BioClinica WebSend Version 2.21

USER MANUAL

Version 1.0

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Introduction

This manual is a guide for the use of BioClinica WebSend. WebSend includes both a desktop application WebSend and the WebView Portal.

1. **WebSend** – a Web-based software application that enables remote users to electronically send complete DICOM studies to other BioClinica-enabled sites via the Internet. BioClinica WebSend runs on a standard PC with Internet access and can be inexpensively and rapidly deployed to many sites. With BioClinica WebSend, you can quickly and easily share complete DICOM studies via the internet to other remote users.

2. **WebView Secure Portal** provides you with the ability to view, search and sort study lists, review clinical trial statistics, and to optionally view streaming (compressed) versions of images from a remote location via an Intranet or Internet connection. The WebSend Secure Portal supports images from the following modalities:
    - CR-Computed Radiography
    - CT-Computed Tomography
    - DD-Duplex Doppler
    - DS-Digital Subtraction Angiography
    - DX-Digital radiography
    - MG-Mammography
    - MR-Magnetic resonance
    - NM-Nuclear Medicine
    - OT-Other Modality
    - PT-Positron Emission Tomography
    - RF-Radio Fluoroscopy
    - RG-Radiographic Imaging
    - SC-Screen Capture
    - US: cardiac ultrasound – including IVUS – Intravascular Ultrasound
    - XA-X-Ray Angiography
    - OCT: Optical Computed Tomography

Features of BioClinica WebSend

Features of BioClinica WebSend include:

- Upload clinical studies to a Core Lab
- Instant data delivery from Investigator Sites to a Core Lab
- Eliminates the need for Investigators to log and mail CDs
- Eliminates the problem of "unreadable" CDs
- Expedites data analysis, workflow is optimized
- Protects patient confidentiality by automatically masking PHI
- PHI automatically removed from DICOM file and overwritten with trial and patient-specific tracking information
- 21 CRF Part 11, HIPAA & HCFA compliant
- Automates the study tracking process
- Provides complete audit trail with time & date stamps
- Prevents incidents of lost studies

- Instant data delivery from Core Lab to Authorized Guests
- Trial Sponsor: case review, real-time tracking of trial progress
- Investigators: real-time tracking of performance / review cases
- Online backup of data / DICOM Redundancy
- Uploaded data is never lost, all cases reside on Internet Data Center (IDC)
- Eliminates the need to manually archive and retrieve studies
- Facilitates data mining during and after trial

Documentation Conventions

User Interface buttons are self-explanatory. The **Cancel** button quits opened informational, alert or prompt dialog boxes. The **OK** or **Save** button in a dialog box authorizes that function, or acknowledges the presented information.

"Click," "double-click," "right-click," "drag," and "draw" are actions performed with the cursor and the mouse. "Click" always denotes "left-click."

"Type" signifies keyboard typing.

"Press" signifies a keyboard command, or the finger-touch operation on a monitor or a central processing unit (CPU).

- "Radio button" describes a circular selection graphic with an accompanying textual description. In a series of radio buttons, only one can be selected.

- "Check box" describes a square selection graphic with an accompanying textual description. In a series of check boxes, more than one can be selected.

'Drop-down list" is an index of selections. Only one entry on a drop-down list can be selected.

Most mouse-driven functions can be duplicated on a touch-enabled monitor by pressing the appropriate area of the screen. Whenever possible, the user interface is large enough to allow for touch-screen operation. However, certain actions require an on-screen tool more precise than a fingertip. For consistency, this user guide exclusively presents a mouse-driven methodology.

Notes and Tips are highlighted in the document:

Note:

Tip:

Customer Support

Collaborate with BioClinica for image and information management systems and gain access to a team of network, database and application experts dedicated to supporting information management systems.

Our Approach

BioClinica efficiently installs hardware and software, thoroughly trains users, regularly monitors systems, reliably ensures secure data access, and promptly resolves issues.

Our Ongoing Support

Direct questions to BioClinica Customer Service:

- Telephone: 1-888-ASK-BIO2 (1-888-275-2462) Option 2
- E-mail: helpdesk@BioClinica.com
- Web address: www.BioClinica.com.

Note: Report critical issues by telephone to ensure the fastest possible response.

Product Overview

BioClinica WebSend is a PC-based software application that enables remote users to electronically send complete DICOM studies to other BioClinica-enabled sites via the Internet. BioClinica WebSend runs on a standard PC with Internet access and can be inexpensively and rapidly deployed to many sites. With BioClinica WebSend, users can quickly and easily share complete DICOM studies via the internet to other remote users.

Installing WebSend

BioClinica WebSend System Requirements

The following system requirements are essential to successfully operate the BioClinica WebSend application:

Hardware

- Processor: 1 GHz.
- RAM: 512 MB or more.
- Available Hard Drive Space: 300 MB
- CD-ROM Disk Drive
- Monitor: 1024x768 pixel display; BioClinica recommends a greater resolution.
- Internet Connection Speed: DSL, Cable, T1 or higher
- Ability to burn DICOM compliant CDs or browse to a DICOM study from the computer

Software

- Microsoft Windows 2000, XP, 7, and Vista.
- Microsoft Internet Explorer 7, SP 1, 8 or later.
- Mozilla Firefox version 3.0 or later.
- Apple QuickTime version 6.4 or later.
- Java JRE 1.6 – Java Runtime Environment
- User Account on the BioClinica network

Installing WebSend

To install the WebSend software:

1. **Quit** all running programs. Then open your internet browser (e.g. Internet Explorer, Mozilla Firefox, etc.)

2. **Go to** http://websend.bioclinica.com/install

    The Installation wizard leads you through the installation process.

3. **Click Next** on each screen until the installation process is complete.

    Note: Refer to Appendix A on page 41 for troubleshooting the installation process.

Using WebSend

Launching and Logging into WebSend

To launch and log in to the WebSend software:

1. **Double-click** the BioClinica WebSend icon on the desktop:

Once the application is started, the software verifies the version of BioClinica WebSend that is running and automatically downloads and installs any updates that may be available over the Internet. The BioClinica WebSend Login window then displays.

Figure 1: WebSend Login Window

2. **Type** the account name, password, and site ID into the appropriate fields.

> **Note**: Contact BioClinica Customer Support if you forgot your login ID or password or if you have any difficulty in logging into the application.

Proxy Settings are available to support sites using a Proxy Server. Generally these settings do not need to be changed. If changes are required, contact BioClinica Customer Support for assistance, if needed.

See Appendix A on page 41 for additional information on Proxy Settings.

3. **Click OK**.

The first time you sign into the system and any time your password is reset by customer support, you are prompted to change your password. Note! Passwords must be between 6 and 14 characters long, include at least one numeric, one uppercase and one lowercase character.

4. **Type** your new password in the appropriate fields and **Click** OK.

The Acknowledgement of training displays.

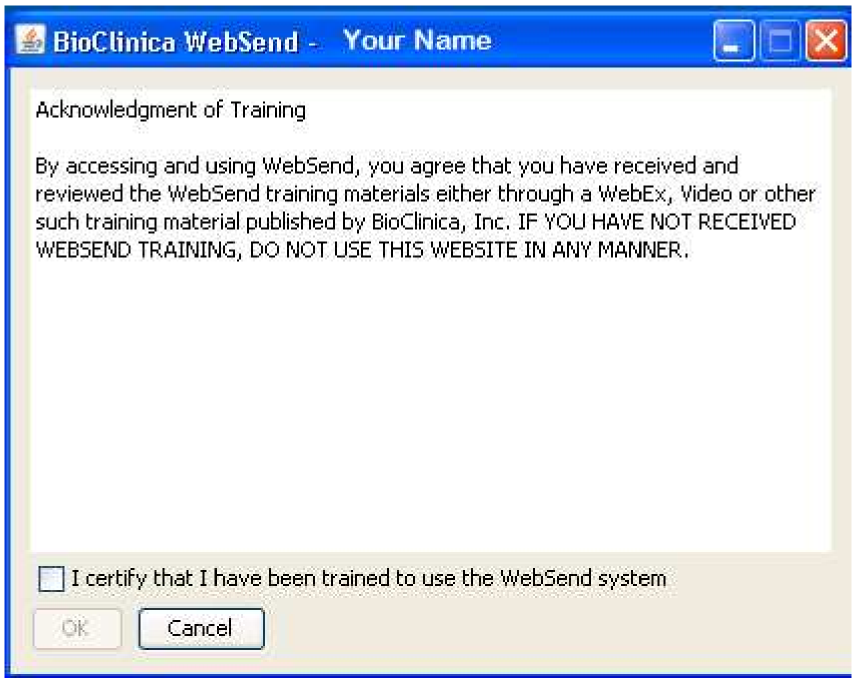


Figure 1.5: Acknowledgment of Training

Acknowledge Training

Refer to your welcome email for information on the current training schedule and video training.

When logging into WebSend, **Acknowledgement of Training** is required.

1. Review the acknowledgement statement, and if you agree with the content, **click** the check box to certify training has been completed.

2. Then **click** OK to complete the page.

The Locate Study screen displays (see Figure 2 on next page).

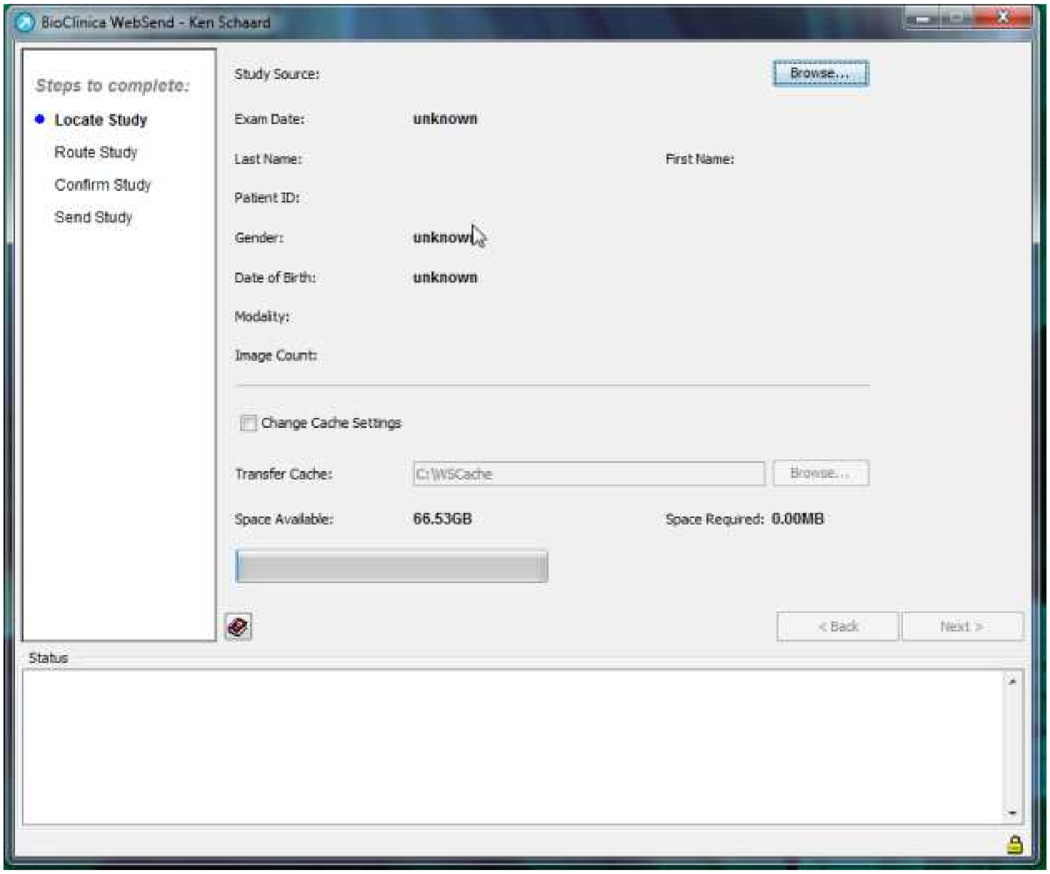


Figure 2: Locate Study Screen

Setting the Cache

WebSend uses cache to store temporary files on your system prior to upload. You can set the folder where you would like the temporary files to be stored by completing the following steps:

1. Click the check box before 

.

2. Click **Browse** and navigate to the folder where you want the files to be stored.

   The Space information under the Transfer Cache box displays both the available and required space.

Locating the Image File to Upload

To locate a study to share:

1. **Insert** the CD containing the DICOM image file to be uploaded.

   Upon inserting the CD, the WebSend software automatically reads the CD to verify that the image file on the CD is DICOM-compliant and then presents you with key patient-specific information which is contained within the header of any DICOM compliant file (e.g., Procedure Date, Patient Name, Date of Birth and Study Modality).

Tip: If the study is not automatically detected, **click Browse** to manually locate the image file(s).

