choosing gray scale brings up a different sub-menu.
•≣∳-́-	Predefined Window Level - displays a sub-menu where you can select preselected window/level adjustments to view the type of tissue in the image.
D₽ ₹	Invert enables you to toggle between a black background with a lighter foreground and a white background with a darker foreground.
X	Reset puts the image back to its original state before you used any controls.
슽	Print enables you to print the image or sequence of images.
I	Text Overlay - This option is only available on any image that is selected. It enables you to toggle between viewing and not viewing image information text on an overlay.
¢	Options - This option is only available when one image is selected. It brings up a sub-menu to select the number of columns to show in the grid.

SMART

Queries

This page lists queries between your site and Bioclinica. Initially, the list excludes closed queries. An option on the Filters panel enables you to include closed queries.

SMART

ilters			Tip: View query lis	st; select row icon to view query detail.			Details
otocol ioClinica - Demo 🗸	PROTOCOL	SITE	SUBJECT	STATUS	DUE DATE RESCAN	ACTION	Site Name Newtown Radiology
e	Demo			Response Review Pending	29-Mar-2014	E.	Type Late time point
01 v	Demo	101	55555	Response Review Pending	02-Aug-2014	T.	Timepoint Type Name
v v	Demo	101	55555	Response Review Pending	02-Aug-2014	E.	Week 20
	Demo	101	101	Response Review Pending	16-Mar-2016	The second s	Study Date
all 🗸 🗸	Demo	101	359158022EE	Response Review Pending	09-Apr-2016	EC.	N/A
	Demo	101	101	Response Review Pending	13-Apr-2016	E.C.	Image Type
all 🗸	Demo	101	359158022EE	Response Review Pending	05-May-2016	■	Creation Date
	Demo	101	101	Sent	18-May-2016	■	14-Mar-2014
dy	Demo	101	359158022EE	Response Review Pending	09-Jun-2016	■	Sequence Name
all 🗸	Demo	101	101	Sent	22-Jun-2016		Unidentified
	Demo	101	101	Sent	27-Jul-2016	≣ Ø	Sequence Modality
Filter	Demo	101	359158022EE	Sent	20-Aug-2016		Description
Reset	Demo	101	101-002-019	Response Review Pending	28-Oct-2017		No images have been rec
	Demo	101	101-002-019	Response Review Pending	28-Oct-2017		Suggested Resolution
	Demo	101	359158022	Response Review Pending	20-Jun-2018		Please submit images and

Left Panel (Filters)

To filter the list, select filters and click Filter. To clear filters, click Reset.

Center Panel: The List

- Protocol ID or # of the protocol with which the query is associated
- Site clinical site with which the query is associated
- **Subject** ID or # of the trial subject

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- Status query status which can be any of the following:
 - Sent The query has been sent.
 - Response Review Pending The query response has been submitted and needs to be reviewed. Once Bioclinica's Core Lab has closed the query, the status changes to "Closed."
 - Overdue The query response is overdue.
 - Expired The date by which a response was due has passed without a response having been submitted.
 - Closed The query response has been reviewed and accepted by Bioclinica.
- Due Date date by which the query response is expected
- **Rescan** used to indicate that the query is either requesting rescans of images or notifying you that Bioclinica has received the rescanned images
- Action symbols that link to specific processing options related to the query
 - Upload Images
 - Query Details

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Right Panel: Details

This panel displays details (some also on the row and some additional) related to the currently selected row.

List Menu (Options vary based on the selected row.)

 Export to Excel - See Export to Excel
 Image -See Image Upload
 Image Upload

Export Query

The Export Query to PDF button allows you to download the query details in report format.

PDF

1. Display query details and click Export Query to PDF

The report is generated and a message displays on the bottom of the page asking if you want to open or save the report.

- 2. Click ^{Open} to open the report in a PDF viewer.
- 3. When you are finished, click Oueries

Query Details

The query form allows you to view the query details. If the site has already responded to the query, the query is in view only mode. If no response has been given, you can reply to the query.

