Site Imaging Manual

DECAMP-1 4703

Detection of Early Lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules
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History of Revisions:

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Letter of Introduction

Dear Fellow Researchers,

This ACRIN 4703 Imaging Manual for Imaging and Image Submission contains the guidelines for image acquisition, processing, storage, shipping, and documenting of all imaging data collected in this study for the ACRIN 4703 trial, “Detection of Early Lung Cancer Among Military Personnel Study 1 (DECAMP-1): Diagnosis and Surveillance of Indeterminate Pulmonary Nodules”

To successfully meet the study objectives, it is critical that the participating sites follow the instructions and guidelines outlined in this manual.

Quality Control (QC) review of all image data will be performed by the ACR Imaging Core Laboratory. This review will be performed in a timely fashion as part of ACRIN standard operating procedures. If any protocol deviations or technical issues are identified during the QC review, an ACR Core Lab Imaging Technologist will contact your site to provide feedback expeditiously. This will allow your site to make any necessary adjustments early in the conduct of the study.

The ACRIN 4703 Research Team wishes to thank you in advance for your diligence in adhering to the procedures described in this manual to ensure the integrity of the image data collected for the study. Please do not hesitate to contact the ACRIN 4703 Research Team.

Sincerely,

Joseph J. Bauza RT(R)(CT)
ACRIN 4703 Imaging Technologist

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JBauza@acr.org
ACRIN 4703 Study Schema

Detection of Early Lung Cancer Among Military Personnel
Study 1 (DECAMP-1):
Surveillance of Indeterminate Pulmonary Nodules
1.0 OVERVIEW OF IMAGING REQUIREMENTS

<table>
<thead>
<tr>
<th>TRIAD Installation</th>
<th>TRIAD should be installed prior to study participant enrollment for secure, electronic submission of imaging to ACRIN.</th>
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</table>
| Image Acquisition          | • Baseline standard of care (SOC) chest CT  
• Yearly follow-up imaging per institutional standards. Imaging may include chest xray (CXR), chest CT, PET-CT, as per institutional norms |
| Image Submission           | ACRIN 4703 SOC imaging should be submitted in DICOM format to the ACR Imaging Core Lab via TRIAD. All imaging should be submitted within 48 hours after acquisition and should include an Image Transmittal Worksheet (ITW). |
| Data Queries               | ACRIN will issue queries, as needed, based on QC review of imaging. |

General Trial Requirements:

- All CT exams must be acquired on a low dose ≥16 slice helical scanner
- Site must submit all SOC to ACRIN within 48 hours after acquisition

2.0 STUDY OVERVIEW/SPECIFIC AIMS

2.1 Overview
The Detection of Early lung Cancer Among Military Personnel (DECAMP) consortium is a multidisciplinary and translational research program that includes 7 Veterans Administration Hospitals (VAH), the 4 designated Military Treatment Facilities (MTF) and one academic hospital. The goal will be accomplished by recruiting 500 smokers with indeterminate pulmonary nodules (0.7cm-2cm) on chest CT who will undergo fiberoptic bronchoscopy and will be followed for 2 years until a final diagnosis is made.

2.2 Primary Aim
To determine the diagnostic accuracy of genomic and proteomic biomarkers in the airway, and blood to detect lung cancer in the study cohort.
2.3 Secondary Aim
To evaluate the added diagnostic value of the molecular biomarkers to routine clinical and radiographic features used in diagnostic workup of pulmonary nodules.

3.0 Participant Eligibility

3.1 Inclusion Criteria
- 50 years of age or older
- Initial diagnosis of indeterminate pulmonary nodule (0.7-2.0 cm)
- Current or former smoker with ≥ 30 pack years (pack years = number of packs per day X number of years smoked)
- Willing to undergo fiberoptic bronchoscopy
- Able to tolerate all biospecimen collection as required by protocol
- Able to comply with standard of care follow up imaging for a minimum of two years
- Able to fill out Patient Lung History questionnaire
- Willing and able to provide a written informed consent

3.2 Exclusion Criteria
- History or previous diagnosis of lung cancer
- Diagnosis of pure ground glass opacities on chest CT
- Contraindications to nasal brushing or fiberoptic bronchoscopy including ulcerative nasal disease, hemodynamic instability, severe obstructive airway disease, unstable cardiac or pulmonary disease; inability to protect airway or altered level of consciousness;
- Allergies to any local anesthetic that may be used to obtain biosamples in the study.
4.0 CT Image Acquisition Recommendations

The ACRIN 4703 protocol is a study to evaluate pulmonary nodules. Recognizing that the DECAMP-1 protocol is utilizing standard of care imaging (SOC), the following Hi Resolution imaging parameters have been chosen as a guide to incorporate a variety Multi-Detector Cat Scanners. Every attempt must be made to incorporate dose parameters As Low As Reasonably Attainable.