Figure 3: Select Study Popup

2. **Click Next**.

   The Route Study screen displays (see Figure 4).

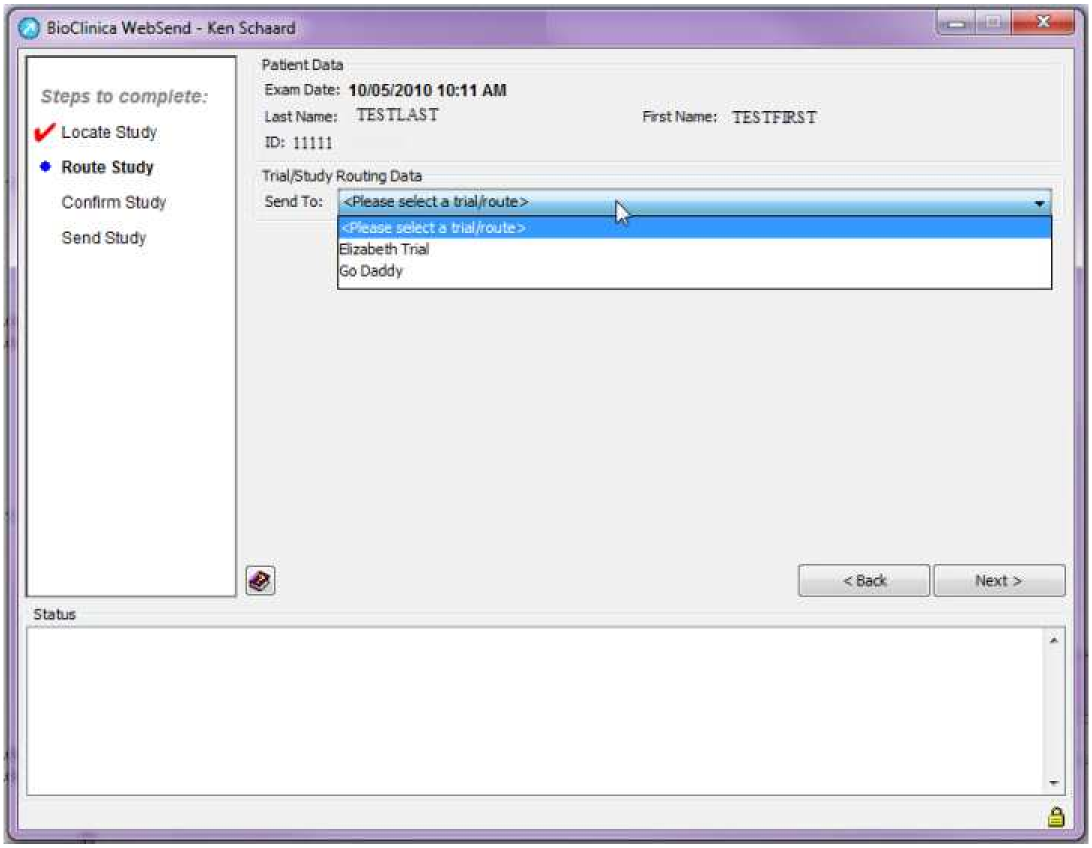


Figure 4: Route Study Screen

Routing the Image file

To identify the recipient:

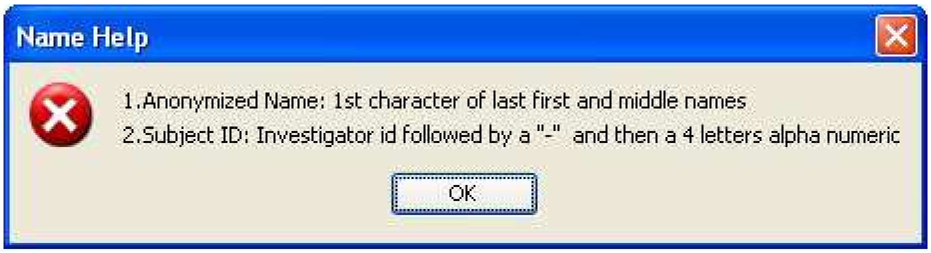
1. In the Send To field, **select** the site name or clinical trial name from the drop-down list.

   When sharing clinical trial cases, the investigator ID number is automatically populated and the patient's name is automatically anonymized to protect patient confidentiality

   The system automatically generates and populates the Anonymous Name based on the defined format on the original DICOM Header.

2. **Verify** that the Anonymized Name is consistent with the naming convention utilized for this specific trial.

   If you click  a dialog box displays listing the naming conventions, as follows:

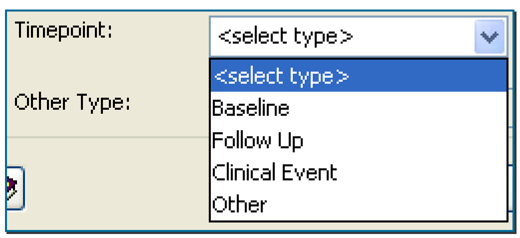
   If changes are required, type over the information presented.

3. To **reset** the patient name, **click Reset**.

4. If the recipient is a clinical trial, **type** the trial patient's ID in the **Subject ID** field, ensuring that the entry is consistent with the naming and/or numbering conventions for this specific trial (see the previous step).

Note: Please double check to make sure that the Subject ID is correct.

5. **Select** the appropriate **Timepoint** from the drop-down list. For example:

   *If the specific timepoint is not listed for this patient study, select "**Other**" and then **type** the procedure or event type in the "**Other Type**" data field.*

6. **Click Next**.

   Note: If Report attachments are required for the clinical trial, the Attach Reports Screen displays. See Appendix D for details on providing attachments with study submission.

   The Trial Questions Screen displays.

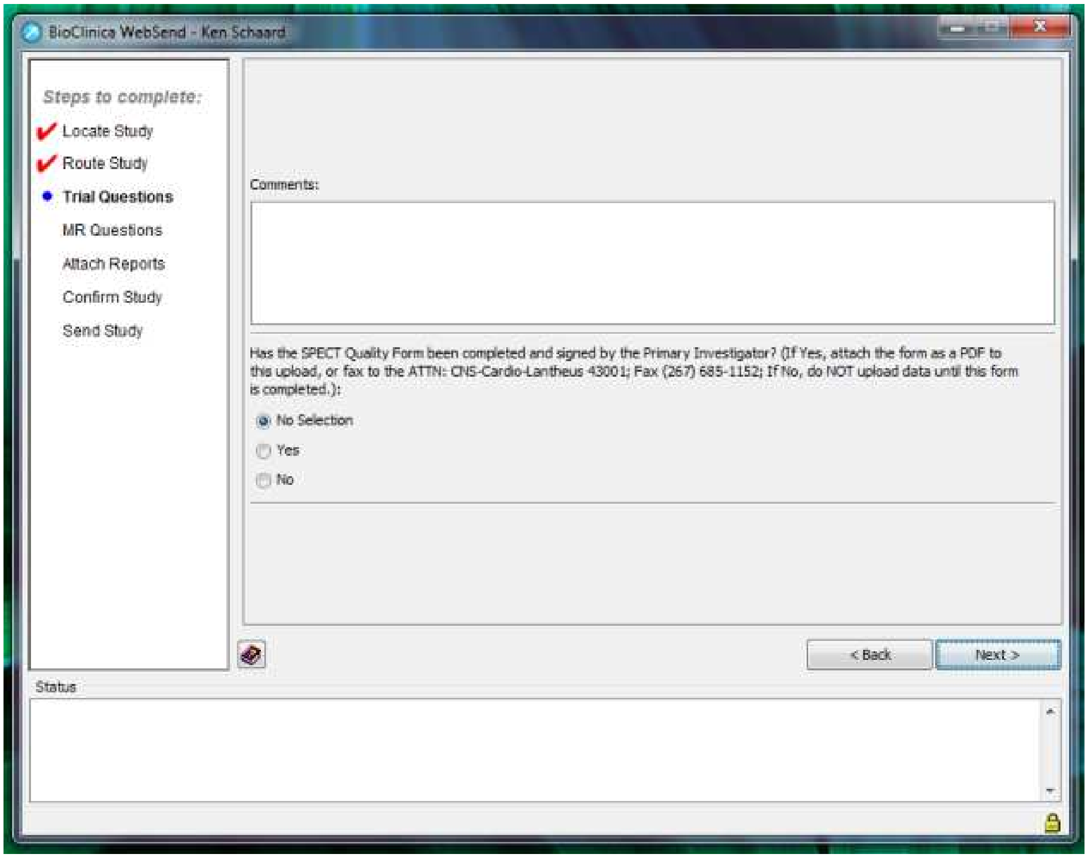


Figure 5: Trial Questions Screen

Answering the Trial Questions

To answer the trial questions:

1. **Review** the trial questions screen carefully.

   Answer the questions provided to the best of your ability. To do this, **click** the appropriate radio button, check box(es), or drop-down menu item associated with the question. If the question has a free text field, **type** the appropriate response.

2. **Click Next**.

   If there are additional questions, these display at this time. Repeat the preceding steps until all questions are answered.

   Note: If a required question is left unanswered, a message displays. Click OK and answer the indicated question.

   The Confirm Study Screen displays.

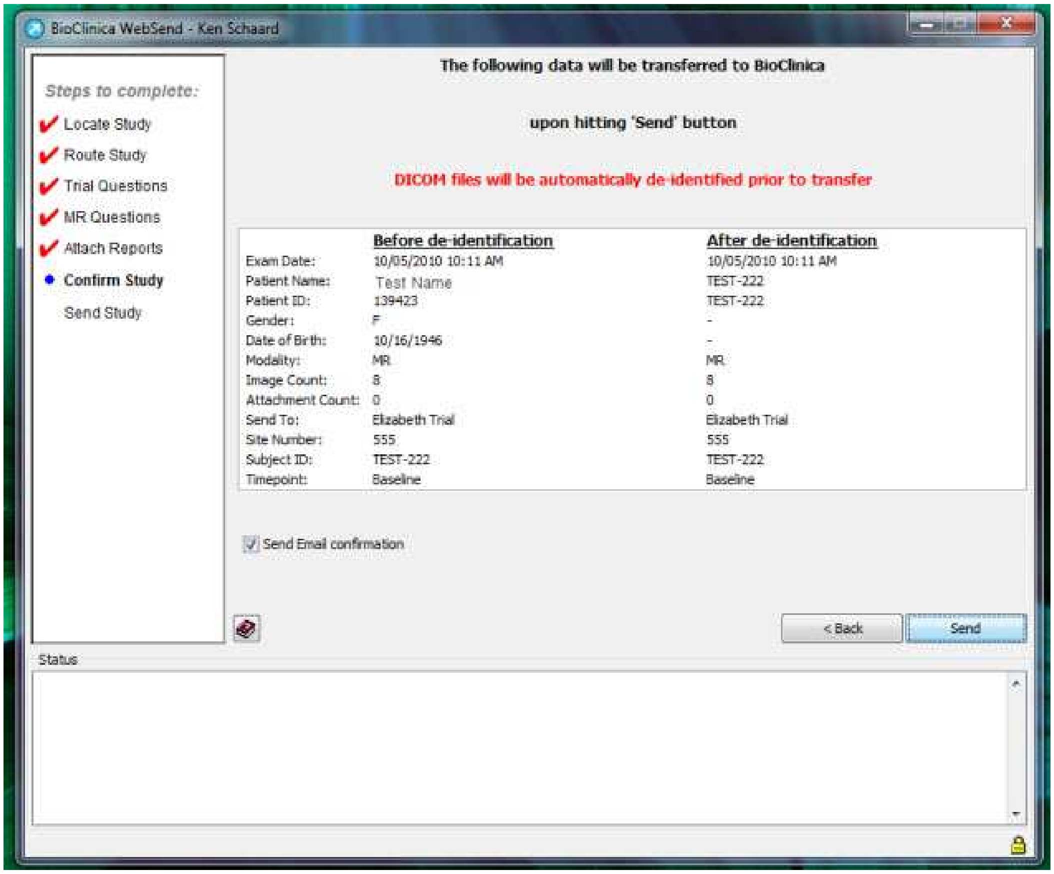
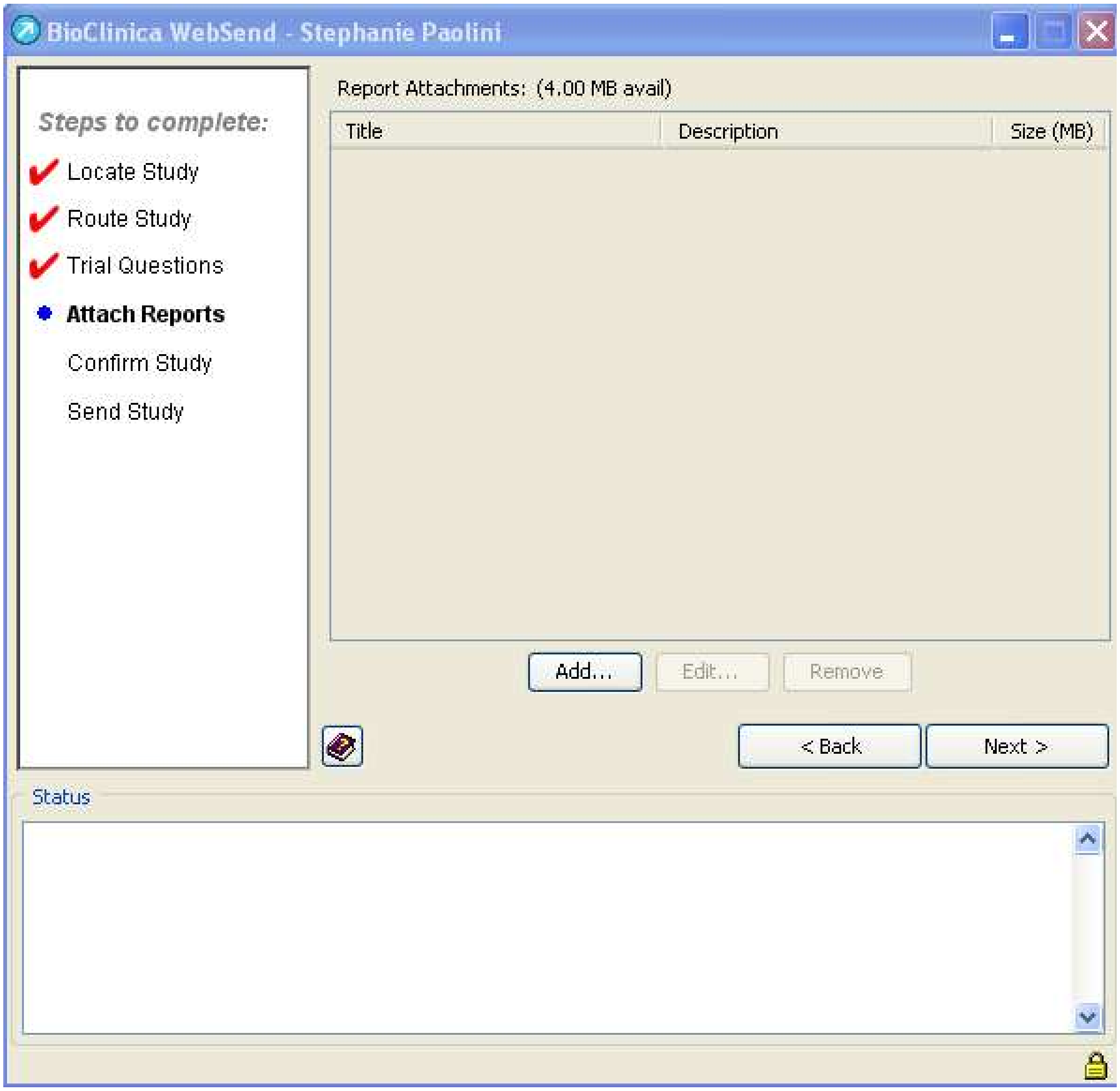