BIOCLINICA [®]	Welcome,
	Contact Help SMART Porta
V3.24.3-Build-2020-06-11.10.00	TO-DO SUBJECTS QUERIES QUALITY-NOTIFICATIONS SURVEYS DOCUMENTS HISTORY FORM-UPLOAD TRAINING IMAGE UPLOAD
© Queries	Tip: View and/or reply to query.
No images have been rec	Context Information
	Site name: Newtown Radiology Study date: 01-Jan-1 Subject number: 359158022EE Image Type: N/A Timepoint: Week 20 Image Type: N/A
	Query Information
	Query ID: 99990-Q0050 Creation Date: 04-Aug-2016 Query Type: Late time point Sequence Name: N/A Timepoint Type Name: Week 20 Sequence Modality: N/A
	Description No images have been received for the specified time point
	Suggested Resolution: Please submit images and/or data for the specified time point to BioClinica.
	Attachments N/A
	Completed by the user ExpectedDataEngineScheduler
	Time Stamp 04-Aug-2016
	Query Reply
	Please provide your reply

Left Panel (Subject)

Click one of the other queries for the given site and subject.

Center Panel: Query Information

The query information is broken down into the following sections

- Context Information -lists the site, subject number, time point, study date and image type.
- Query Information lists the details of the query
- Query Reply lists any reply to the query

List Menu (Options vary based on query status)



Export Query to PDF – exports the selected query to a PDF document and brings up a set of Save/Open options at the bottom of the list



Reply to Query - See Reply to Queries .



Submit - Submits the query response.

View Queries

- 1. Scroll through the query.
- 2. Click Queries to return to the Queries list.

Reply to Queries

1. Enter the reply in the text area provided.



2. Click Submit

This sends the response to Bioclinica and sets the status to Response Review Pending.

3. Click Queries to return to the Queries list.

Quality Notifications

BIOCLINICA

This page lists image quality notifications generated for your site. These are displayed in the same way as queries, but no response is expected from the site.

SMART

filters		Tip: View qua	ality notification list; s	elect row icon to v	ew quality notificati	ion detail.		Details
rotocol								Site Name
lioClinica Test Client - 🔻	PROTOCOL	SITE	SUBJECT	TIMEPOINT	TYPE	DATE	DETAILS	999
	Demo			Week 8	Image Quality	30-Jun-2016		Туре
te	Demo	999	Q 22	Week 16	Image Quality	27-Jun-2016		Image Quality
99 🔻	Demo	999			Image Quality	22-Feb-2016		Timepoint Type Name Week 8
	Demo	999	00001	Baseline	Image Quality	12-Jan-2015	■ ℓ	Study Date
all 🔻								30-Jun-2016
								Image Type
all 🔻								Creation Date
								30-Jun-2016
ıdy all ▼								Sequence Name
all *								Unidentified
Filter								Sequence Modality MR
Reset								Description
			211	Ē				Anatomy outside field o

Left Panel (Filters)

To filter the list, select filters and click Filter. To clear filters, click Reset.

Center Panel: The List

- Protocol ID or # of the protocol with which the quality notification is associated
- Site clinical site with which the quality notification is associated
- Subject ID or # of the trial subject
- Timepoint timepoint with which the quality notification is associated
- Date date the quality notification was generated
- Details symbols that link to additional details for the quality notification
 - Quality Notification Details

Right Panel: Details

This panel displays details (some also on the row and some additional) related to the currently selected row.

List Menu

Export to Excel - See Export to Excel

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View Quality Notification

- See Quality Notification Details



Export to PDF

- See Export Quality Notification



Export Quality Notification

The Export to PDF button allows you to download the quality notification details in report format.

- 1. Display query details and click Export to PDF

The report is generated and a message displays on the bottom of the page asking if you want to open or save the report.

- 2. Click ^{Open} to open the report in a PDF viewer.
- 3. When you are finished, click

Quality-Notifications

SMART





Quality Notification Details

The quality notification form allows you to view the full details for the quality notification. Unlike the query form, it is not possible to reply to a quality notification.

