SMART Submit Release 9.0.3 User Guide

Document Version 1.0

StudyDirect Site Submission has been updated to be part of Bioclinica's SMART Services Suite and is now known as SMART Submit. As a result, there have been changes to the look and feel but no change in functionality.

Table of Contents

Welcome to SMART Submit

> ⚠️ SynarcConnect has been updated to be part of Bioclinica's SMART Services Suite and is now known as SMART Submit. As a result, there have been changes to the look and feel.

SMART Submit is Bioclinica's web-based system for clinical trial image uploads and related communication management. Clinical sites use SMART Submit to upload images along with completed electronic Data Transfer Forms and access and reply to queries.

9.0.3 Release Updates

System Requirements

A section has been added to display all the system, workstation, and network requirements of SMART Submit 9.0.3. See Introduction for more information.

Forgot Password

There is now a Forgot Password feature on the login page. If you select this feature, a new password is sent to the email associated with your account. See Forgot Password for more information.

Change Password

For external users, there is now a Change Password feature on the SMART Portal Page. Click this link to change your password.

Introduction

Image Requirements

SMART Submit supports several data types. When uploading images, we primarily support DXA, JPEG, and DICOM formats.

DICOM requirements can vary greatly from study to study. In general, we recommend using no compression on the images. If compression is used, only lossless compression is supported. We also recommend using the highest quality pixel density available on the scanner. Finally, whenever possible, multiple image files should be zipped into an archive using WinZip or a similar application. This will help facilitate image uploads.

Bioclinica does not support configuring medical devices and equipment at sites. If you require assistance configuring devices, please contact your support staff or the equipment manufacturer.

Workstation Requirements

- Operating System- Windows 7 or higher
- Browser- Internet Explorer 10 or higher
- Java – 6 or higher
- AsperaConnect – 3.3.4 (Upload Only)

Network Requirements

- Speed- Broadband 1Mbs or greater upload speed
- Firewall- Outbound Ports
  - TCP port 80 - HTTP
  - TCP port 443 - HTTPS
  - TCP port 7600- SSH (Upload with Aspera Only)
  - UDP port 33001- Data Stream (Upload with Aspera Only)

Getting Started

SMART Submit is Bioclinica's web-based system for clinical trial image uploads and related communication management. Clinical sites use SMART Submit to upload image and transmittal form data to Bioclinica.

Login

Once you have received the welcome email, you will be able to log into SMART Submit – https://smart.bioclinica.com – and change your default password.

1. **Enter** your email address and default password.

2. **Click** Sign In.

   If this is the first time that you are logging on, the Change Password box automatically displays.
   If you have already changed your password, the Select a Study page displays.

Update Password

You must update your password because your password has expired.

| yourname@company.com |
| Old password |
| New password |
| Confirm new password |

[Submit] [Cancel]

3. **Enter** your email address and default password.

4. **Enter** a new password.
    The password must be at least 8 characters long and must contain at least three of the following: an upper-case letter, a lower-case letter, a number, and a symbol.

5. **Re-enter** the new password in the Confirm Password field.

6. **Click** Submit.

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]

Change Password

If you are an external user, you can change your password by clicking the Change Password link. The update Password Page, above, displays.

com   Change Password   Logout

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:

1.   **Click** the study or form you wish to work with from the list.

     If you select an item beginning with Image Submissions- the Site Submission Home page displays.

     If you select an item beginning with Forms - the Study Forms page display.

     If you select an item beginning with Site Portal- the Study Portal page display.

Logout

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

UPLOADING IMAGES AND DATA

After you have selected the project the File Upload Activities Summary page displays. The upper right corner of the page displays your Login ID. You can always return to this page by clicking **Site Submission Home** in the upper right of the page.

The center section highlighted below only displays if you don't already have the Aspera Connect Browser Plug-in installed.

> **Note:** You must download and install the Aspera Connect Browser Plug-in before you can upload any files. Please see Aspera Connect Browser Plug-in for more information.