Figure 6: Confirm Study Screen

Attach Reports

Some trials will require worksheets.reports to be attached with your images.

1. Select “Add...”
2. Select “Browse...” to search and select the worksheet/report you wish to attach.
3. Enter in a title and description (optional) name
4. Click “Ok”


BioClinica WebSend - Stephanie Paolini
Steps to complete:
Locate Study
Route Study
Trial Questions
Attach Reports
Confirm Study
Send Study
Report Attachments: (4.00 MB avail)
Title
Description
Size (MB)
Add...
Edit...
Remove
< Back
Next >
Status


Select WebSend Attachment
Filename:
Browse...
Title:
Description:
(optional)
OK
Cancel

Confirming the Study

To confirm the information prior to sending the study:

3. **Review** the confirmation screen carefully, verifying that the selected study, intended recipient and other relevant data fields are correct.

   If the information is incorrect, **click <Back** to return to the desired screen to make any necessary changes

4. **Select** the **Send Email Confirmation** check box to receive an e-mail notification once the study has arrived at the BioClinica Data Center.

   Tip: Email Confirmation is not required, but is strongly recommended. An email confirmation notice completely automates the Image Tracking process and also provides real-time "proof of delivery" for the site's records.

5. **Click Send** to begin transferring the study.

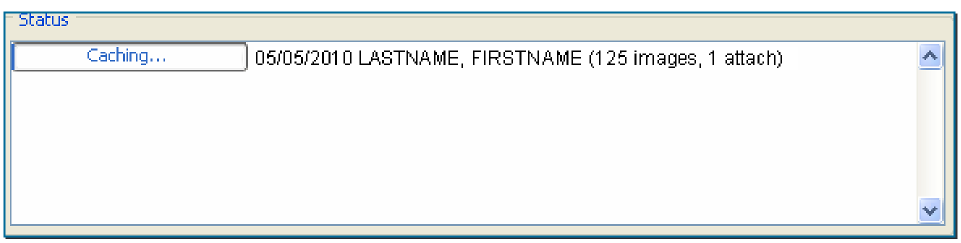
   Note: Email confirmation notices are automatically forwarded to the e-mail address that was originally provided when the account was established on the BioClinica Network. If the e-mail address has changed, update the BioClinica user profile with the preferred e-mail address (see Appendix B on page 44).

e-FAX

If this is an e-FAX enabled Trial, see Appendix C.

Sending the Study

Once a study is sent, it is temporarily cached (copied) onto the local PC. This process can take seconds or minutes, depending on the size of the study and the speed of the computer. A status indication displays at the bottom of the screen, as follows:



Study transmission begins automatically once the caching process is complete. While the study is transferring you have the option to:

1. **Click New Study** to send additional studies.
2. **Minimize** the WebSend application window and continue working on the PC while the study transfers in the background.

   Note: If you attempt to close the WebSend application while a study is being transferred, the following error message displays:

3. **Select** an option and **click OK**; or **click Cancel** to leave the application open.

Once the study is uploaded the images are deleted from the cache.

> **Note**: If the transfer is interrupted before the entire study is transferred to the WebSend Server, the files remain intact, but not uploaded to the IDC since the complete study is not present. If you reconnect within 48 hours, the data transfer is continued from where it previously left off.

Email Confirmation

Once the study is successfully transferred to the IDC, the BioClinica system automatically generates an e-mail a "Proof of Delivery" notification message, similar to the one presented in Figure 7, to you.

Dear Stephanie Paolini

The following study was successfully received and archived at the BioClinica WebSend Internet Data Center on 06/12/2012 08:55:49 EDT.

Exam Date	De-identified Name	Patient Id (Trial Pt. Id)	Timepoint	Trial/Study Routing Name	Modality	Image Count
12/27/2011 09:11:44 EST	B-C	100-400	Week 0	Protocol 2012 Test Trial	DX	4

This study was sent to one or more core labs associated with Protocol 2012 Test Trial. The patient information was de-identified as shown above before being transferred to the core lab systems.

NOTE: Click on the above de-identified name hyperlink to view images for this study. Click on the above paperclip icon to view the eFax received (if any) for this study. These links require an active WebSend user account.

Figure 7: Sample Email Confirmation

*** FAILED UPLOAD ***

Dear Stephanie Paolini

There were errors processing some of the image files in the following study when attempting to archive it to the BioClinica WebSend Internet Data Center on 06/12/2012 08:52:20 EDT.

Exam Date	De-identified Name	Patient Id (Trial Pt. Id)	Timepoint	Trial/Study Routing Name	Modality	Image Count
07/07/2008 12:00:00 EDT	C-B	123-001	Screening	CRF Demo	XA	0/6

This study was sent to one or more core labs associated with CRF Demo. The patient information was de-identified as shown above before being transferred to the core lab systems.

loop(s) failed to be archived for the following reason(s):

- 6 - DICOM files are already archived at the BioClinica WebSend Internet Data Center.

Figure 7.1 Sample Email Notification of Failed Upload

Helpful Hints

The following helpful hints should be considered when using WebSend:

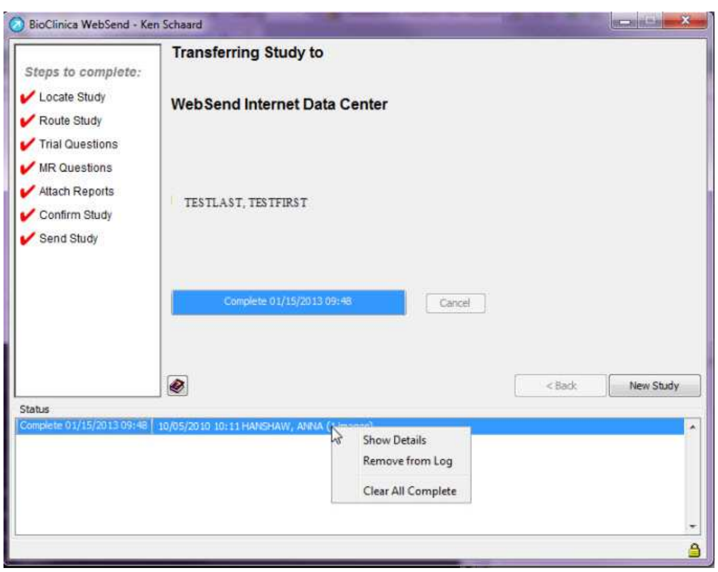
- Only one instance of WebSend can be running on the same PC at once.
- **A study can only be submitted once.** If you attempt to re-send a study, the WebSend log generates an error or if you have cleared the log and re upload the study an error email confirmation is sent. (See **Resending a Study** below.)
- If a study is missing information, you receive a prompt to enter the information. The following fields must be present:
  - Date of Birth (DOB)
  - Gender
  - Last Name
- A CD is rejected if the following information is missing:
  - Modality
  - The following DICOM Header Tags:

Tag ID	Description
0020,000d	STUDY_UID
0020,000e	SERIES_UID
0008,0018	SOP_INSTANCE_UID

Note: If your site attempts to anonymize the study prior to using WebSend, the SOP_INSTANCE_UID may be modified in the process. Altering the SOP_INSTANCE_UID can lead to lost images when uploading the study.

Resending a Study

A study cannot be resent successfully without the WebSend Status Queue first being cleared. Using the screen below, choose "Clear All Complete" or "Remove from log" from the drop-down list.

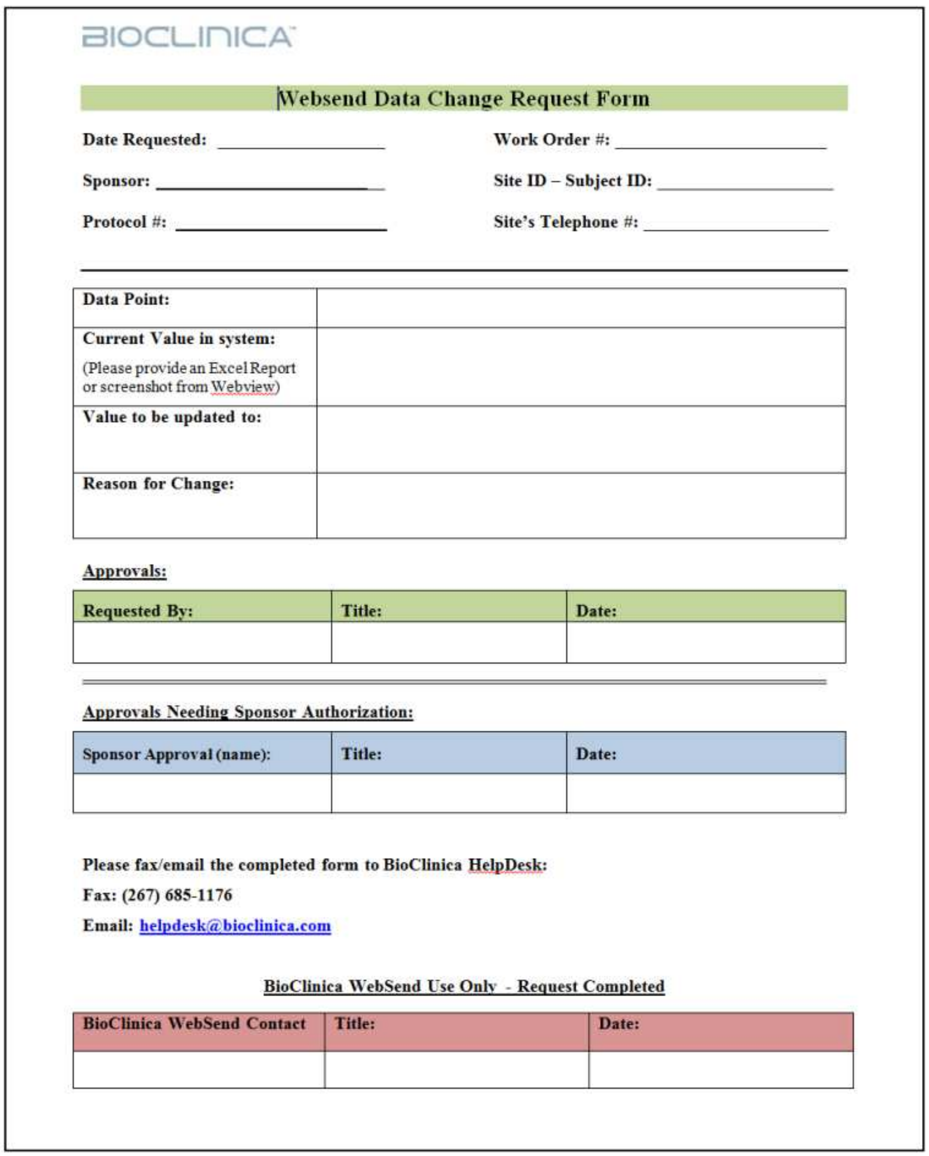


WebSend Data Change Process

In the event that you need to change data in an already uploaded study, please fill out a WebSend Data Change Request (DCR) form (image below) and email the form to the BioClinica Help Desk. The Help Desk will issue a work order number for the request and forward the request to the BioClinica WebSend Administration team for execution.