C Quality-Notifications	Тір	: View quality notification context, details and export.					
Subject is Eligible	Context Information						
Missing Unique Subject Id	Site name: 999	Study date: 30-Jun-2016					
Inconsistent Parameters	Subject number: F22	Image Type: MR					
Anatomy outside field of v	Timepoint: Week 8						
Subject is Eligible	Quality Notification Information						
Anatomy outside field of v	Quality Notification ID: 06423-Q0177	Creation Date: 30-Jun-2016					
Subject is Eligible	Quality Notification Type: Image Quality Timepoint Type Name: Week 8	Sequence Name: Unidentified Sequence Modality: MR					
Incorrect Matrix : This is a		Sequence modality. Mix					
Incorrect Matrix	Description Anatomy outside field of view.						
Phantom Discrepancy	Suggested Resolution: No response required. For future submissions, please refer to the imaging guidelines for						
Exam submitted will not b	acquisition parameters.						

Export to PDF

Left Panel

Click one of the other quality notifications listed with the current filter selections.

Center Panel: Quality Notification Information

The query information is broken down into the following sections

- Context Information -lists the site, subject number, time point, study date and image type.
- Quality Notification Information lists the details pertaining to the notification

List Menu



Export to PDF - exports the selected quality notification to a PDF document and brings up a set of Save/Open options at the bottom of the list

View Quality Notification

1. Scroll through the query.



Quality-Notifications

to return to the Quality Notifications list.



Surveys

The Survey List

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If enabled for your protocol, this page will list surveys created by Bioclinica. The list initially includes only published surveys. The Status filter includes an option to list all surveys.

SMART

3.20.0-Build-2018-11-05.12.30	TO-DO SUBJECT	S QUERIES	QUALITY-NOTIFICATION	S SURVEYS I	DOCUMENTS HISTOR	RY FORM-UP	LOAD TRAIN	NING IMAGE UPLOAD
Filters			Tip: Select	surveys requiring you	action.			Details
Protocol	CLIENT NAME	TITLE			STATUS	DUE ON	ACTION	Client BioClinica Test Client
BioClinica Test Client - 🔻	Demo	999 - 999			Re Published	11-Mar-2014		Protocol BioClinica Test
Site 999 •	Demo	999 - 999			Re Published	07-Mar-2016		Project Site Number
	Demo	999 - 999			Re Published	15-Mar-2016		999
tatus Published & RePublish ▼								Project Site Name 999
Filter	SURVEYS							Status Re Published
Reset								Survey Due Date 11-Mar-2014

Left Panel (Filters)

To filter the list, select filters and click Filter. To clear filters, click Reset.

Center Panel: The List

- Client Name name of Bioclinica's client on whose behalf the survey was generated
- Title Title of the survey
- Status survey status which can be any of the following:
 - Published The survey is available to be completed.
 - Answered The survey has been answered (completed) by the site and requires review by Bioclinica.
 - Approved The survey has been answered by the site and has been approved by Bioclinica.
 - Denied The survey has been answered by the site and has been denied by Bioclinica
 - RePublished The survey has been republished and needs to be answered by the site.
 - Due On date by which the answered survey is expected by Bioclinica
- Action symbols that link to specific processing options related to the query
 - <u>Answer Survey</u> displays the survey form in edit mode (option only available for surveys with a status of Published or Republished)
 - View Survey displays the survey in view only mode

Right Panel: Details

This panel displays details (some also on the row and some additional) related to the currently selected row.

List Menu (Options vary based on the selected row.)

Export to Excel - See Export to Excel

View (ReadOnly) - See View Survey



Survey Form

						Welcome, ws_use	
V3.12.2 Build 20151208.10.10	TO-DO SUBJECTS QU	ERIES SURVEYS	DOCUMENTS	HISTORY FORM-UPLO	AD TRAINING	Help IMAGE UPLOAD	SMART Portal
⊖ Surveys		Tip: Ans	wer survey questions	i.		Questions	
Sat01 - BioClinica Test Si	Personnel information					Technologists	^
Sat01 - BioClinica Test Si	0					Designated Tech Designated Tech	
Sat01 - BioClinica Test Si	Technologists					O Designated Tech	
111 - Test Site1	1 . Designated Tech						
111 - Test Site1	Designated Technologist						
111 - Test Site1	Last	Name:					
004 - BioClinica	First	Name:					
Sat01 - BioClinica Test Si	2. Designated Tech						~
Export to Exce	View (ReadOnly)	C Reset	Save	Submit	Export Blank PDF	Export Answered PDF	

SMART

Left Panel (Surveys)

Surveys

- allows you to go back to the Survey List.