Upload Methods: Aspera Connect vs. "Classic SFTP"

SMART Submit supports two methods for uploading files. "Classic SFTP" is a fallback method available to sites where the Aspera Connect plug-in cannot be installed, or network restrictions at a site prevent its use. This uses Unlimitech's web-based file transfer client. It is handy as a back-up solution, but it is slow compared to using Aspera Connect.

You can switch between the Aspera and SFTP methods. On the electronic Transmittal Form data entry page that you are presented with prior to uploading the data (after selecting Upload or Test), there is a link at the bottom of the web page if you are using Classic SFTP:

> Currently using Classic SFTP to upload files.
> Use Aspera (recommended)

Clicking on the "Use Aspera (recommended)" link switches your session to use the Aspera Connect method. When Aspera is selected, you will see this at the bottom of the electronic TF data entry page:

> Currently using 'Aspera' to upload files (no de-identification).
> Use Classic SFTP

If you have not installed the Aspera Connect file transfer software, or if you have it installed for a single user rather than for all users, a warning displays at the top of the electronic Transmittal Form data entry page.

Download Aspera Connect Browser Plug-in

The first time you access SMART Submit, a message on the Site Submission Home Page announcing the Aspera high-performance *fasp*™ transport technology that SMART Submit now uses for site submissions displays in the middle of the page.

We are pleased to announce that SMART now utilizes Aspera's high-performance fasp™ transport technology for site submissions. This enhancement will provide significantly faster upload times and more reliable transfers.

To send files to BioClinica you will first need to install the Aspera Connect browser plug-in. Please navigate to the following page and download the version for your particular operating system. After installing, you will need to restart your browser and log in to SMART again.

For any questions regarding this upgrade, please send email to websupport@bioclinica.com.

Download Aspera Connect (Installation Guide)

> ⚠️ **Note:** You must have local administrator permissions to install this plug-in.
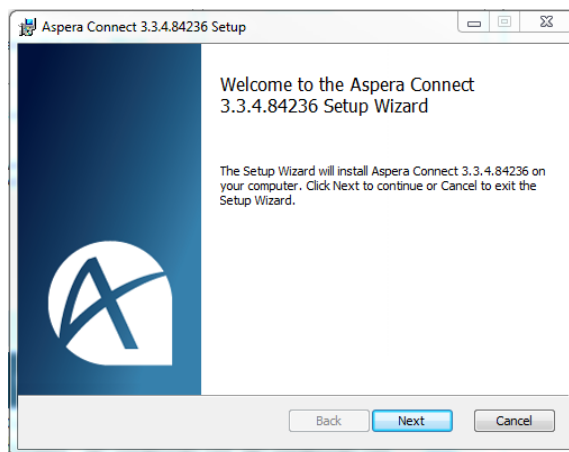
1. **Click** Download Aspera Connect.

    The security warning displays at the bottom of the page.

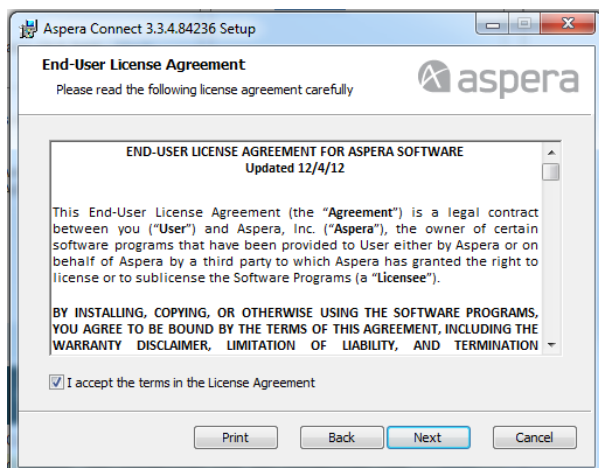2. **Click** Run.

    The Welcome box displays.