The WebSend Administration team will inform the Help Desk and the affected Core Lab when the data change request has been fulfilled.

The Help Desk will then close the Work Order and provide you with the completed Data Change Request form.



BIOCLINICA

Websend Data Change Request Form

Date Requested: ____________________ **Work Order #:** ________________________

Sponsor: ___________________________ **Site ID – Subject ID:** _____________________

Protocol #: _________________________ **Site's Telephone #:** ______________________

Data Point:	
Current Value in system: (Please provide an Excel Report or screenshot from Webview)	
Value to be updated to:	
Reason for Change:	

Approvals:

Requested By:	Title:	Date:

Approvals Needing Sponsor Authorization:

Sponsor Approval (name):	Title:	Date:

Please fax/email the completed form to BioClinica HelpDesk:

Fax: (267) 685-1176

Email: helpdesk@bioclinica.com

BioClinica WebSend Use Only - Request Completed

BioClinica WebSend Contact	Title:	Date:

WebView Portal

WebView Portal Minimum Requirements

Hardware

- Processor: 1 GHz.
- Memory: 512 MB or more.
- Monitor: 1024x768 pixel display; BioClinica recommends a greater resolution.
- Network interface card: 10baseT or cable broadband connection. Functional using 56K-band modem, but BioClinica recommends a broadband connection.

Software

- Microsoft Windows 2000, XP, 7, and Vista.
- Microsoft Internet Explorer 7, SP 1, 8 or later.
- Mozilla Firefox version 3.0 or later.
- Apple QuickTime version 6.4 or later.

Launching the WebView Portal

To launch the application via Microsoft Internet Explorer (version 7.0 SP 1 or higher) or Firefox (version 3 or higher), type the follow URL for BioClinica Secure Website:

https://websend.bioclinica.com

This URL brings you to the Login page (see Figure 8 on the next page).

Tip: For faster access to WebView Portal, create a Favorite within Microsoft Internet Explorer or Firefox or create a shortcut on the desktop.

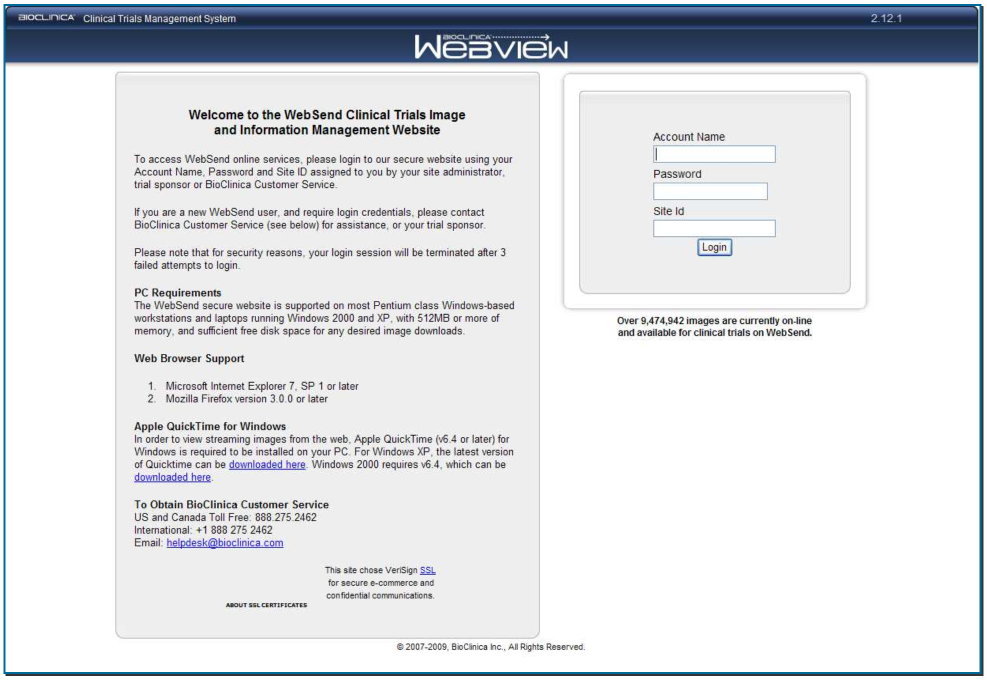


Figure 8: Login Screen

Logging On

To log on:

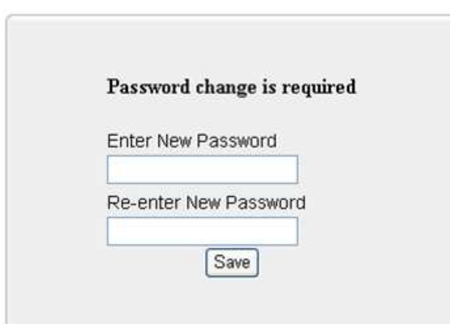
1. **Type** your BioClinica account ID (assigned by BioClinica's Client Service department) in the **Account Name** field on the Login page.

2. **Type** your assigned BioClinica password in the **Password** field.

3. **Type** your site-specific domain in the **Site ID** field.

4. **Click Login**.

   The first time you log onto the system and any time your password is reset by customer support, you are required to change your password. Note! Passwords must be between 6 and 14 characters long, include at least one numeric, one uppercase and one lowercase character.



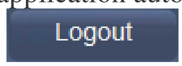
5. **Type** your new password and **click Save**.

The Search screen automatically launches upon logging in (see Figure 9 on page 25).

After a successful login, your name is displayed on the top right corner of the study page. Three consecutive failed login attempts result in an error message which notifies you that the login session is being terminated due to too many successive failed login attempts. After acknowledgement of this dialog, you should be redirected to the public www.BioClinica.com web page.

Logging Off

If the WebView Portal is inactive for 30 minutes, the application automatically logs you off by default.

To exit the application manually, **click** the Logout tab 

on the **Search** page.

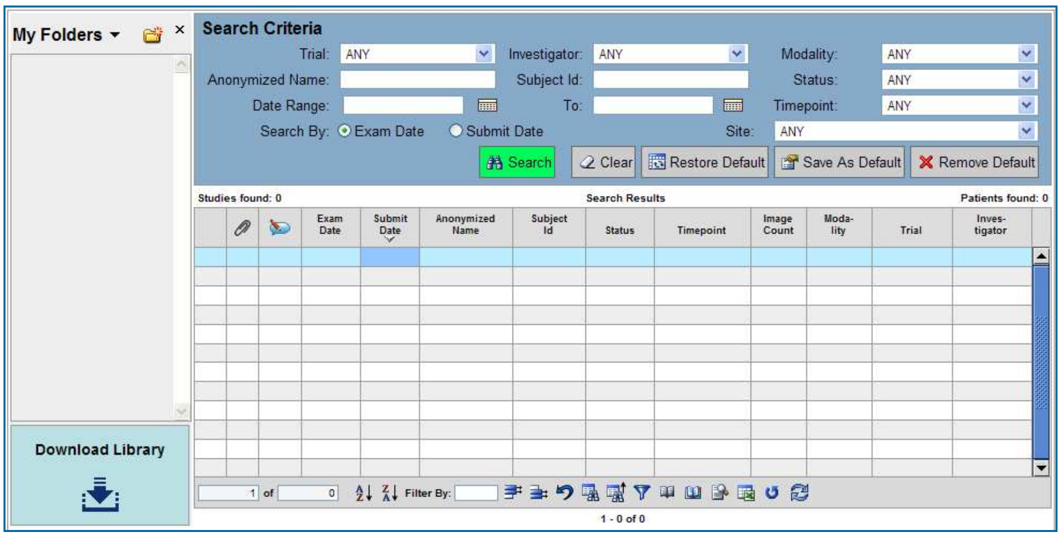


Figure 9: Search Screen

Searching for Studies

To search for a particular study set, you must provide specific information in the appropriate fields or use the multiple dropdown fields to refine your search. Narrow a search further by entering all known data. You can save all current search criteria as your default for the next login session by clicking on the **Save As Default** button located on the Search Criteria panel. The default search criteria can be cleared by selecting the Clear button and reset back to the default settings by clicking on the Restore Default button. In order to completely remove the default criteria from your preferences, select the Remove Default button (see Figure 9).

The application offers multiple ways to search for a study:

- By Trial
- By Patient Name
- By Date Range
- By Investigator
- By Trial Patient ID
- By Modality
- By Status
- By Procedure Type
- By a combination of the above search criteria

Searching For a Study by Trial, Investigator, Modality, Status, and Procedure Type

1. **Select** the **Trial** from the drop-down menu.

Selecting the trial automatically populates the drop-down menus for Investigator, Modality, Status, and Procedure Type.

2. **Select** the **Investigator** from the drop-down menu.
3. **Select** the **Modality** from the drop-down menu.
4. **Select** the **Status** (i.e. approved, billed, chart created, etc.) from the drop-down menu.
5. **Select** the **Timepoint** (i.e. baseline, clinical event, unscheduled visit) from the drop-down menu.
6. **Click Search**.

Searching For a Study by Patient Name, Trial Patient ID, or Date Range

1. **Type** the patient's name in the designated **Patient Name** field.
2. **Type** the **Trial Patient ID** in the appropriate field.
3. **Click** the calendar icon next to **Date Range** field to choose the beginning date and repeat the process next to the To field to complete the date range.
4. **Click Search**

> **Tip:** You don't have to populate all available fields when searching for a study. As stated previously, a search can be narrowed further by populating as many known fields as possible.

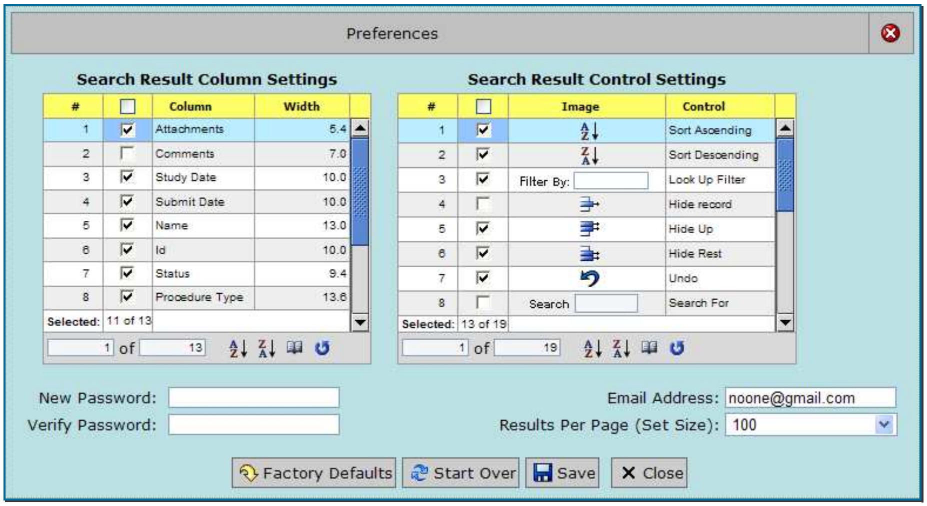
Searching For All Available Studies

1. **Click Clear** to reset all search criteria.
2. **Select Any** from the any of the (Trial, Investigator, Modality, Status, and Procedure Type) drop-down menus.
3. **Click Search**.

To search for studies by Study Date or Submit Date, click on the appropriate radio button and click the Search button.