**NOTE:** These parameters should be utilized for all follow-up CT imaging to allow for future 3D post processing if necessary

<table>
<thead>
<tr>
<th>Series</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scout/Topogram</strong></td>
<td>• 100 kV&lt;br&gt;• 10-40 mA&lt;br&gt;• On Inspiration</td>
</tr>
<tr>
<td><strong>Hi-Resolution</strong></td>
<td><strong>Axial Imaging</strong>&lt;br&gt;• 120 kV&lt;br&gt;• mA: per standard of care&lt;br&gt;• Utilize Dose Modulation&lt;br&gt;• Single Collimator Width&lt;br&gt;  <em>Sub-Centimeter to allow for 1mm Post Processing</em>&lt;br&gt;• 5mm Slice Thickness&lt;br&gt;• 5mm Slice Spacing&lt;br&gt;• Soft Tissue Algorithm (Kernel) -and-&lt;br&gt;• Bone/Lung Algorithm (Kernel)</td>
</tr>
<tr>
<td><strong>Post Processing</strong></td>
<td>• <strong>Axial Plane:</strong>&lt;br&gt;  o 1mm Slice Thickness&lt;br&gt;  o 1mm Slice Spacing&lt;br&gt;  o Soft Tissue Algorithm (Kernel) -and-&lt;br&gt;  o Bone/Lung Algorithm (Kernel)&lt;br&gt;• <strong>Sagittal Plane:</strong>&lt;br&gt;  o 1mm Slice Thickness&lt;br&gt;  o 1mm Slice Spacing&lt;br&gt;  o Bone/Lung Algorithm (Kernel)&lt;br&gt;• <strong>Coronal Plane:</strong>&lt;br&gt;  o 1mm Slice Thickness&lt;br&gt;  o 1mm Slice Spacing&lt;br&gt;  o Bone/Lung Algorithm (Kernel)</td>
</tr>
</tbody>
</table>
5.0 Image Data Submission

Each participating site is required to submit CT and all other follow-up image data to the ACR Imaging Core Laboratory within 48 hours of the image acquisition.

5.1 Image Transmittal Worksheet (ITW)

All image submissions should include an Image Transmittal Worksheet (ITW). An Image Transmittal Worksheet (ITW) is used during the exam QC review to verify a complete transfer of images has been submitted to the ACR Imaging Core Lab. The ITW is completed in the Medidata/Rave data management system and upon the completion of this form, an email will be automatically generated to the ACRIN Imaging Technologist to notify an image submission has taken place.

5.2 Image Submission via TRIAD

The preferred image transfer method is via TRIAD. TRIAD is a software application that ACRIN provides for installation on a site’s PC. One or several computers of choice within the institutional “firewall” and on the institutional network may be equipped with TRIAD software; internet access is also required. The TRIAD application can then be configured as a DICOM destination on either scanner(s) and/or PACS system for direct network transfer of study related images into the TRIAD directory. When properly configured, the TRIAD software anonymizes, encrypts, and performs a lossless compression of the images before they are transferred to the ACRIN image archive in Philadelphia.

5.3 Image submission via CD/DVD media

The other option for image submission includes submitting images in DICOM format via a CD/DVD

Please label with the following information:

- Site Name
- Trial Name (ACRIN 4703)
- Date of Imaging (DD-MMM-YYY)
- Type of Imaging (e.g. Chest Xray (CXR), CT Chest, PET-CT)

Ship all disk media, along with a copy of an Image Transmittal Worksheet to:
American College of Radiology
1818 Market St., Suite 1600
Philadelphia, PA 19103
Attn: ACRIN 4703 Imaging Technologist
6.0 Image Quality Control (QC)

6.1 ACRIN Core Laboratory Quality Control Technical Review

The ACRIN 4703 protocol explicitly requires participating centers to meet technical specifications of the Cat Scanners for data uniformity and image quality. Additionally, specific parameters for image acquisition are outlined in the protocol and provided in this manual. ACRIN will provide ongoing quality control through the ACRIN Imaging Core Laboratory. Specifically, the ACRIN Imaging Core Laboratory will conduct quality control evaluations on all submitted imaging data to help centers maintain trial grade quality. The ACR Imaging Core Laboratory Imaging Technologist will provide feedback to sites, especially during early trial imaging to ensure high-quality images. However, repeat of imaging will not be requested once the trial is under way.