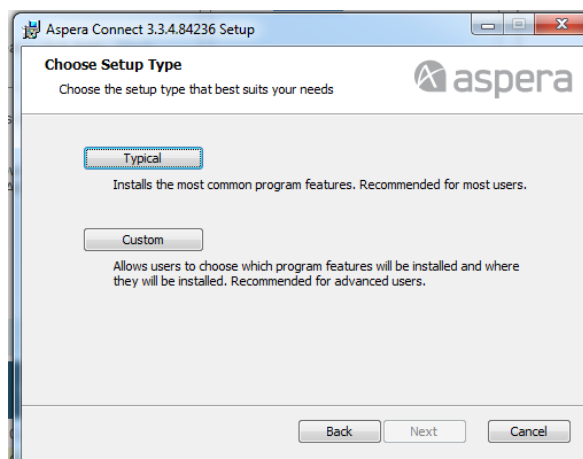3. **Click** Next.

    The License Agreement box displays.

4. **Click** the check box to accept the License Agreement and **click** Next.

    The Choose Setup Type box displays.

5. **Click** Custom.

   The Installation Scope box displays.
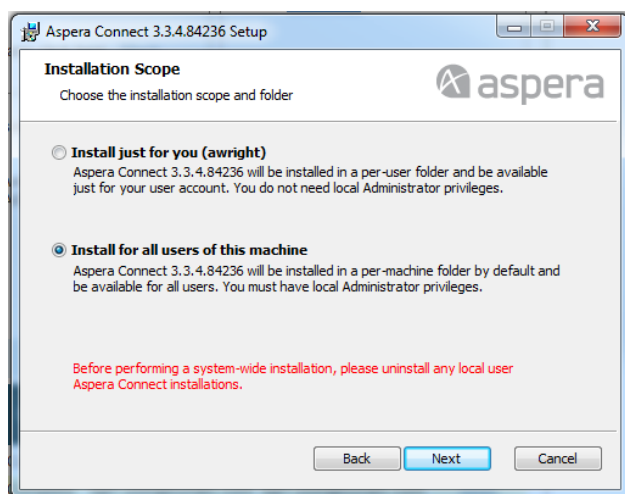
6. **Click** the radio button next to Install for all users on this machine and **click** Next.

   The Ready to install box displays.

7. **Click** Install.

   After the installation is complete the Complete box displays.

8. **Click** Finish.

Further Information:

Sometimes the Aspera Connect software is not able to communicate with the SynarcConnect web site from a location where the networking security is blocking its access. Aspera Connect uses two "port numbers" in its communications with Synarc. These must be allowed for in your network firewall configuration. If you have trouble after installing the software, be sure your network infrastructure personnel allow for communications on the following two network port numbers:

TCP/7600 UDP/33001

Additional Help:

For additional assistance, contact the Help Desk:

Toll Free from the US and Canada: 1-888-ASK-BIO2 (1-888-275-2462)

International: +1-484-928-6076

Email: helpdesk@bioclinica.com

Search Criteria for Files

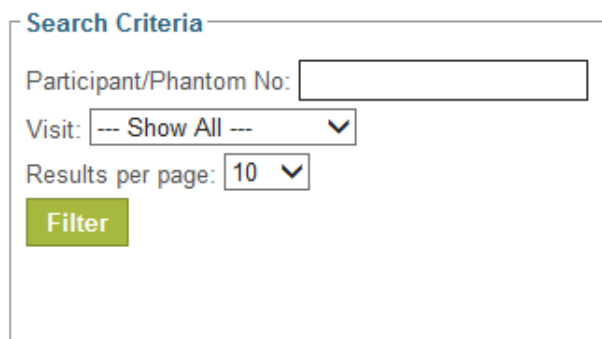The **Search Criteria** section allows you to filter and view a history of previously uploaded images.

```
┌─ Search Criteria ──────────────────────┐
│ Participant/Phantom No: [            ]  │
│ Visit: [--- Show All ---    ▼]          │
│ Results per page: [10 ▼]                │
│ [ Filter ]                              │
└─────────────────────────────────────────┘
```

1. **Define** your filter using one or more of the following criteria:
   - Participant/Phantom Number
   - Visit

2. **Select** the number of Results per Page you wish to display (the default is 10).

3. **Click** the **Filter** button.

   The File Upload History section at the bottom on the page displays the results of the filter.