Setting Search Preferences

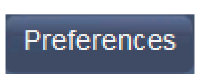
WebView Portal enables you to configure the Search Result Column Settings from the following list of available fields located in the Preferences section: Attachments (paper clip), Comments, Study Date, Submit Date, Name, ID, Status, Procedure Type, Images, Modality, Trial, and Investigator. Once configured, these settings stay in place until you change them. In the event that you do not configure the search results criteria, the factory default columns include every field except Comments. You can revert to the factory default settings by clicking on the **Factory Defaults** button located in the Preferences section.



You can also configure the Search Result Control Settings from the following list of available fields located in the Preferences section: Sort Ascending, Sort Descending, Look Up Filter, Hide Record, Hide Up, Hide Rest, Undo, Search For, Find Next, Find Previous, Match Case, Filter, Exclude, Regular Report, Grouped Report, Detail Report, Export, and Start Over. Once configured, this list applies to your ID independent of what PC or workstation is being used. If no criteria are configured, factory default settings are in place including: Sort Ascending, Sort Descending, Look Up Filter, Undo, Match Case, Filter, Regular Report, Grouped Report, Detail Report, Export, and Start Over.

Customizing the Results Per Page (Set Size) allows you to significantly affect the performance of the WebView Portal. For example, if all the search results fit within the defined set size, then all sorting, filtering, and reporting take place on the client side and are processed much faster. However, if the total search results exceed the defined set size and cause them to be divided into multiple sets, the above functions occur on the server and take longer to process.

Configuring Search Results

1. **Select** the 

tab at the top of the search page to access the Preferences dialog box.
2. **Select** the desired criteria using the check boxes for the Search Results Column Settings and Search Results Control Settings.
3. **Select Results Per Page** (Set Size) by using the drop-down menu.
4. **Click Save** to successfully update new preferences.

Tip: Click Start Over in the Preferences dialog box to reset the enabled search results columns and control settings back to their original values established at the last save operation. If a save operation had not been performed, values reset to the original settings established upon activation of the dialog box.

To Rearrange Search Results Columns

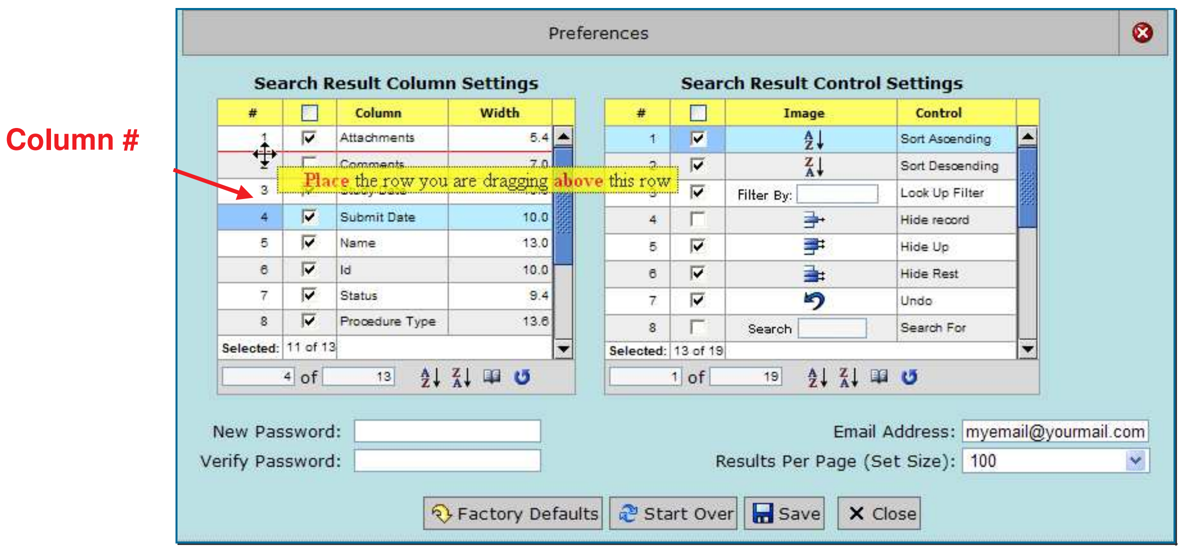
1. **Position** the **mouse** over the **column number** in the **Search Results Column Settings** area to highlight the row to be moved.

2. **Click** and **drag** the desired column number to reposition the entire row within the list of available fields.

   If the desired row is dragged in a downward direction, the message "Place The Row You Are Dragging Below This Row" displays.

   If the row is dragged in an upward direction, the message "Place The Row You Are Dragging Above This Row" displays.

   After dropping the row in the desired position, a corresponding change of column position for that field is reflected on the study list



Tip: The same drag and drop feature exists when configuring the layout in the Search Result Control Settings list.

In addition to reconfiguring search results column settings from the Preferences dialog, columns can also be rearranged manually from the search results list. You must click on a column heading and drag and drop the column to the desired position on the search results list.

The width of each column in the study list can be manually adjusted from the default setting by using the mouse to "grab" and drag the column boundary to the desired width. Both column adjustments remain in effect during a given session but revert to the default in future sessions.

Changing E-Mail

You can change your e-mail address in the Preferences dialog by entering the appropriate e-mail address in the corresponding text field. The E-Mail Address text field is located directly below the Search Result Control Settings area of the Preferences dialog.

Changing Password

You can change your password in the Preferences dialog by entering the appropriate password in the corresponding text field. For verification purposes you must re-type the same password in the appropriate text field. The password text fields are located directly below the Search Result Column Settings area of the Preferences dialog. Passwords must be between 6 and 14 characters long, include at least one numeric, one uppercase and one lowercase character.

Search Results List

Upon clicking the Search button, the search results list is displayed below the Search Criteria panel. The number of studies found for a given search is displayed at the top left corner above the search results list. The number of patients found is displayed at the top right corner. If the number of studies found exceeds the number of results per page (set size) previously configured in the Preferences section ("Setting Search Preferences" on page 27), the search results are broken up into multiple sets. Set size is located at the bottom left corner of the search results page as illustrated in Figure 11 below.

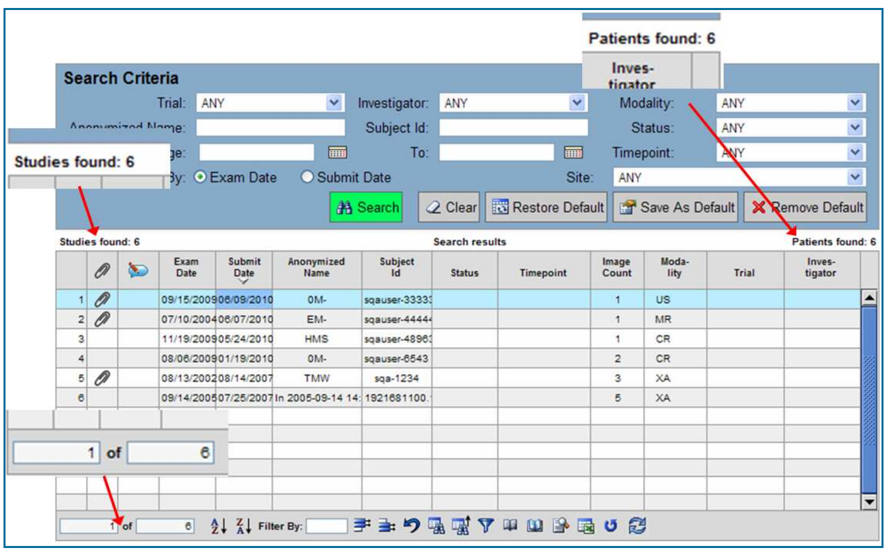
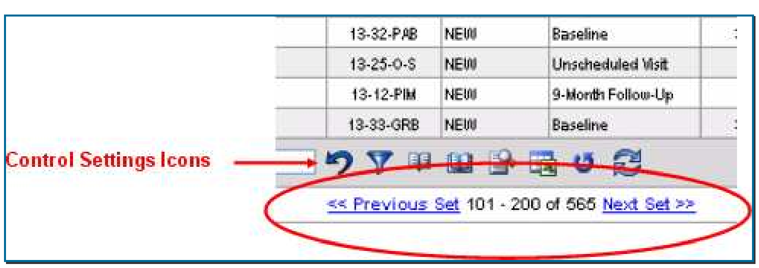


Figure 10: Search Results List

In order to access the next set of studies, click the Next Set link located below the search results list. To return to the previous set of studies, click the Previous Set link. The search result control settings are located above the Previous Set/Next Set buttons and below the search results list.

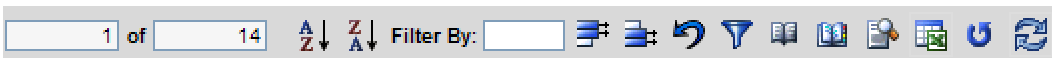


Sorting a Search Results List

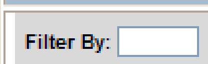
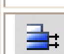
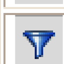
Upon initial login to the BioClinica system, the search results list are sorted by the Submit Date in descending (most recent first) order by default. You can sort the Submit Date column, as well as any other column in the search results list, by either ascending or descending order in multiple ways. The sort order is graphically indicated by an up or down arrow within each column header, up for ascending and down for descending. Clicking on the column header reverses the ascending and descending sort order (and associated arrow) each time the column is clicked.

You can also sort columns in the search results list by using the Sort Ascending and Sort Descending buttons  located on the control settings tool bar below the search results list. Left-click a cell within the desired column and click on the Sort Ascending or Sort Descending buttons to sort accordingly.

Search Result Control Settings Icons

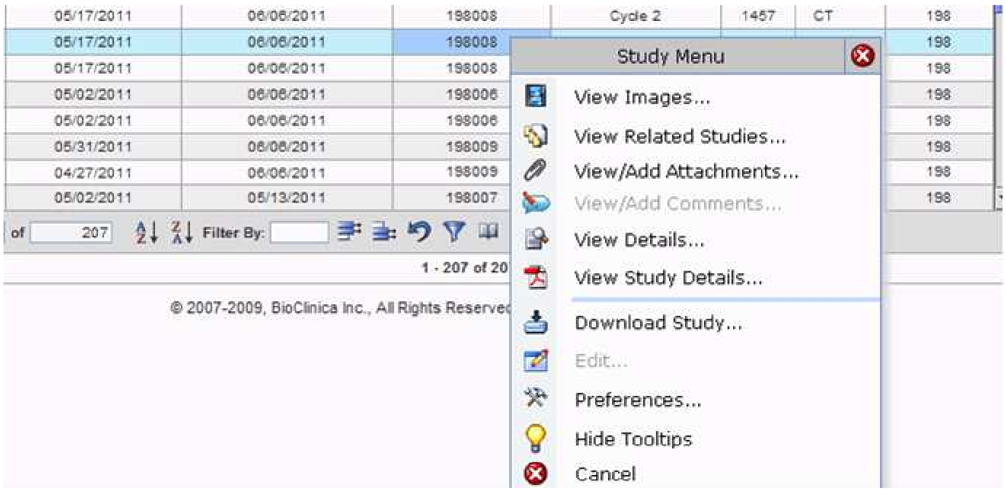


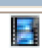
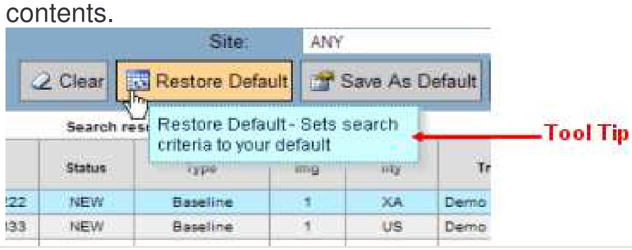
In addition to the Sort Ascending and Sort Descending icons detailed above, you can use the following control setting icons used to navigate the search results list.

Icon	Description
	**Lookup Filter** -This text entry sorting tool causes the currently selected column to be filtered by the characters typed into the text box. For example, typing an “a” in the text box results in all items starting with an “a” being displayed. If you type “ab”, then everything starting with “ab” is displayed, etc.
	**Hide Up** - Hides all records located above the highlighted record on the search results list.
	**Hide Rest** - Hides all records below the currently highlighted record.
	**Undo** - Resets the search results back to its previous state, i.e. prior to the last operation performed.
	**Filter** - Sorts a column by the currently selected cell, i.e. if the cell called “New” is highlighted within the Status column, the results are filtered to include only studies with a status of “New”.
	**Standard Report** - Generates an HTML view or report of the search results list.
	**Grouped Report** - Generates an HTML view or report of the search results list grouped by the user-selected column.
	**Detailed Report** - Generates an HTML view or report containing details of the single study you have selected.
	**Export** - Exports an entire search results list as a Comma Separated Value (CSV) text file which can be opened in Excel.
	**Start Over** - Returns the original search results records received and deletes any changes made after the initial search.
	**Restore Last Search** - Resets the search results list to the last search made.