6.2 Image Data Queries

If it is found during the QC review that the submitted exam has missing data or does not follow the protocol guidelines, detailed in this manual, the Medidata/Rave data management system will generate an auto-query. Sites are expected to resolve data queries expeditiously. Queries not resolved within 7 business days will be sent to the ACRIN 4703 trial team for additional follow-up.
Appendix I

Sample:
Image Transmittal Worksheet
Sample: Image Transmittal Worksheet

Purpose of the Worksheet:

The Image Transmittal worksheet is utilized by the ACRIN Imaging Technologist during the exam QC review to verify a successful exam submission to the ACR Imaging Core Lab. This worksheet is completed in the Medidata/Rave data management system and upon the completion of this form, an email will be automatically generated to the ACRIN Imaging Technologist to notify an image submission has taken place.
Appendix II

Tips for Creating a CD/DVD
Tips for Creating a CD/DVD

Tips:

- Always utilize a **DICOM Compliant** CD/DVD
- Utilize a **CD-R** for exams less than 700MB in size
- Utilize **DVD+R** (4.7GB) for exams larger than 700MB in size
- Exams **should not** be archived on multiple disks, as the potential for missing data is increased
- Utilize a workstation that has the capability of anonymizing patient information without altering the original format of the image
  
  **Note**: This workstation is usually in the Cat Scan Suite or can be created in the film library
- CD/DVD labeling **must be** done using a dedicated CD/DVD inkjet printer or thermal printer
- Adhesive labels **must be** made on a dedicated label maker to prevent an unbalanced CD/DVD
- A fine point or rolling ball marker **should not** be utilized on a CD/DVD for they have the potential of depressing the surface of the disc and permanently damaging the data layers
- The following information should be included on the disk label:
  - Site Name
  - Trial Name (DECAMP- 4703)
  - Date of Imaging (DD-MMM-YYY)
  - Type of Imaging (e.g. Chest Xray (CXR), CT Chest, PET-CT)
Appendix III

TRIAD User Registration Procedure
TRIAD User Registration Procedure

➢ **Purpose:**

The purpose of this document is to explain steps required for TRIAD user registration

➢ **Procedure:**

1. Open the following link (Triad Web Portal) in a web browser
   
2. Provide the required details in the “Login Information” screen.

a. **Username:**
   This will be required when you try to login to Triad Web Portal or Triad Windows Client
   - Should be minimum 8 and maximum 20 Characters
   - Should contain combination of Upper & Lower case alphabet(s) and Numeral(s)
   You can check the availability of provided username from ‘Check Availability’ button provided under the field.

b. **Password:**
   Provide a desired password which will be required when you try to login to Triad Web Portal or Windows Client from the next time.
   - Should have minimum 8 characters
   - Should contain combination of Upper & Lower case alphabet(s) and Numeral(s)

c. **Confirm Password:**
   Provide the same password that was given in the previous field

d. **Security Question:**
   Please select a security question from the list that can be expanded from dropdown or you can type your own question in the same field.
   **Note:** Remember the Question, it will be required if you have forgot and need to retrieve your password.

e. **Answer:**
   Provide the answer for the Question selected or entered.
   Please remember the answer for the question for future purposes or further levels of authentication.

3. Click ‘Continue’ to move to the ‘User Information’ screen.
4. On the ‘User Information’ screen provide the following information:
   
a. **First Name, Middle Name and Last Name:**
   Provide the user’s First Middle and Last names as desired

b. **E-mail & Confirm E-mail:**
   Provide a correct and valid e-mail address of the user. This e-mail address is
   used to send a verification mail during the rest of the registration process which
   will help to activate your account. The same e-mail address will be used for
   communicating with the user in future. Provide the same e-mail address in the
   confirm e-mail field

c. **Mailing address:**
   Provide the contact address of the user

d. **Phone Number:**
   Provide the user’s phone number in the mentioned format (along with ‘−’)

e. **Additional Information:**
   Provide any additional information in the field that could be necessary.
   **Note:** The fields that are marked as (*) are required to be filled compulsorily to
   move to the next screen

5. Click ‘Continue’ to move to the ‘Trial Details’ screen
6. On the ‘Trial Details’ screen and provide the following information:
   a. **User Type:**
      Select the User type as ‘Non-ACR Staff’
   b. **Trial:**
      Select any Trial in which your facility is participating with ACR from dropdown.
      *(It is not required to select all the Trials in which your facility is participating; you may select just one of them.)*
   c. **Site:**
      Select the Site for which you are registering the account from the dropdown list

7. Click on ‘Continue’ to move to the ‘Confirmation’ Screen
8. Verify the information displayed on the Confirmation screen and check if there are any changes that need to be done.