Center Panel: Survey Form

The query information is broken down into the following sections

- Context Information -lists the site, time point, study date and image type.
- Query Information lists the details of the query
- Query Reply lists any reply to the query

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Right Panel (Questions)

Links to all the questions that need to be answered in the survey.

List Menu (Options vary based on survey status)



Export to Excel - See Export to Excel

- submits the survey.



Submit

- resets the survey to the last save.

PDF



View a Survey

- 1. Scroll through the survey.
- 2. Click bone to return to the Survey list.

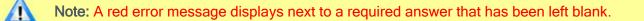
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Answer a Survey

- 1. Scroll through the survey.
- 2. Answer each question.
- 3. You can **click** at any time to save your progress.

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4. When you are finished, click Submit



5. Click Surveys to return to the Survey list.

Export Blank PDF

The Export a Blank PDF button allows you to download a blank survey (no answers).

1. Display Survey Form and click Export Blank PDF

The survey is generated and a message displays on the bottom of the page asking if you want to open or save the survey.

- 2. Click Open to open the survey in a PDF viewer.
- 3. When you are finished, click



Documents

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The Documents list contains files that Bioclinica has uploaded to the SMART Portal for one, some or all sites within a given trial. From the Documents list, site users can download selected documents.

SMART

Contact Help SM V3 12 2 8uid 20191200.10.10 TO-DO SUBJECTS QUERIES SURVEYS DOCUMENTS HISTORY FORM-UPLOAD TRAINING IMAGE UPLOAD Filters Tip: You can download documents here. Protocol BioClinica Test Client - Y Site CLIENT NAME BioClinica Test ABC12345 003 004 word doc-site 003, 004 TEST.doc 29-Apr-2015	r1 Logout	/elcome, ws_u	Weld						BIOCLINICA [®]
Filters Tip: You can download documents here. Protocol Elient NAME PROTOCOL NUMBER SITE NUMBER DESCRIPTION File NAME DATETIME STAMP ACT Site BioClinica Test ABC12345 003 004 word doc- site 003, 004 TEST.doc 29-Apr-2015 Site BioClinica Test ABC12345 001 File upload to site 001 - Excel TEST.xls 29-Apr-2015 Site	MART Porta	Help	Contact						BIOCLINICA
Protocol BioClinica Test Client ▼ Site all ▼ Filter Filter Fi		PLOAD	NING IMAGE UPL	FORM-UPLOAD TRAIN	I DOCUMENTS HISTORY FO	RIES SURVEYS	I SUBJECTS QUE	TO-DO	3.12.2 Build 20151205.10.10
BioClinica Test Client - Site CLIENT NAME PROTOCOL NUMBER SITE NUMBER DESCRIPTION FILE NAME DATETIME STAMP ACT Site BioClinica Test ABC12345 003 004 word doc- site 003, 004 TEST.doc 29-Apr-2015 Site BioClinica Test ABC12345 001 File upload to site 001 - Excel TEST.xls 29-Apr-2015 Site Filter					download documents here.	Tip: You can			Filters
BioClinica Test ABC12345 003 004 word doc- site 003, 004 TEST.doc 29-Apr-2015 BioClinica Test ABC12345 001 File upload to site 001 - Excel TEST.xls 29-Apr-2015									Protocol
BioClinica Test ABC12345 001 File upload to site 001 - Excel TEST.xls 29-Apr-2015	CTION	STAMP	DATETIME ST	FILE NAME	DESCRIPTION	SITE NUMBER	PROTOCOL NUMBER	CLIENT NAME	BioClinica Test Client - 🗸
- all V Filter Filter			29-Apr-2015		word doc- site 003, 004	003 004	ABC12345	BioClinica Test	20
Filter	0	5	29-Apr-2015	TEST.xls	File upload to site 001 - Excel	001	ABC12345	BioClinica Test	0.00 million (1997)
									1
E#E Download									

Left Panel (Filters)

To filter the list, select filters and click Filter. To clear filters, click Reset button.