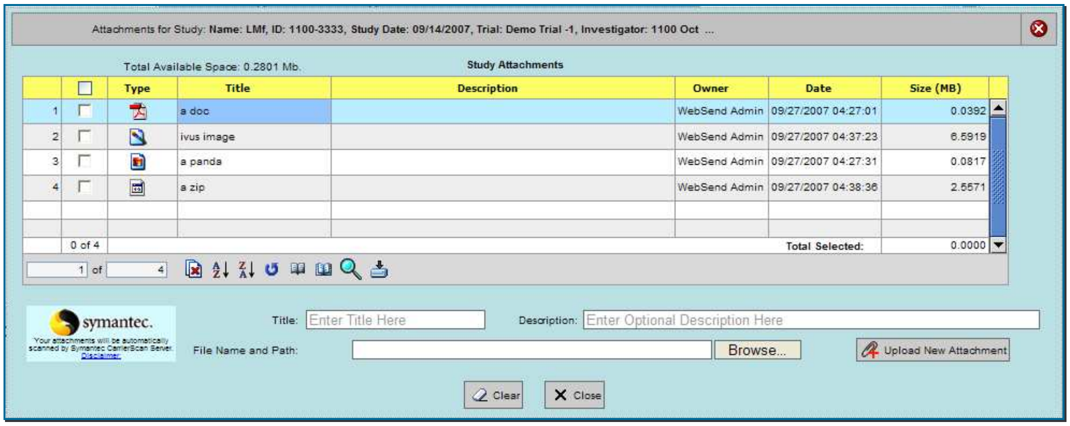
Right-Click Menu Actions

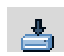
You can trigger a Study Menu of actions to be applied to a selected study by right-clicking on the selected study within the search results list.

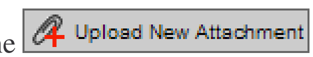


Icon	Description
	**View Images** - The pop-up Viewer Page displays (see "Opening a Study in Viewer" on page 37).
	**View Related Studies** - Refreshes the search results list to display only studies related to the selected study i.e. the: Trial Name, Investigator, and Anonymous Name or ID match exactly.
	**View/Add Attachments –** Displays a drop-down list of the attachments for a study. Double-click on the paper clip icon to display the Attachments for Study dialog (see "Displaying Attachments for a Study" on page 32).
	**View/Add Comments** – Available on a trial by trial basis only. This option is normally grayed out.
	**View Details** - Displays a pop-up of the study details dialog (see "Viewing Details on page 32).
	**Download Study** – Downloads the study to your computer.
	**Edit** – Allows Administrators to edit the items listing in the Study Details screen. This option is normally grayed out.
	**Preferences –** Displays the Preferences dialog box detailed in "Setting Search Preferences" on page 27
	**Hide Tooltips** - Eliminates the feature which gives you a description of each function on the Search Criteria screen or the control settings icon as illustrated below, as well as tips on how to view or download a folder's contents. 
	**Cancel** – Cancels the action.

Displaying/Adding Attachments for a Study

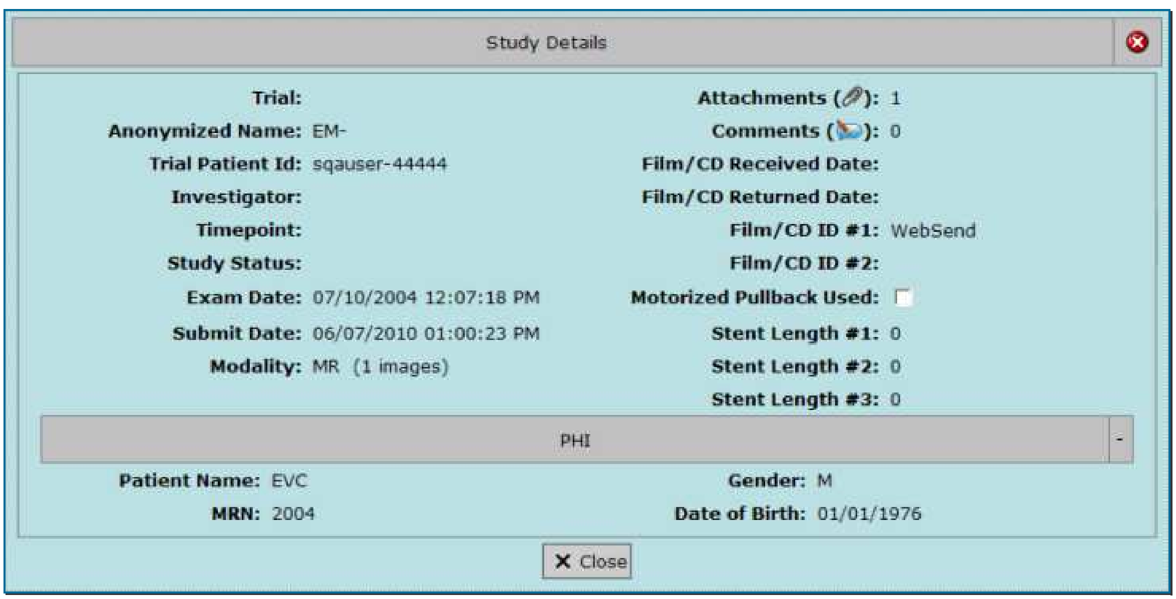


You can view and/or download a selected attachment by clicking on the View Attachment button  or Download Attachment button  located on the Attachments dialog

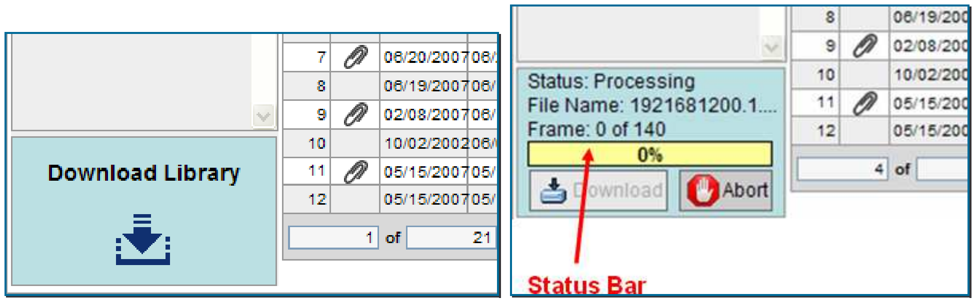
You can also add a new attachment by clicking on the 

button in the pop-up Attachments for Study dialog.

Viewing Details



You can transfer an entire DICOM study from the BioClinica IDC to a specific location on your PC by selecting Download Study from the Study Menu. When the download request is made, the Download Library section at the lower left corner of the main screen changes to a processing status bar as seen below:



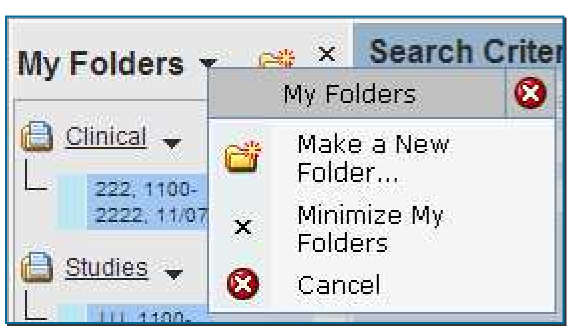
Once the WinZip file has been created on the server, the download phase starts and initiates the actual data transfer to your PC.

My Folders (On-line Collaboration)

The My Folders control located at the top left corner next to the Search Criteria screen is used to gather studies of interest in one place for on-line collaboration with other web-based users. Your user-created folders are listed below the My Folders heading and arranged in a tree view such that a folder's contents are listed below the folder itself.

The My Folders control contains a vertical scroll bar to allow you to access and view all folders not visible in the viewing area. There is no limit to the number of folders a user is allowed to create, nor is there a limit on the number of studies that can be contained within a folder.

There is an action menu associated with the My Folders control and accessible by clicking on the down arrow  next to the My Folders title. The action menu allows you to perform the actions indicated below.



To Make A New Folder

1. **Click** the down arrow to enable the My Folders pop-up dialog.
2. **Click** **Make a New Folder**.
3. **Type** the name of the new folder in the text field provided.

> **Tip:** Clicking on the new folder icon located next to the down action arrow also creates a new folder

To Minimize the My Folders Control

1. **Click** **Minimize My Folders** in the My Folders pop-up dialog.

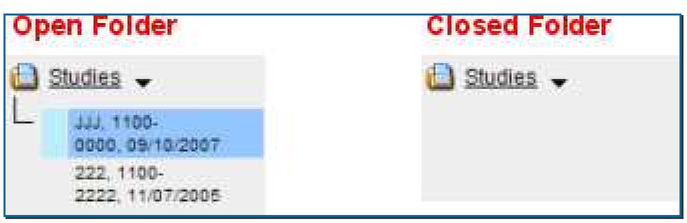
   The ***My Folders*** *control contracts leaving only the Search Criteria and Search Results list visible.*

2. **Click** the folders icon to expand the My Folders control back to its original state.

> **Tip:** Clicking the ✕ next to the new folder icon also contracts the My Folders control.

To Open and Close a Folder

1. **Click** the study folder icon next to the folder name to close the folder, i.e. hide the content tree view. In this view, only the folder name is displayed.
2. **Click** the study folder icon a second time to open. In this view, all the studies contained within the folder are displayed.



Drag and Drop Operations

You have a few drag and drop options that allow you to transfer individual studies to a folder, viewing a folder's contents in the Search Results table.

To View a Folder's Contents

1. **Click** on the folder name and drag it over the Search Results table.
2. **Drop** the folder into the table.

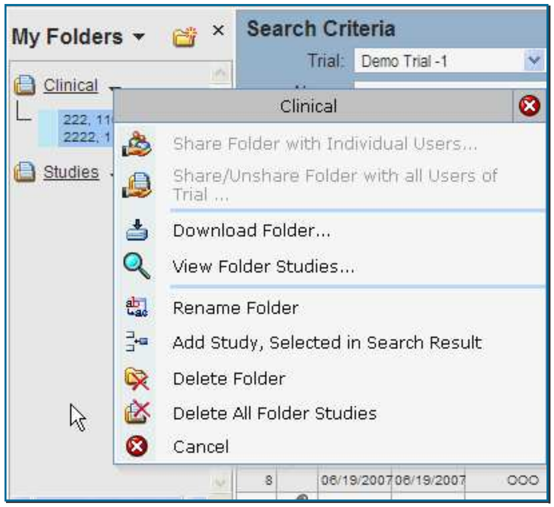
   The Search Results list becomes the Studies from Folder list displaying only those studies from the chosen folder.

To Add a Study to a Folder

1. **Highlight** a study on the Search Results list.
2. **Click** on the row number and drag the desired study to a folder in the My Folders control.
3. **Drop** the study into the folder to add it to the folder's contents.

Folder Action Menu

There is an action menu associated with each individual folder within the My Folders control which can be activated by clicking on the down arrow next to the folder name. The action menu allows you to perform the actions detailed below.



Icon	Description
	**Share Folder** displays a dialog box containing a list of all BioClinica users associated with the same home site, as well as all users with access to the same clinical trials as the folder being shared. You can use the check box to select one or more users from the list to give them access to the selected folder.
	**Download Folder** - Allows you to transfer the entire contents of the selected folder to a selected location on your PC.
	**View Folder Studies** - Changes the Search Results list from all studies in the previous search to just those contained within the chosen folder (see “To View a Folder’s Contents” on page. 35 for a similar function).
	**Rename Folder** - Creates a text field where you can enter a new name for a folder.
	**Add Study, Selected in Search Result** - Allows you to add a highlighted study in the Search Results list to a specified folder (see “To Add a Study to a Folder” on page. 35).
	**Delete Folder** - Action enables the person that created a folder to delete that folder (and all its contents) from the My Folders control and remove it from the view of shared users.
	**Delete All Folder Studies** - Deletes the contents contained in a folder but does not delete the folder itself or remove it from the My Folders control.
	**Cancel** – Cancels the action.

Opening an Image File in Viewer

To open a patient image file, double click on any line on the Search Results list to launch the image file into the viewer and display the Viewer Page (see Figure 11). The image automatically zooms to fit the viewer window upon launching. In addition to the image, the Viewer Page consists of three main components: the title bar, thumbnail images, and plug-in controls.