9. If everything seems to be fine, click on ‘Confirm’. If you need to edit anything, click ‘Back’ button to the corresponding page and modify the information and proceed with previous steps and come back to ‘Confirmation’ page.

10. You should then be taken to a screen with ‘Success’ and will also receive an e-mail to the address provided in the User information screen.
TRIAD User Registration Procedure

11. The e-mail sent contains a confirmation link along with the details of the Username and Password that you have provided during registration.

Note: You may save this e-mail in case if you forget your authentication details.

12. Click the confirmation link provided in the e-mail (or) if it doesn’t work, copy and paste the link into a web browser for a confirmation message in your browser.

13. You will then receive the following e-mail that the Registration is complete.
TRIAD User Registration Procedure

14. Even though the registration is complete, the account created is not yet ready for use until the TRIAD (ACR) Administrator activates the account. You will receive another e-mail once your account is activated which will look like the following.

15. Now you can start using your account to login to the Triad Web Portal or Triad Windows Client to submit exams to ACR through TRIAD.
Appendix IV

TRIAD Web Client Installation Procedure
TRIAD Web Client Installation Procedure

➤ **Purpose:**

The purpose of this document is to explain steps required for installing the TRIAD web client.

➤ **Procedure:**

1. Login into Triad Web Portal (click here) with the username and password registered and activated for TRIAD

2. Select the ‘Submission’ tab and go to ‘Submit files’ page.

3. To setup submission controls from web page, please use the following instructions and run the setup as a local Administrative user. (This installation is only required one time at the beginning.)

4. Click here to download the setup package and extract it after the download completes.

5. Right click the ‘Setup.bat’ file and select ‘Run as Administrator’ from the context menu.

6. System shall prompt for username and password. Provide local administrative user details in the prompt to proceed with the installation.
TRIAD Web Client Installation Procedure

7. System shall display a command prompt while running the installation.

8. Microsoft Silverlight is required to send images through web client. You will be asked to install it while running the setup. If you already have it installed, you can close the Silverlight window. If you don’t have it, click ‘Install now’ to install Silverlight.
9. Once all the steps in installation are completed, the command prompt shall display as follows.

10. If you are using Microsoft Internet explorer for submission through web, please continue to perform the following steps (if not skip to Step 11):
   a. Open 'Internet options' from right hand top corner of IE browser.
b. Go to the 'Security' tab and select 'Trusted Sites'.

c. Click 'Sites' button and add the Triad website URL to the trusted website and close.
11. **Restart** your browser and login to Triad URL using your registered Triad account.

- [https://cr-triad4.acr.org/TriadWeb4.0](https://cr-triad4.acr.org/TriadWeb4.0)
Windows Client Installation and User Guide

TRIAD 4.0
Hardware & Software Requirements

Hardware requirements (recommended):

- 4 GB RAM
- 2.4 GHz Processor
- 150 GB Hard Disk space

Software requirements:

- Microsoft .NET 4.0 Framework Full Version (requires administrative privileges on the computer to install)
- OS: Window XP (SP2, SP3), Windows 7 (32 or 64 bit)
Installation

- Please open the following link to install TRIAD 4.0 Windows Client:
  
  https://cr-triad4.acr.org/TriadClient/

- TRIAD will launch after the installation is completed successfully.
- Please make sure you register for a TRIAD account before you login to the Windows Client. Details on how to register are provided in the TRIAD User Registration User Guide.
Logging in to TRIAD

Use the Username and Password that you have received when registered on TRIAD website.
Select Site & Trial Information

Select the Site & Trial from the dropdowns for which the files are to be uploaded.
Submission Sources

- TRIAD provides features for submitting files from multiple sources:
  - Local computer / network drive: Files can be located in local computer folders, local CD/DVD drives or network drives. There are two ways to get upload data:
    - Files: User can select single or multiple files
    - Folders: User can select a folder and by selecting folder, all files in the folder will also selected automatically
  - PACS: TRIAD has ability to query PACS for the study to submit
Submit Files from Computer / Network Drive
Submit Files from PACS (1/3)

Select ‘Choose Files from PACS’ and click ‘Choose Files’ button to open a new window to search for images in PACS.