Center Panel: The List

- Client Name name of Bioclinica's client on whose behalf the document was uploaded
- Protocol Number ID or # of the protocol with which the document is associated
- Site number clinical site
- Description of the document
- File name file name including any extension (file type)
- Datetime stamp
- Action symbols that link to specific processing options related to the task
 - New Download
 - III Download

List Menu Options

Download - enables you to download the selected document

.

New Download - enables you to download a selected document that is new.

Download a Document

A message box displays at the bottom of the page asking if you want to open or save the document.

2. Click Open to open the document, or click Save to save the file.

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Welcome, v._____

Contact Help SMART Porta

History

The History screen shows a list of prior uploads. Options to re-access previously uploaded data are available.

SMART

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V3.29-Build-2022-07-26.12.30 TO-DO	SUBJECTS		LITY-NOTIFICATI	ONS DOCUM	ENTS HISTORY	FORM-UPLOAD	TRAINING IMA	GE UPLOAD
Filters		Details						
Protocol BioClinica Test Client - 💙					Quick Su	bject Search: Date Last	Refreshed: 16-Sep-2022	Timepoint Week 8 (Default Schedule)
	PROTOCOL	SITE NUMBER	SUBJECT NU	EXAM DATE	UPLOAD DATE	QC STATUS	ACTION	Business Modality
Site	BioDemo17	999	999 2200	09-Mar-2009	06-Jun-2016	Σ		ст
999 🗸	BioDemo17	999	999 2200	01-Jun-2016	06-Jun-2016	Σ	e	Status Received
Subject	BioDemo17	999	999 2200	02-Jun-2016	06-Jun-2016	•	W	Sequence count
all 🗸	BioDemo17	999	999 2200	03-Jun-2016	06-Jun-2016	Z	E	1
	BioDemo17	999	999 1200	12-May-2016	11-May-2016	Z	Ø	Delivery Method
Timepoint	BioDemo17	999	999 1200	13-May-2009	11-May-2016	\bigotimes		SMART Portal
all 💙	BioDemo17	999	999 1200	03-May-2016	11-May-2016	Z		Processing Status
Modality	BioDemo17	999	999 1200	02-May-2016	11-May-2016	Z	Ø	New 🗸
all 🗸 🗸	BioDemo17	999	999-1000	09-Mar-2009	22-Mar-2017	2		

Left Panel (Filters)

To filter the list, select filters and click Filter. To clear filters, click Reset.

Center Panel: The History List

Subject Search

- 1. Enter all or part of the subject Id.
- 2. Press the Enter key.

The search goes across all authorized protocols to find matches.

Note: A search for 001 returns 001 as well as 117001 as matches. The search is done for the string, not for a number.

- Protocol ID or # of the protocol with which the upload is associated •
- Site clinical site with which the upload is associated •
- Subject Number ID or # of the trial subject •

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- Exam Date Date the exam. •
- Upload Date -Date the files were uploaded. •
- QC Status Status of the data QC (pending, passed or failed) •
- Action symbols that link to specific processing options related to the item •
 - Uiew eDTF •
 - III Download Image
 - Attachments
 - loads the images into the Image Grid.

Right Panel: Details

This panel displays details (some also on the row and some additional) related to the currently selected row. You can also set the processing status of the Upload if configured in BioPACS.

List Menu (Options vary based on the selected row.)



CLARIO.

Export to Excel - See Export to Excel



Delivery Method	
all	~
Filter	
Reset	







Download Image -See Download Image

Attachments - See <u>Attachments</u> (available only for protocols allowing attachments)

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Visualize Study - loads the images into the Image Grid.

Set Processing Status

The details panel of the History screen allows you to set the processing status if one has been configured for the project in BioPACS.

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1. Select the row in the Upload History List.