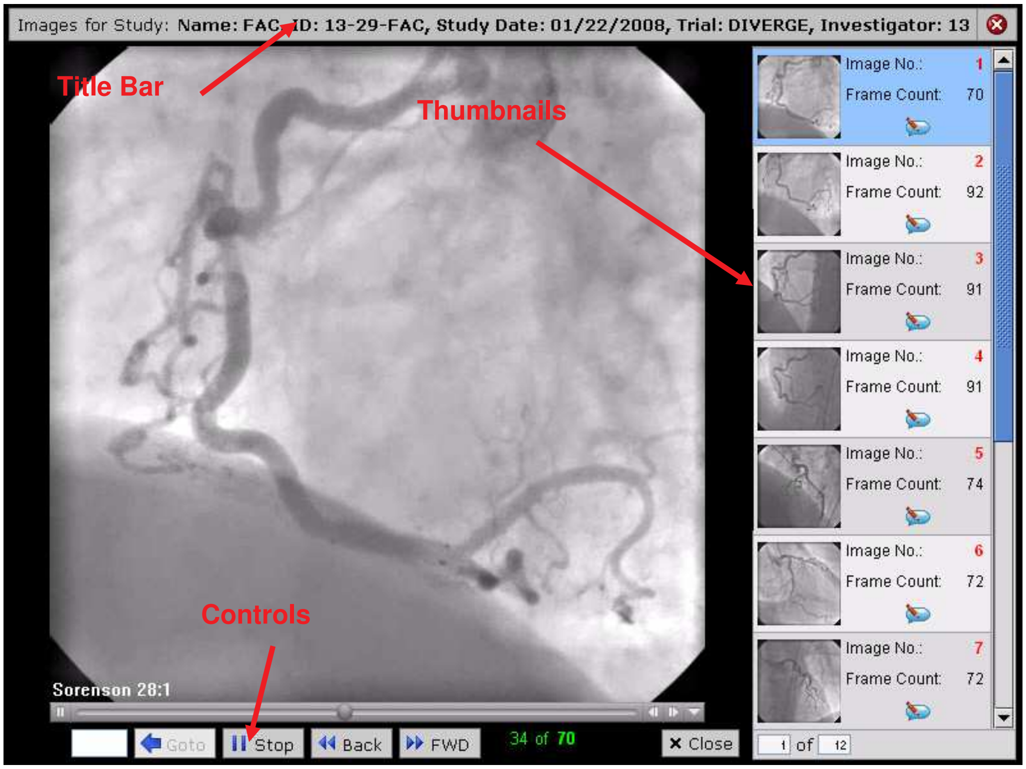


Figure 11: Viewer Page

Title Bar

The title bar on the Viewer Page displays the following information:

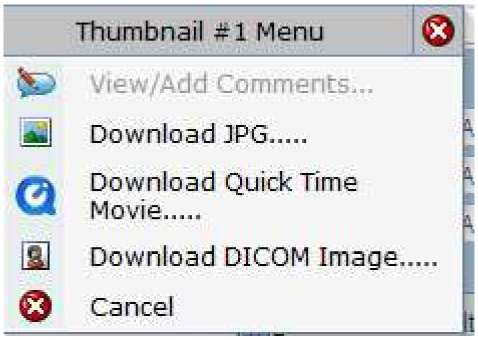
- Name, i.e. an anonymous name for a clinical user or patient name for a HSS user.
- ID, i.e. the trial patient ID for a clinical user or the patient's Medical Record Number (MRN).
- Imaging Date
- Trial Name
- Investigator

Thumbnail Images

The Viewer Page contains multiple thumbnail images on the right side of the page representing each loop or image associated with a patient study. It is possible to have more images than can be displayed on the screen at one time, in which case a vertical scrollbar is provided to allow you to scroll through all available images. Clicking on a thumbnail image causes the Quick Time plug-in to refresh and display the desired image loop. Each thumbnail contains the loop number, meaning the order in which the loop was originally acquired, and the number of frames in the current loop which can be one or more.

Thumbnail Action Menu

Right-clicking on any thumbnail image on the Viewer Page give you an action menu dialog containing the actions detailed below.



Icon	Description
	**View/Add Comments** - Allows you to add or review any notations associated with a selected image if comments are turned on for the particular trial.
	**Download JPG** - Allows you to download the selected JPG thumbnail image to a browser-managed location on the PC.
	**Download QuickTime Movie** - Enables you to download the selected image loop to a browser-managed location on the PC.
	**Download DICOM Image** - Enables the selected DICOM image file to be downloaded to a browser-managed location on your PC.
	**Cancel** – Cancels the action.

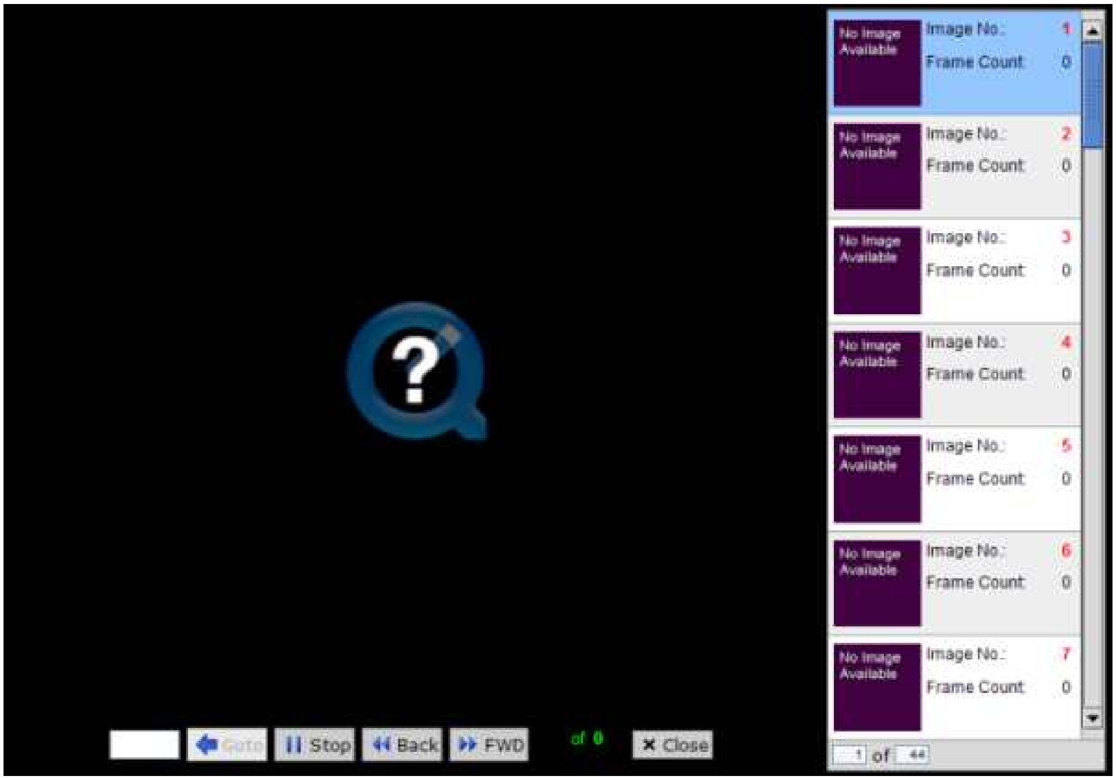
Controls and Displays

The Viewer Page uses a QuickTime plug-in to display the selected image loop and features a standard QuickTime control bar, including a built-in slider control and simply play/stop buttons. The controls also feature a real-time frame counter that shows the current frame being displayed for the current loop.

Icon	Description
Stop	**Play/Stop Button -** A toggle between play and stop which causes the selected loop to begin playing and then pause when clicked. The selected loop always begins play from the current frame number. You can reset the frame using the slider or entering a specific frame number in the Go To text box.
Goto	**Go To Button -** Clicking this button causes the movie to jump to the frame number entered into the adjoining text box. The Go To button is only enabled when the movie is in a paused/stopped state.
Back	**Back Button -** Selecting this button causes the current movie to go backwards by one frame.
FWD	**Forward Button -** Selecting this button causes the current movie to go forward by one frame.
Close	**Close Button -** Clicking on this button closes the Viewer Page and returns you to the Search Results screen.

View Images Disabled

If “view images” is disabled for a trial, no images will be available.



Appendix A: Troubleshooting

Installation Prerequisites

Consider the following topics, prior to installation:

- Secure Internet Access—Verify the connectivity to the Internet using SSL protocol. To do this, browse to the main BioClinica web site: (http://www.BioClinica.com), and click the option to access the secure site. If the login page is presented, then the access is correct. Otherwise, contact your IT department for assistance.
- Check Available Disk Space—A minimum of 300MB of free disk space is required in order to cache one average-sized procedure to the hard disk. However, if multiple studies are queued up at once, more disc space may be required, possibly as much as 1GB.

Installation Errors

The most common installation errors include:

- Java WebStart Cannot be Installed—This error is likely due to a conflict with a newer version of the Java Runtime Environment (JRE). To resolve this error, navigate to Control Panel->Add/Remove Programs and search the installed software for Java 2 Runtime Environment SE V1.6 (or later). Uninstall this version of the JRE first, and then continue with the WebSend install. After WebSend is installed, reinstall the newer version of the Java JRE (above) if desired.
- Insufficient Disk Space for Cache—If there is not at least 300MB of available disk space, this warning message displays. WebSend still uploads DICOM studies to the Internet Data Center, but the software transfers the images direct from the CD. The ability to queue up multiple studies at once is not available and the uploading process is much slower. Local anonymization is not available when there is insufficient disk space for cache.

User Credentials and Login Information

To use BioClinica WebSend, you are prompted for a user-specific account name, password and Site Id. This information is provided by BioClinica. These are the same credentials needed to log into the BioClinica secure website to view the studies that have been uploaded. Please contact BioClinica Customer Support to obtain credentials.

Performance and Internet Connectivity

WebSend works with any speed Internet connection, however a **384K (DSL) connection or better** is recommended for best results given the size of most DICOM studies.

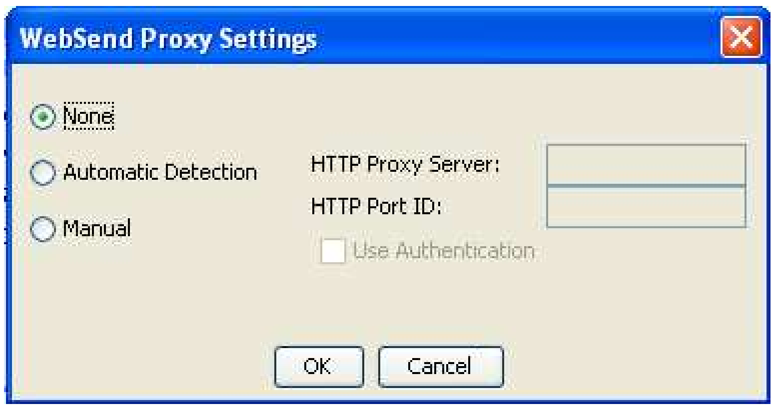
WebSend is also designed to work as a "background" program. Multiple studies may be cached (copied) from CD to the local hard drive, and in turn are queued for transmission to the BioClinica Internet Data Center. While images are being transferred in the background, the PC is available for use at the same time, and/or let WebSend run overnight. The WebSend application can be minimized (to the Windows task tray) so that it does not get in the way of other work.

Network Proxy Environments

For purposes of security, it is common practice in corporate and/or hospital environments for Internet connectivity to use a "Proxy" server. A proxy server is a gateway, through which all Internet traffic is routed and controlled.

BioClinica WebSend software supports these proxy environments, and in most cases, automatically configures itself for the proper settings. In the event a connection to the BioClinica IDC cannot be established, an error message to this effect is displayed. Manual configuration of the proxy server settings may be required.

To manually configure the proxy settings, launch WebSend. On the initial login screen, click the "Proxy Settings…" button. You can click the "Manual" option to override automatic detection, and enter the IP address and Port # for the proxy server. Contact the local IT department if these settings are not known.



If the proxy server environment requires "authentication", then check the "Use Authentication" box on this screen. Using authentication means that you are prompted to login to the proxy server each time the WebSend application is run. The account and password to the proxy server is provided by the local IT department.

If proxy settings have been verified to be correct, but connectivity to the BioClinica Internet Data Center still cannot be established, then there may be a conflict with a specific configuration of the Microsoft Internet Security and Acceleration (ISA) Server. If the IT department is using Microsoft ISA, then please contact BioClinica Customer Service for further assistance.

Problems Reading DICOM CDs

BioClinica WebSend is compatible with the latest DICOM 3 standard, Part 10 for CD and CD-R media interchange. If a particular CD cannot be read by the application, it is likely that the CD is in some way non-DICOM compliant. The most common causes are:

- Image files are not in DICOM 3 format (e.g. .gif, .jpeg, .bmp, etc.)
- Corrupt or damaged CD or CD-R media (DVD?)

In these cases, BioClinica suggests trying to read/view the CD using another vendor's DICOM Viewer. If it can be viewed by a third-party viewer but cannot be read by WebSend, please contact BioClinica Customer Service for assistance. A copy of the CD will be requested for analysis.

Confirmation Email

On the Confirm Study Screen of the WebSend application, there is an option to receive an email confirming the upload of the study. **BioClinica highly recommends that you always request this confirmation**.