Click ‘Manage’ to add information of PACS from where you will retrieve files.
Submit Files from PACS (2/3)

- Click “Add” in the pop-up window and provide details for your PACS
- Click “Test Connection” to verify the connectivity
- Click “Save” to save device details and close the window
Submit Files from PACS (3/3)

Select PACS from dropdown

Provide the ‘Search’ details (Patient ID is mandatory) and click on ‘Search Images’

Select the images from search results by clicking the checkboxes

Click on ‘Select Images’ to load the selected files into TRIAD preview panel.
Files selected from Computer/PACS are loaded into TRIAD preview panel

Click on ‘+’ icon to expand the DICOM study and view all the series in that study
View Images

- You can view the images in the preview panel before moving them to “Submission Queue”
- Double click on the thumbnail to view images in series by using default “QC Viewer”.

![QC Viewer interface](image-url)
Clean Pixel Data

- You may clean any patient data that may be on the images by using ‘Clean Pixel Data’ feature.
- Open the clean pixel data window by clicking ‘Clean’ button.
- Draw a rectangle that would cover the data.
- Click ‘Apply Pixel Data Cleanup’ icon to clean the area selected.
Add Attachments

You may add non-DICOM files, such as reports, at study or series level by clicking ‘Select’ in the ‘Attachment’ column.
Click ‘View’ in the Metadata column to open the series metadata for the DICOM files in the preview panel.
You can provide comments for each series by clicking “Comments” link. Click ‘Save’ after entering comments in the pop-up window.
Select the series / series that are ready for submission by clicking the check boxes.

Click ‘Move to Submission Queue’ button to move the studies to Submission Queue.
Verify if all the studies are moved into Submission Queue.

Enter the proper subject ID in “Subject ID” field in the Submission Queue. TimePoint ID and TimePoint Description fields are optional.

Verify all the columns shown in the queue
Submission Queue -- Submission Type

Select the Submission type from the dropdown.
- Clinical Trial -- default
- Test Submission
- Quality Assurance
Submission Queue -- Anonymization Result

You may view DICOM header anonymization results by clicking ”Anonymization Result” button. Both the Original Value and De-identified value are shown in the results pop-up windows.

An ‘Export’ button is also available to export the anonymization results in the form of pdf or word document and save it in your computer.
Validation Result

1. Click the “Validation Result” to check whether the series have the values to satisfy for the requirements of the trial.
2. You may also check how many of the series are in Range or Out of range of the validation parameters and how many are not validated.
3. System will allow you to submit the studies irrespective of the validation result.
Click “Complete Submission” when you are ready to submit the files to ACR.

Anonymization and validation will be done in the background even if you did not select “Anonymization Result” or “Validation Result” before.

System shall change the status to ‘Submitted’ after the files are submitted successfully.
TRIAD Support

- If you have any questions or issues, please contact ACR TRIAD support services
- Support Hours: 8:30am – 5pm EST Monday – Friday except ACR observed holidays
- Support contact:
  Phone: 215-940-8820; E-mail: triad-support@acr.org
Appendix VI

Data Submission via TRIAD Web Client
Data Submission via TRIAD Web Client

➢ Purpose:

The purpose of this document is to explain steps required for the submission of image data via TRIAD Web Client.

➢ Procedures:

➢ Initial Login:

Login to Triad website using your registered user account https://cr-triad4.acr.org/TriadWeb4.0

1. Select the ‘Submission’ tab after logging into Triad web site
Data Submission via TRIAD Web Client

**Browsing for Specific Files:**

1. Click the 'Browse Files/Folders' button to browse for the DICOM files that are to be loaded into Web Client.

![Triad Web Client Interface]

2. If you would like to pick up *specific DICOM files* from a folder, expand the folder hierarchy to select the respective folder so that the DICOM files are displayed in the right side panel.

3. Select the desired DICOM files and click 'OK' to load those files into Triad client.
Data Submission via TRIAD Web Client

**: Browsing for Folders:**

1. If you would like to load **all the DICOM files or all the files with in the subfolders;** expand the folder hierarchy and select the desired folder.
2. Check the following options provided in the ‘Select File(s)’ window:
   - **Include all files in selected folder**
   - **Include all files in child folders**
3. Click ‘OK’
Data Submission via TRIAD Web Client

Browsing PACS:

- To import DICOM files from your PACS:
  
  1. Click the ‘Browse PACS’ button
Data Submission via TRIAD Web Client

- **Add a Device**

  1. To provide the details of your PACS click the ‘Manage’ button to open a Device Window
Data Submission via TRIAD Web Client

2. Click ‘Add’ button

3. Give the Name, AE Title, IP Address, Port number details

4. Click ‘Save’

5. To test the connectivity of the Web Client with the PACS click ‘Test’ button

6. Close the Device Window

7. You may add multiple PACS devices to the Web Client and select the ones from dropdown menu depending on the PACS from which you would like to import the files.