File Upload History

The **File Uploads** section, on the bottom half of the screen, shows the file upload history by the date uploaded. The most recent uploads are listed first. This list includes the Upload Date, Site Number, Participant (or Phantom) Number, Visit, Number of Files, and the file Size of the uploads. The last two fields include the total number of DICOM files and the overall Total (DICOM and non-DICOM), with the values separated by a forward slash.
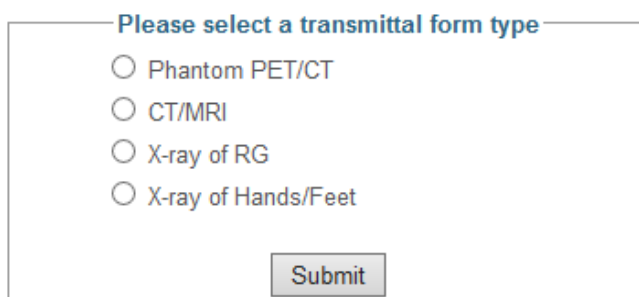
The upload history displays items up to the number you specified in the Search Criteria, so any items over this amount will show on another page, which can be accessible via the Next and Previous arrow buttons, or by clicking on a particular page number. You can also sort the files by clicking on the column name. All files in the upload history are included in the sort process, not just the files showing on the page.

Uploading Files

The **Upload Files** section includes a button for initiating an upload, a link to test upload functionality, and links to the online help and User Guide.

1. From the Site Submission Home Page, **click Upload Files**.

   The Select Transmittal Form Type page displays.

```
┌─ Please select a transmittal form type ─┐
│ ○ Phantom PET/CT                         │
│ ○ CT/MRI                                 │
│ ○ X-ray of RG                            │
│ ○ X-ray of Hands/Feet                    │
│           [ Submit ]                     │
└──────────────────────────────────────────┘
```

2. **Select** the transmittal form type and **click Submit**.

   The Transmittal Form data page displays.

BIOCLINICA | SMART Submit

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DemoCompany Protocol US-DEM-999

Welcome IQUser1

Help | SMART Portal | Sign Out

Study: DEMO-9999   Site: 001

SiteSubmission Home > Transmittal Form

Transmittal Form For CT/MRI

Site, Patient, and Visit Information

Screening Number: [____] (e.g. 12)   *Participant Initials: [_____] (FML or F-L)   *Visit: [--- ▾]   ☐ Repeat Request

Subject Number: [____] (e.g. 12)

*Date Of Birth: [_____] (DD-MMM-YYYY)(31-DEC-1906 to 31-DEC-1990)   Patient Gender: [___ ▾]   ☐ Resubmission Request

CT Information

Exam Site (check all that apply):   Exam Date:
☐ Chest ☐ Abdomen   [_____] (DD-MMM-YYYY)
☐ Pelvis
Comments: Tech Initials: [_____]
[_____]

MRI Information

Exam Site (check all that apply):   Exam Date:
☐ Chest ☐ Abdomen   [_____] (DD-MMM-YYYY)
☐ Pelvis
Comments: Tech Initials: [_____]
[_____]

[Submit and Upload]

Currently using 'Aspera' to upload files (no deIdentification).
Use Classic SFTP
Use Aspera + client deIdentification (DICOM files only)

3. **Enter** the Site, Patient, and Visit Information fields.

4. If the form is being submitted as a **Repeat Request** or **Resubmission Request**, **check** the appropriate box.

5. **Check** the Exam Site(s), enter Exam Date, Tech Initials, and any applicable Comments for each modality identified on the transmittal form.

6. **Click Submit and Upload**.

    Your transmittal form data is saved.

Submit and Upload

After the image upload program connects, you will see the File Uploads page. This page shows two panels: a Current Upload Status panel, and an Upload Files panel.

The Current Upload Status panel always displays the status of the current file upload session, and have values such as "Ready", "Completed", etc.

At first the Upload Files panel has two enabled buttons:

Add Files – is used to add individual files to your upload list.

Add Folders – is used to add all the contents of a folder or folders to your upload list

After you select files, the other three buttons are enabled:

Upload Files/Folders – is used to upload the files or folders with the status of "Ready to Upload."

Remove Selected Files – is used to remove files that have been placed on the upload list in error but not yet uploaded. Click the check the box to the left of the files and click this button to remove the selected files from the list.