The Processing Status displays in the Details panel.

2. Select a new status from the drop-down.

Download Image

Images that have been uploaded to Bioclinica can be viewed and downloaded after the image QC process has been completed. The images are downloaded in their original format. *(If the images needed to be wrapped before being added to the SMART database, they are unwrapped before they are downloaded back to your machine).*

1. Select the row with the upload that you want to download.



An Open/Save menu displays at the bottom of the list.



A window listing the downloaded files is displayed.

The files are downloaded to a folder named using the following convention:

TrialName_Initials_SubjectNumber_TimePointType_ExamDate

A	Notes:
	• The downloaded directory is automatically zipped and must be unzipped to access files.
	 All images are downloaded in their original format.
	• The subject initials displays as XXX when configured as non-display for the trial

The subject initials displays as XXX when configured as non-display for the trial.

If configured for your trial and user account, the reader annotation files will be included in the downloaded directory. Annotations will be provided in separate folders for Reader 1, Reader 2, etc.

View eDTF

The View eDTF button and icon allow you to access the eDTFs created when the images were uploaded.

CLARIO. THE BEST OF ERT & BIOCLINICA 1. Select the row in the Upload History List and click either or View eDTF.

The View eDTF page displays with the file or files associated with the image upload.

SMART



2. Highlight a row and click View eDTF

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The eDTF displays.

3. Click to save the file or click to print the eDTF.

Attachments

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The attachment screen allows you add new attachments and download existing attachments.

					Welcome, ws_	user1 Logout
BIOCLINICA [®]				Contact	Help	SMART Portal
V3.12.2 Build 20151208.10.10	TO-DO SUBJECTS QUERIES	SURVEYS DOCUMENTS HISTORY	FORM-UPLOAD	TRAINING	IMAGE UPLOAD	
🕞 History		Tip: view, download and add attachments				
Timepoint Baseline	TYPE FILE NAME	DESCRIPTION	UPLOAD USER	UPLOAD DATE		^
Protocol ABC12345	O9731sample_doc.doc>			05-Sep-2016		
Site Number 004						
Subject Number 9999						
	Add Attachments					
	Browse					
		Download Attachment Upload Attachment				

SMART

Download Attachment

Attachments that were added to an image upload can be viewed and downloaded.

1. Select the attachment you want to download from the upper table.



2. Click Download Attachment

A message box displays at the bottom of the page asking if you want to open or save the attachment.

3. Click Open to open the document, or click Save **v** to save the file.

The attachment file is listed in a window.

4. **Double- Click** the file name to open the file for viewing and/or saving to a location other than the Downloads folder.

Note: If you download a single document, that document type is downloaded. If you download multiple documents or images, a single .zip file is downloaded.

Add Attachments

1. Click Browse...

A browser box displays allowing you to search for the attachment.

2. Select the Attachment and click

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The attachment displays in the lower table.

3. Click 🛄 in the BCSP column if you want the attachment to be associated with the baseline time point.

If you check the box, the document is automatically inserted in baseline time point, if you don't check the box, the attachment is inserted as general document.

4. **Type** a description in the Description field.



5. Click Upload Attachment .

The attachment file displays in the upper table.

5. Click History

to return to the History page.

Welcome, v._____ Logout

Form Upload

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The Form Upload screen allows you to upload a document to Bioclinica for a specific subject and timepoint. Only PDF files are accepted.

SMART

CLARIO.

V3.29-Build-2022-07-26.12.30 TO-DO	SUBJECTS	QUERIES	QUALITY-NOTIFICATIONS	DOCUMENTS	HISTORY	FORM-UPLOAD	TRAINING	IMAGE UPLOAD	

Filters	Tip: Select a file to upload. Only PDF files are supported							
Protocol BioClinica Test Client - 🗸	Upload Form							
Site 1104	Choose File No file chosen							
Form Type	File Name Description							
Subject all 🗸 🗸 🗸 🗸								
Timepoint all 🗸								
Exam Date								
Reset								

Uploading a Form

- 1. **Select** the Protocol and Site, using the filters in the left panel.
- 2. **Select** a Form Type from the pull-down list. The following form types may be permitted, depending on the protocol:
 - <u>DTF</u>
 - <u>Clinical Data</u>
 - Biopsy Report
 - Phantom Data
 - <u>BCSP</u>
 - <u>ICQ</u>
 - <u>Site Questionnaire</u>
 - Certificate

Additional custom types may be presented, depending on the protocol; custom types will prompt you to **select** an exam date.