- **To C-Find:**

1. Enter the search details and click ‘Search’ button to find the files that belong to the provided search criteria from the selected PACS
Data Submission via TRIAD Web Client

To C-Move:

1. After the DICOM studies are displayed, click ‘OK’ to load the selected studies into the Web Client
Data Submission via TRIAD Web Client

File Submission:

- Submission Parameters:
  1. After loading the files into Triad, provide the following submission parameters in the left panel.
  2. Select Submission Type from dropdown based on the type of submission you are going to perform.
  3. Enter the Subject ID, Timepoint ID and Timepoint Description.  
     **Note:** Subject ID field is mandatory; however Timepoint ID and Timepoint Description are optional.
  4. Click the ‘Submit Files’ button once you are ready to start the submission for selected Studies.

Anonymization:

1. To perform Anonymization click on ‘View Anonymization Result’ button and open the results.
Data Submission via TRIAD Web Client

2. Click on ‘View Validation Result’ button to open the results.

3. Click ‘Start Upload’ button to upload files to ACR. All the files submitted to ACR will be anonymized in Triad automatically.
Data Submission via TRIAD Web Client
Appendix VII

TRIAD v4.0 FAQ’s
1. **What are the differences between TRIAD Windows Client and Web Client?**

Both the Windows Client and Web client can be used to submit images and data.

The differences between the Web client and Windows client can be grouped into two areas:

- **System requirements:**
- **Features:** The Windows Client offers more extensive features than the Web Client. They are:
  a. Preview of images by using supported image viewers
  b. Clean pixel data feature that provides ability to clean the embedded PHI from the images.
  c. Viewing metadata
  d. Saving anonymization/validation results,
  e. Submission history where you can view studies you already submitted.

2. **Can I use web client on any browser or any environment?**

The user will need Microsoft Silverlight 5.0 and Web Client setup installed on their system to use the Web Client. It is a one-time installation and would need administrative privileges.

Below are the details for browsers and versions supported by the web client:

<table>
<thead>
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<th>OS/browser</th>
<th>Internet Explorer 7</th>
<th>Internet Explorer 8 or later</th>
<th>Mozilla Firefox 3 or later</th>
<th>Google Chrome</th>
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<tbody>
<tr>
<td>Windows 7</td>
<td>N/A</td>
<td>SilverLight 5</td>
<td>SilverLight 5</td>
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3. **What are the hardware and software requirements for the TRIAD 4.0 Windows Client?**

**Hardware requirements (recommended):**
- Window XP (SP2, SP3), Windows 7 (32 or 64 bit)
- 4 GB RAM.
- 2.4 GHz Processor
- 150 GB Hard Disk space

**Software requirements:**

4. **What are the hardware and software requirements for the TRIAD 4.0 Web Client?**

**Hardware requirements (recommended):**
- Window XP (SP2, SP3), Windows 7 (32 or 64 bit)
- 4 GB RAM.
- 2.4 GHz Processor
- 150 GB Hard Disk space

**Software requirements:**
- SilverLight 5
- Browsers: IE 8 or above, Firefox 3 or above, Google Chrome

5. **How can a user set up the Web Client?**

TRIAD Web Client is a Microsoft Silverlight based application that runs with elevated trust inside the browser using Microsoft Silverlight Runtime. To setup the client, you will need to have administrative privileges on your computer:

1. Extract the Setup Package.
2. Right click the Setup.bat file and select "Run as Administrator".
3. If you are using Microsoft Internet explorer, please continue to perform the following steps (otherwise skip to Step 4).
   i. Open 'Internet options' from right hand top corner of IE browser.
   ii. Go to the 'Security' tab and select 'Trusted Sites'.
   iii. Click 'Sites' button and add the Triad website URL to the trusted website
4. Restart your browser and login to [https://triad4-web-test.acr.org/CT/](https://triad4-web-test.acr.org/CT/) using your registered TRIAD user account.