Remove All Unsent – is used to remove all the files in the upload list that have a status of "Ready for Upload". Files already uploaded cannot be removed from the list.

Upload Files/Folders

Current Upload Status

Ready   *0MB uploaded this session.*

Upload Files

1. | Add Files | Add Folders | 2. | Upload Files/Folders | Remove Selected | Remove All Unsent | Display Aspera Transfer Manager

Local Folder/File	Status

1. **Click** either **Add Files** or **Add Folders**.

   A pop up a window displays showing your local file system on your computer.

2. **Navigate** to the directory where your file(s) are located using the buttons inside the local system view, select the file(s). - Use SHIFT + Click / CTRL + Click to highlight multiple files -- and click Open.

   The File Uploads page displays with the selected files/folders in the upload list.

Current Upload Status

Ready   *0MB uploaded this session.*

Upload Files

1. | Add Files | Add Folders | 2. | Upload Files/Folders | Remove Selected | Remove All Unsent | Display Aspera Transfer Manager

| Local Folder/File	Status
☐ IM-0001-0001.dcm	Ready for upload
☐ IM-0001-0002.dcm	Ready for upload
☐ IM-0001-0003.dcm	Ready for upload

3. **Click Upload Files/Folders**.

   An additional popup window alerting you that an attempt is being made to initiate a transfer with the Bioclinica server may display.
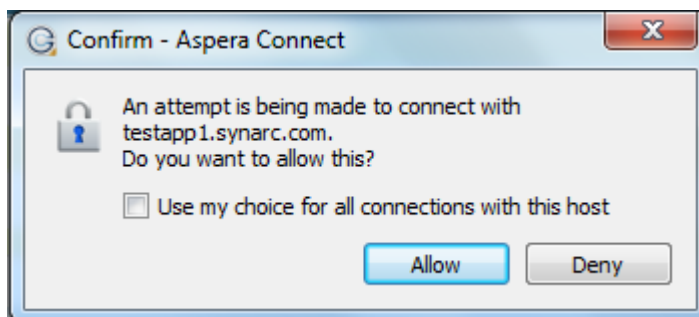
4. Click **Allow** to permit the image upload to proceed.

   When the file is uploading, the Current Upload Status panel displays the percent and status of upload. In addition, a popup Transfer Manager window displays the status of the transfer.
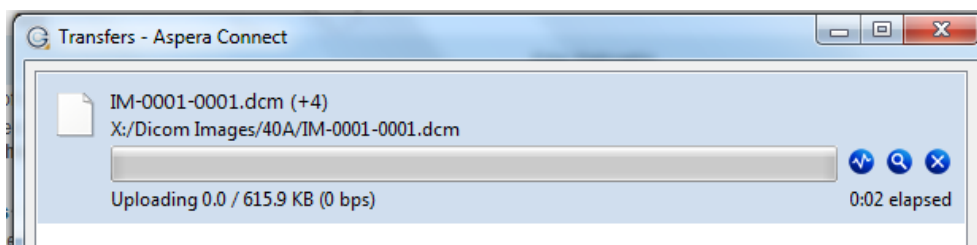
The first time you attempt to upload files to Bioclinica, you may see a Windows Security Alert regarding the ascp Application. If you do, click **Unblock** to continue with the upload.

When the upload is complete, the Upload Files panel displays the status of each uploaded file.

> **Note:** When all the files have been uploaded, you must sign the session to complete the process.

5. **Enter** your password in the signature box below and click **Sign and Complete**.

    If you attempt to sign before the upload is complete, the system prompts you to wait.

    After you sign the upload session, a confirmation of your upload is sent. An image verification is run on your uploaded files to check for valid DICOM images. If there was an error with the files, then the system asks if you want to re-upload the files.

    If there were no errors encountered by the verification process, then a confirmation displays.

You will also receive a confirmation email with a summary of the uploaded files, including the study, site, participant, and visit the upload was associated to. The email also lists any files that failed the DICOM verification check.

> **Note:** The system continues uploading a file for up to 24 hours. After 24 hours, the system stops loading the file and times out. It is suggested that you segment very large files so they load in the time allowed.