- 3. Select the Subject ID and Timepoint from the pull-down lists.
- 4. Click Choose File

A menu opens to allow you to select a file from your hard drive. Only PDF format is accepted by default, your file may need to be converted before being uploaded.

5. Select the file to be uploaded. The file name is displayed under the

File Name heading.

The Upload Form icon is enabled at the bottom of the screen



6. Click Upload Form

A confirmation message is displayed

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BCSP Form Upload

When uploading a BCSP form, the Baseline timepoint is automatically selected.

ICQ Form Upload

When uploading an ICQ form, you will only be permitted to select a designated Qualification subject and timepoint configured for the protocol.

Site Questionnaire Form Upload

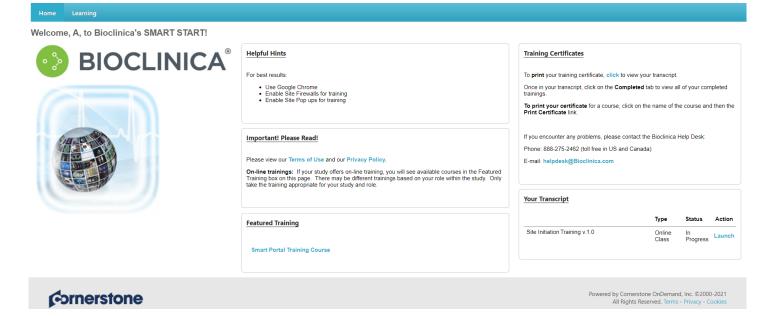
When uploading a Site Questionnaire form, you will only be permitted to select a designated Site Assessment subject and timepoint configured for the protocol.

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Training

BIOCLINICA SMART START Site Training and Resources Tool

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SMART

The Training Tab gives you access to the training necessary for your specific protocol or for general SMART Portal training.

Featured Training

- 1. Click the course name of the training you need to take in the Featured Training pane.
- 2. Click Launch to start your training.

Note: Once you launch your training, it will open in a different window. This window must be closed at the completion of your course in order for the Smart START site to be updated with your progress.



Note: You need to enable pop-ups for this website in order to view the training. If you have any questions about how to do this, please contact our Help Desk at 888-ASK-BIO2 (888-275-2462).

3. If you stop the training before it is finished, you can later find the course on your Transcript. You can access all active trainings directly on the home page or you can access you full transcription by clicking the Learning tab at the top of your screen, and then the View Your Transcript link.

Home	Learning	
A/- 1	View Your Transcript	
Nelcome,	Events Calendar	



SMART Portal Training

1. Click the Learning tab at the top of your screen and then select Events Calendar.

The Events Calendar displays all of the available live training sessions that you may select from to attend.

SMART

2. Click the course name for the event you want to register for.

The Training Details page displays with all the details of the course.

3. Click Request to register for this course.

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The course displays on your transcript with a registered status as well as on your home page in the Your Transcript pane.

- 4. To add the course to your Outlook calendar.
 - a. Click Course name from your transcript.

The Course details screen displays.

b. Click Add to Calendar.

The event is added to your calendar.



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Image Upload

Overview

For users who are approved to submit images to Bioclinica, the IMAGE UPLOAD tab will redirect to the SMART Submit system or the AG Mednet upload client per trial configuration.

10-DO | SUBJECTS | QUERIES | QUALITY-NOTIFICATIONS | SURVEYS | DOCUMENTS | HISTORY | FORM-UPLOAD | TRAINING (MAGE UPLOAD)

To learn more about SMART Submit, see:

• SMART Submit Knowledge Base

For more information on AG Mednet see:

- <u>FAQ</u>
- Quick Reference
- <u>User Manual</u>