6. **Why is Web Client not working in Internet Explorer for submission?**

Try adding the TRIAD URL to trusted websites list in the browser settings:

- Open 'Internet options' from right hand top corner of IE browser.
- Go to the 'Security' tab and select 'Trusted Sites'.
• Click ‘Sites’ button and add the Triad website URL to the trusted website
If adding the link to your trusted websites does not work, contact the TRIAD helpdesk

7. **When I tried to login the Web client/Windows client, there is an ‘account locked-out’ message displayed. How do I unlock my account?**

If you try to login to TRIAD using a wrong password for 5 consecutive times (or) if you have not changed your password for 90 days, your account will be locked. Please contact TRIAD support team by sending an e-mail to triad-support@acr.org to have your account unlocked.

• Account locked out message for Web Client: **User is locked out**
• Account locked out message for Windows Client: **Login failed. User account is locked.**

8. **Does TRIAD software require any specific firewall ports to be opened?**

TRIAD client uses the secure HTTPS protocol thus will use port 443 to communicate securely with TRIAD Central server. Facilities firewall will need to have port 443 open to internet traffic.

9. **Can TRIAD v3.0 and v4.0 application co-exist on the same client computer?**

Yes, both TRIAD v3.0 and v4.0 can run on the same Windows computer.

10. **Can I use TRIAD 4.0 and PACS on the same PC? Will there be any issues?**

It is recommended that you install TRIAD v4.0 on a system which doesn’t have PACS running on same machine. There might be issues caused if there are multiple DICOM applications running on the same IP address.

11. **Should we create a backup for the sent studies?**

TRIAD 4.0 does not move/delete any of the files from the remote device or folders. It simply copies the file(s) and sends to the ACR. TRIAD 4.0 maintains a temporary cache, which will be deleted after successful submission.
12. How do I send studies using folder/files?

Click ‘Choose Files/Folders’ button to browse for the DICOM files that are to be loaded into Client. If you would like to pick specific DICOM files from a folder, expand the folder hierarchy to select the respective folder so that the DICOM files are displayed in the right side panel. Select the desired DICOM files and click ‘OK’ to load those files into the TRIAD client. If you would like to load all the DICOM files or all the files with in the subfolders; expand the folder hierarchy, select the desired folder and check the following options provided in the ‘Select File(s)’ window ‘OK’ to include all files in the selected folder and include all files in child folders.

13. How do I send images directly from my PACS?

1) Click on “Choose files from PACS” tab to import DICOM files from your PACS and select “Choose Files”
2) Click the ‘Manage’ button to open a Device Window.

1) Select ‘Choose Files from PACS’ and click ‘Choose Files’ button to open a new window to search for images in PACS.
2) Click ‘Manage’ to add information of PACS from where you will retrieve
i. Click ‘Add’ in the pop-up window and provide the Device details for your PACS.
ii. Click ‘Test Connection’ to verify the connectivity to the PACS.
iii. Click ‘Save’ to save the device details.
iv. Close the window.
3) Select Images

- Select the PACS from dropdown
- Provide the ‘Search’ details and click on ‘Search Images’
- Select the images from search results by clicking the checkboxes
- Click on ‘Select Images’ to load the selected files into TRIAD panel.
14. How do I send studies from TRIAD Client to a DICOM device?

Select a particular study then click on “send to device”. A window appears with a drop down for selecting a remote device, select the remote device name and then click on send button.

15. What if I send a study to the wrong trial?

The study will still be submitted successfully. However, to delete the study after an erroneous submission, you will need to contact the ACR Clinical Research Center to request that the study be deleted from the central server. Once deleted, you can re-send the same study to the appropriate trial.

16. What if I would like to send a study in JPEG format?

First you will be need to contact the clinical trial project manager to make sure that you can send images in JPEG format based on the trial protocol. TRIAD accepts JPEG images as non DICOM files and submits them to ACR, so the user need to anonymize the image first before submitting it since TRIAD application will not anonymize JPEG files.

17. My images contain PHI. Don’t I need to anonymize the images prior to sending via TRIAD?

No. TRIAD software for clinical trials performs all necessary anonymization before the images leave your institution using profiles that meet or exceed anonymization standards for clinical trials established by DICOM Working Group 18. Anonymization of images prior to using TRIAD is NOT recommended, as various third-party applications can corrupt the headers of images you intend to submit. See “Can I view / save the anonymized metadata?”. 
18. **What if I have already anonymized the images using a third-party software?**

The use of any software other than TRIAD for anonymization of images to be submitted for clinical trials is not recommended. However, if the images have already undergone anonymization, the TRIAD application will anonymize the images again and re-identify them using the anonymization profile assigned for the trial before sending them to the central server.