Resubmit Images

If there is an issue with an image, a query may be initiated asking for the image to be resubmitted. In DCF Resolution, a "Resubmit" button displays under Query Status. After uploading the new image, click "Resubmit" to go to Image Submission.

Submitting Study Forms

Study Forms refers to any study specific non-image data other than the Transmittal Form, configured for electronic submission. Study Forms are be enabled if your studies have been set up to include one or more of them.
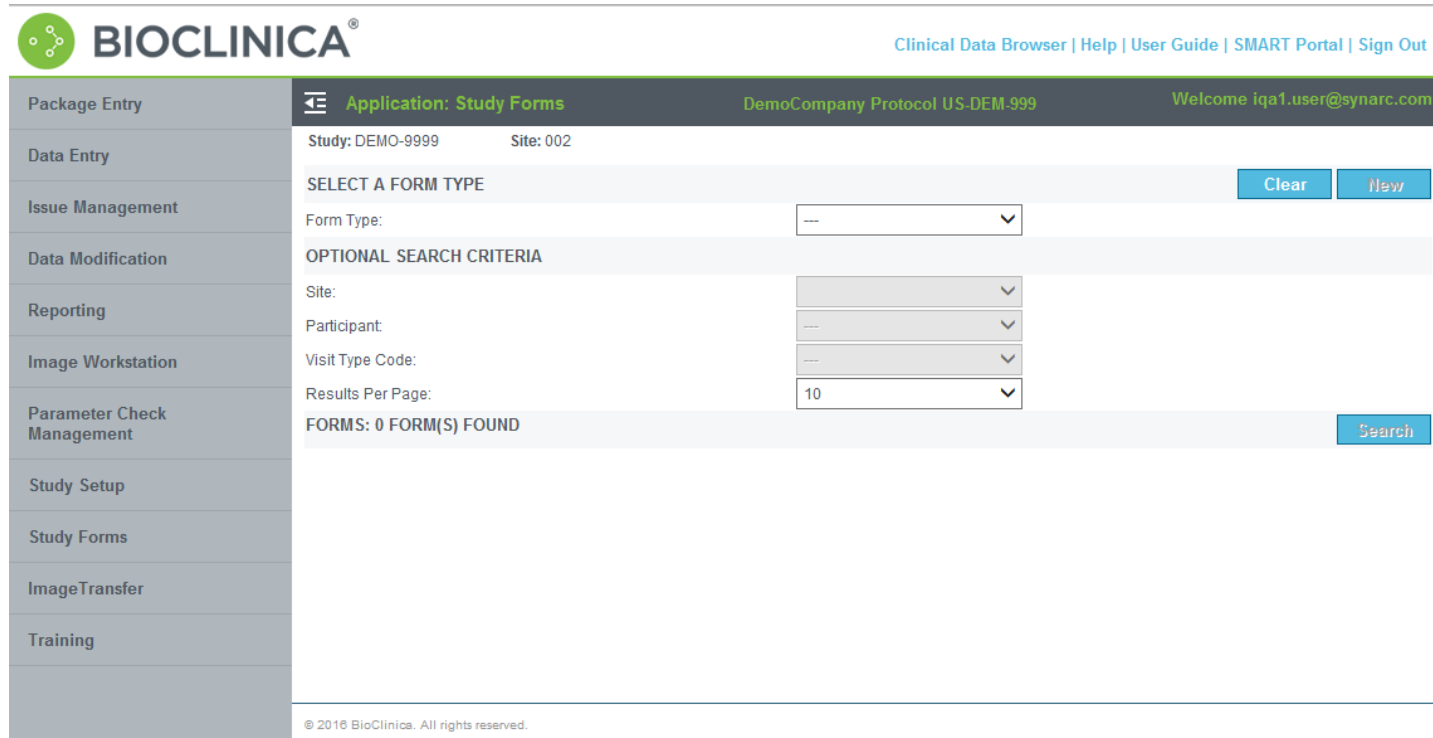
If the Study Form has been enabled for your studies, they display on the SMART Portal page in the format:

> Forms - Study/Protocol Number – Site Number

Submit New Study Form

1. From the SMART Portal page, **click** the item beginning with Forms for the Study and Site you wish to use.

   The Study Form Selection page displays.