The contents of the email indicate success or failure for the given upload. When successful, you can visit the BioClinica secure web site immediately afterwards to view the study/images using WebView™.

In the event of an error, the reason for the failure is indicated in the email. Always contact BioClinica Customer Service immediately when errors are indicated, for resolution and tracking of the problem. The most common issues are:

- *Duplicate files* — The image file or files already exists at the BioClinica IDC, and it cannot be uploaded again. This may occur if the file or files have been previously transmitted to the IDC from another BioClinica-enabled hospital site, or previously from this site.
- *Non-DICOM or Corrupt Image Files*— The images were not DICOM compatible, or could not be read.
- *Virus Detected* — A virus in either an image or attachment was detected.

Appendix B: Changing User Profile Information

Overview

User login credentials within the BioClinica system are consistent between all related BioClinica applications including WebSend and the BioClinica secure web site. In other words, all BioClinica applications use the same user account name, password and Site ID.

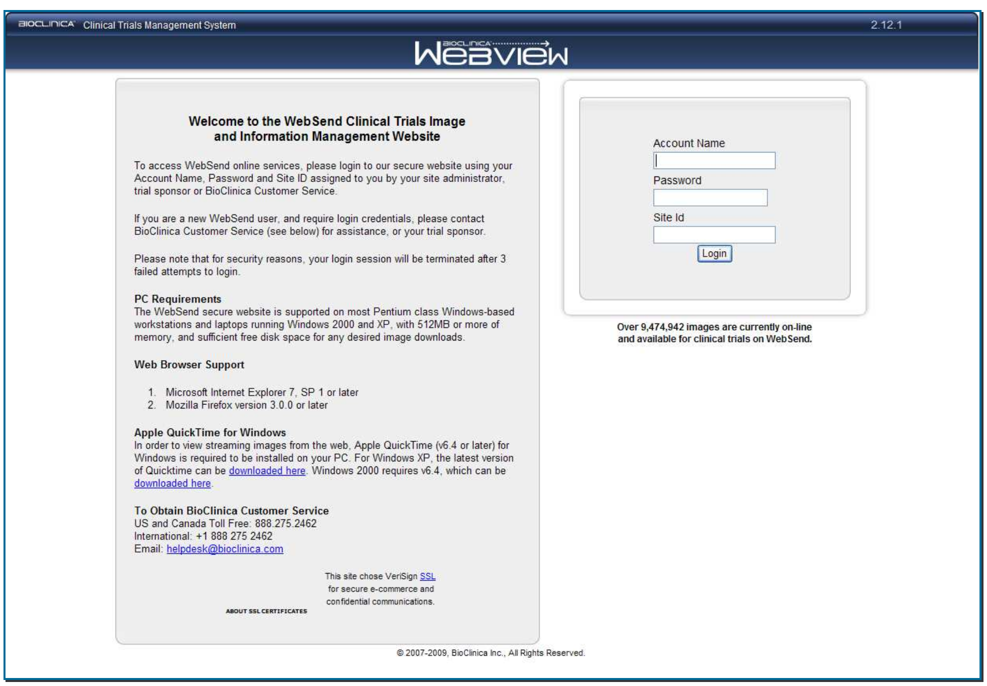
BioClinica users are responsible for periodic maintenance of their own account information including password and email address changes. The most convenient and easiest place to make these user profile updates is the BioClinica secure web site. Procedures for changing the password and/or email address are outlined below.

> **Tip:** Changes to the account information made via the secure web site are automatically synchronized with all other BioClinica applications

Password or Email Change Procedure

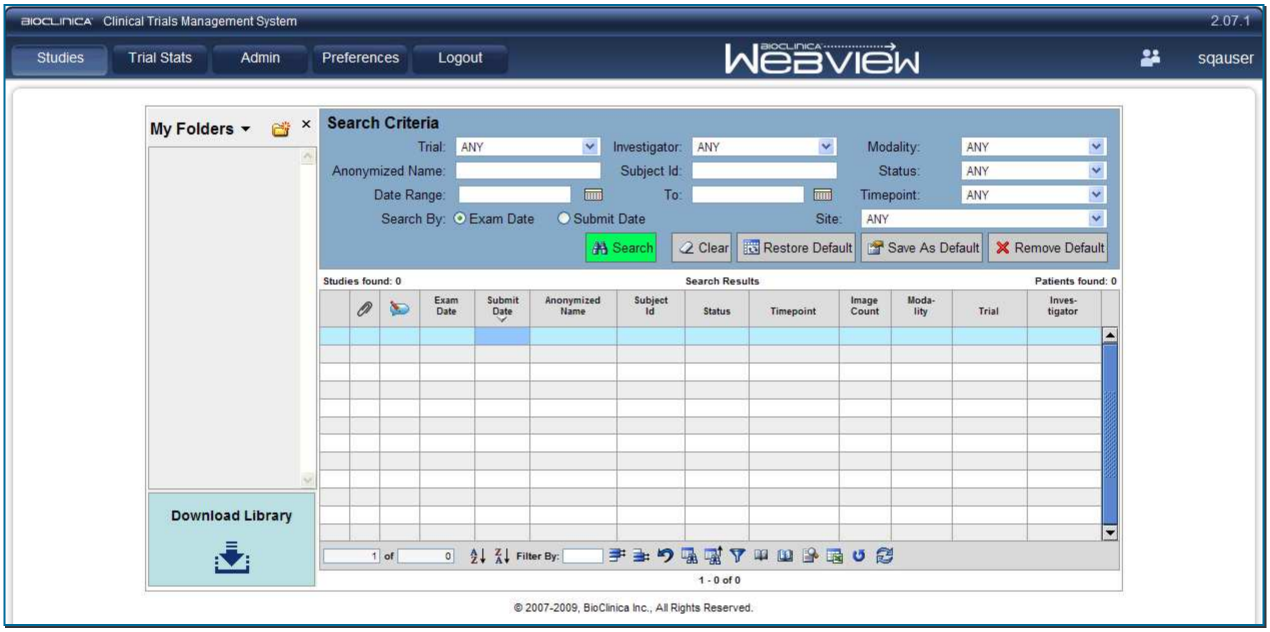
To change a password or email address:

1. **Open a web browser** and **navigate** to the WebSend Portal login page. The web site address (URL) is: https://websend.BioClinica.com as shown in the following:

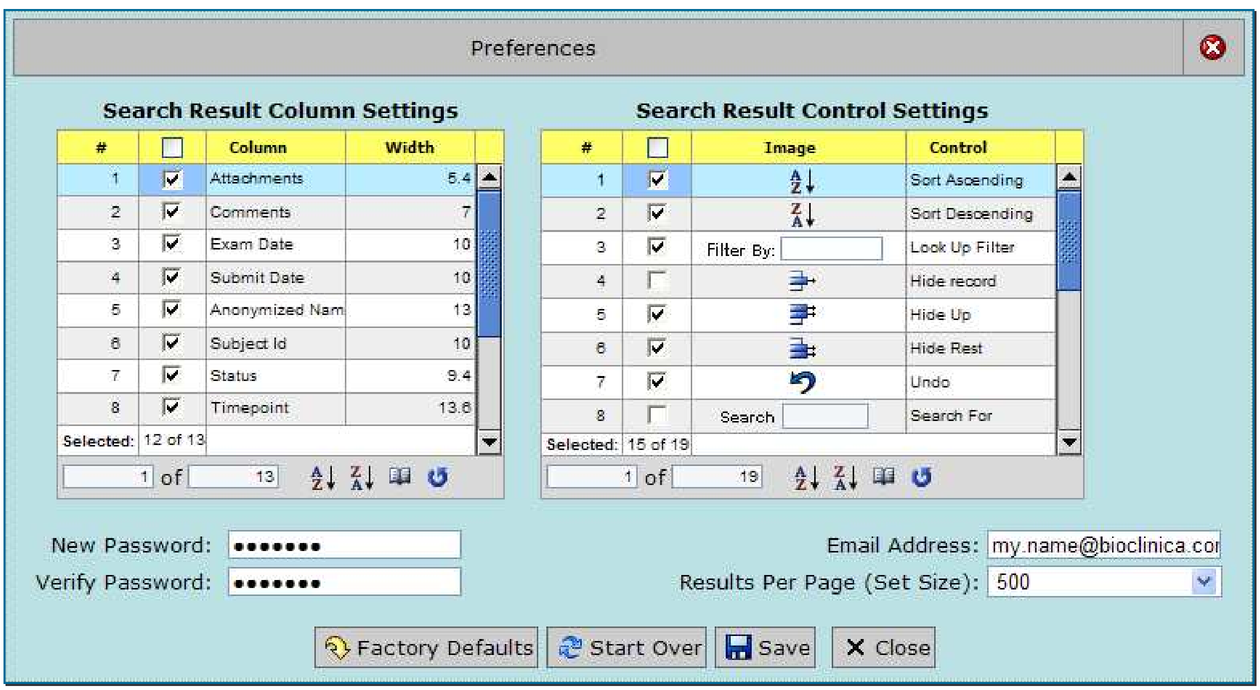


2. **Enter** the current **login credentials** (account name, password and site ID) on the login page, and click the Log In button. If the login credentials are unknown, please contact the site administrator, trial coordinator, or contact BioClinica customer service.

3. From the WebSend Search page, **click** the **Preferences** button at the top of the page, as follows:



4. In the Preferences window, enter the new password in both New Password and Verify Password text entry boxes as follows:



5. **Change** the email by typing over the information in the Email Address field.

6. When complete, **click Save**.

Appendix C: e-FAX

e-FAX

A fax cover page containing a bar code is generated for you. You should print the page and fax it to BioClinica using the numbers on the cover sheet, along with the worksheet documents required to be sent for your study. These documents are automatically converted to Adobe Acrobat format (.PDF) and attached to the proper record using the barcode on the cover page.

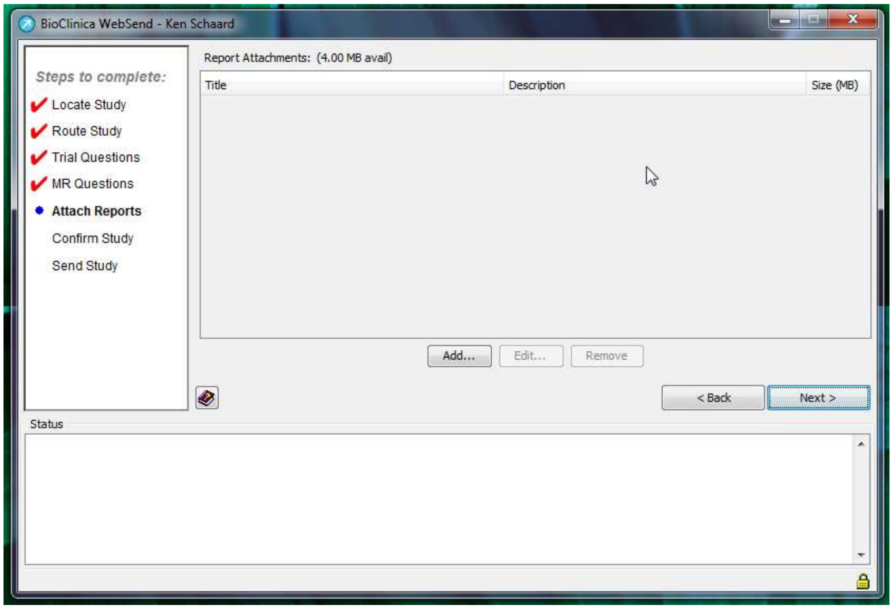
Remember to **only fax one e-FAX cover page and associated documents at a time** – do not fax a stack of e-FAX cover pages and documents as one fax transmission.

If you do not see e-fax page, you can **right click** on the **Status** section of the Confirmation page to display the page.

Note: If the fax is not sent, an email reminder is generated every 24 hours to remind you to fax the documents.

Appendix D: Attaching Reports

Attaching Reports



If the clinical trial requires that you submit reports with the medical imaging study, the above Attach Reports Screen displays prior to the Confirm Study Screen.

To attach report(s):

1. **Click Add**, which opens the following window.

2. **Click Browse** to select a file to attach to the submission. **Type** a title for the file (required) and a description (optional). **Click OK**.
3. Once the file has been attached, additional files can be attached using the same procedure.

To remove a file:

1. **Highlight** the file in the attachment list and **click Remove.**
2. To edit the title, description, or file of an attachment, highlight the attachment in the attachment list and **click Edit**.
3. Once all reports are attached, **click Next>**.

Appendix E: Supported File Compressions

WebSend supports transmission of files with the following compression types:

- Explicit VR Little Endian.dcm
- Implicit VR Little Endian.dcm
- JPEG Baseline.dcm
- JPEG Extended.dcm
- JPEG Lossless 1.dcm
- JPEG Lossless 3.dcm
- RLE Lossless.dcm