2. **Select** the type of form you wish to submit from dropdown list under Form Type.
3. **Click New**.

   The selected form displays.

BIOCLINICA SMART Submit

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Clinical Data Browser | Help | User Guide | Sign Out

Return Home

Global Pharmacovigilance and Risk Management
BRAIN MRI WORKSHEET (BMW)

Protocol #:   ○ 101
              ○ 102

＊Site # - Subject #:   002 - [--- ▼]

Or Enter Site# - Subject#: 002 - [_____] (e.g. 999 - 9999)

＊MRI Scan Visit: [--- ▼]

MRI Scan Date: [_____] (dd/mmm/yyyy)

Date Of Birth: [_____] (dd/mmm/yyyy)

Country: ○ USA ○ Canada ○ Other

＊Reason for Referral:

☐ VE ☐ Microhemorrhage ☐ Macrohemorrhage ☐ Other MRI

＊Date of latest MRI Reviewed: [_____] (dd/mmm/yyyy)

＊Significant Changes:

○ Yes ○ No

If Significant changes, describe MRI findings. Please note VE (or changes in VE), microhemorrhage (or changes in microhemorrhage) and any other clinically significant abnormalities (or changes) not present on previous timepoints including baseline.

SECTION 1: VASOGENIC EDEMA

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4. **Enter** the study form information. Fields marked with an asterisk (*) are required.

5. If you don't have all the information needed to complete the form, or simply need to finish it later, enter your electronic signature (by default, located in the lower right of the form) and click **Finish Later**.

    This saves the information you have entered, but does not submit the form.

Meaning: Authorship

＊ Signature: [_____]

As the Author of this update, I acknowledge that the information I have entered is complete and correct to the best of my know   © 2016 BioClinica. All rights reserved.

This form is marked incomplete. (Mark this form complete)

[Finish Later] [Invalidate] [Cancel]

6. If you have finished the form, click (Mark this form complete), then enter your electronic signature and click **Save**.
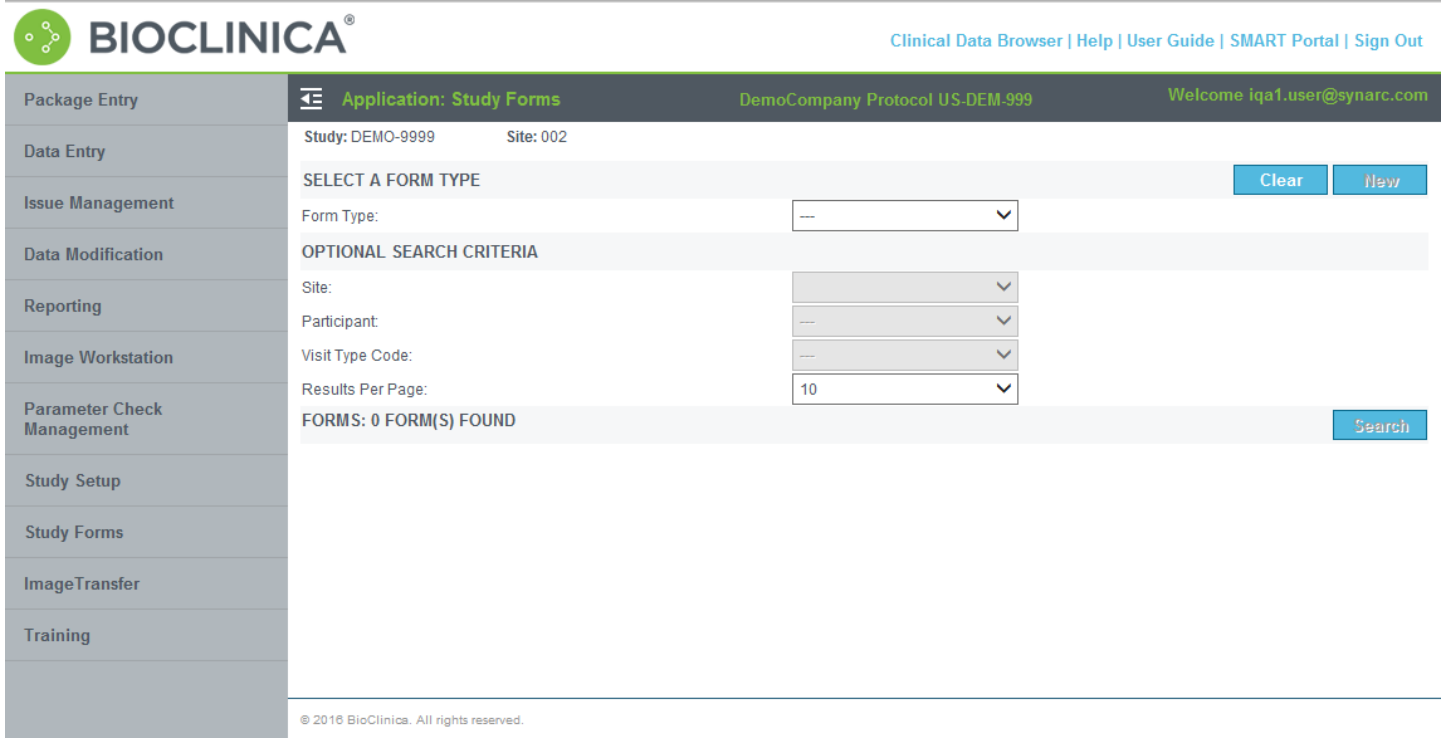
    The form is saved as Complete.

> ⚠ **Note:** If the form was submitted from a site, you receive a confirmation email. (Study forms submitted by internal Bioclinica personnel do not generate a confirmation email.)

Search and Edit a Study Form

You can search for previously saved study forms and edit them using the Site Submission interface.

1. **From** the SMART Portal page, **click** the item beginning with Forms for the Study and Site you wish to use.

   The Study Form Selection page displays.

2. **Select** the form type and any of the **Optional Search Criteria**, as applicable.

3. **Click** Search.

   Any submitted forms matching the form type and search criteria display on the bottom half of the page.

	FORMS: 4 FORM(S) FOUND						Search
ID		Submission Date	Last Modified	Created By	Site	Participant	Visit
1000000585697469		14-Nov-2011 10:58	22-Mar-2012 10:53	demo.site@synarc.com	002	11	BASELINE
1000000369970571		16-Jul-2011 16:18		demo.site@synarc.com	002	11	BASELINE
1000000369940226		16-Jul-2011 12:05		vineela.regulapati@synarc.com	002	11	BASELINE
1000000369940210		16-Jul-2011 12:02		demo.site@synarc.com	002	11	BASELINE

* - Incomplete

4. **Use** the arrow keys to navigate through multiple pages of results, if necessary. You can also sort the results by clicking on the header of each column.

5. **Click** a form ID (the leftmost column) to open the saved form.

6. **Edit** the data in the selected form as required.

7. You can **Save** and **re-submit** the edited form, or **Cancel**.

Viewing Study Portal

Depending on the permissions granted to you and the study setup, you may be able to view study-specific documents and other information uploaded by BioClinica. These documents are available through the SMART Portal.

> ⚠️ **Note:** Not all studies utilize this functionality.

If the Site Portal has been enabled for your studies, they display on the SMART Portal page in the format:

Site Portal - Study/Protocol Number – Site Number

View Site Portal/Study Documents as a Site User

1. **From** the SMART Portal page, **click** the Site Portal link.

   The Site Portal Selection page displays.

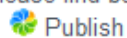*The options display on the Quick View Menu to the right of the screen.*

2. **Click** on Site Documents to list documents for site users within your browser.

    The list of Site Documents displays.

Site Documents

Please find below the latest documents.

🌀 Publish

Mahesh-test-dec-15. - 15-Dec-2015
001_SiteDocsu.docx - 01-Dec-2015

3. **Click** the link for the document you wish to view.

    A warning similar to the one below displays.

Do you want to open or save **001_SiteDocsu.docx** from **val.smart.bioclinica.com**?   Open   Save ▼   Cancel   ×

4. **Click** Open or Save to view or save the file.