19. **What if my site has a proxy server? Where can I enter the details?**

To enter the proxy details you need to follow the path:

**Actions → Settings → Proxy Server Config → Select Checkbox – Use a Proxy Server → Enter the proxy address along with the custom authentication if required → Save**

![Proxy Server Configuration]

Select the Checkbox “Use a proxy server”, enter the “Address” and “Port”
If the proxy requires any authentication enter the proxy authentication details “Username” and “Password”

20. **Does the TRIAD client application run as a background service or does it need to have a user logged in to work?**

TRIAD client does not run a background service. You need to send the studies manually by logging in to the TRIAD client (both Windows and Web).
21. How to submit selected studies?

Submission Parameters after loading the files into TRIAD provide the following submission parameters:

- In the left panel Select Submission Type from dropdown
- Select the type of submission you are going to perform.
- Enter the Subject ID, Time-point ID and Time-point Description. (Subject ID field is mandatory; however Time-point ID and Time-point Description are optional).
- Click the ‘Complete Submit Files’ button to the right once you are ready to start the submission for selected Studies.
22. What if internet is disconnected while sending the files from the Web client?

After clicking the “complete submission” button, studies will begin transmission to the TRIAD central server. If your network is down or connection from your client PC to the TRIAD central server is interrupted, TRIAD 4.0 will wait for 2 minutes. If the network connection is restored within the two minutes, the files will be submitted successfully. If the network connection is not established within two minutes, the studies will not get submitted.

The site user will need to submit the studies again once the network connection is established.

23. Can I work on the PC while sending the studies?

Yes, this will not affect the process of sending studies. The performance of your PC will depend on processor power and memory.

24. What happens if the wrong password is entered multiple times?

If the user tries to login more than 3 times by using an incorrect password, the account will get locked. Once the account is locked, user will have to contact ACR to have it unlocked.

25. How do I reset my password?

When the user clicks the ‘Reset password’ link on the Web Portal, they are prompted for their TRIAD username and security question. If they provide both these details correctly, an e-mail will be sent to their registered e-mail with a new password (generated by the system) that they can use and login.

26. Does my TRIAD password expire?

Your TRIAD user account password will expire after 90 days. Please make sure to change your password before it expires.

27. I forgot my password. How do I recover it?

You can retrieve or reset your lost password by selecting the “Forgot Password?” link on the TRIAD Web Portal. Provide you’re TRIAD “Username” on the “Reset Password” page and click “Continue”. On the next page, enter the answer for your secret question and click “Submit”. You will then receive a message on the Web page that your password has been reset and your new password is sent to the registered email ID.

You can open the link provided in that e-mail and login with your username and the new password. If you have trouble entering your password, try to copy and paste the password directly from the email. It is advised that you then change your password from the “My Account” page.

28. How can I change the default DICOM viewer?
TRIAD supports multiple DICOM viewers. Users can change the default viewer, from the main Window “Choose DICOM Viewer” pull down menu. Users will need to install that specific viewer on their workstation before changing the default viewer.

Viewers supported:
QCViewer, ClearCanvas, MIM Viewer, MicroDICOM, iQ-VIEW, ATI: ClearCanvas

29. What kind of non-DICOM file formats are accepted?

The TRIAD client (both Windows and Web) will allow only limited non-DICOM file types for submission. The system will show an error message if the user tries to attach any files other than the file types listed below:

Avi, bmp, crw, dcm, doc: ppt, xls, docx: pptx, xlsx, gif, jpeg, mov, mp4, mpeg, mpg, pdf, png, tiff, tif, wmv, zip

30. Can I view the studies submitted by other users at my site?

Yes, you can see the studies sent by any other user at your site in the submission history tab.

31. Can I view / save the anonymized metadata?

Yes, you may view the results of the anonymization processes by clicking the “Anonymization Result” button in the submission queue to make sure that the DICOM tags are de-identified before submission. Both the original and de-identified values are shown in the anonymization result table. An ‘Export’ button is also available to export the anonymization results in the form of a .pdf or word document and save it in your computer.

32. How can my site change the anonymization profile?

While site users or site administrators cannot directly modify the default anonymization profile for a clinical trial, a customized anonymization profile can be created for their needs. Your site must first contact ACR if they will require a custom anonymization profile for their image data. Once approved and established, an appropriate ACR Staff member (ACR administrators) can make the changes to the profile and assign it to the designated site.

33. How can we identify that a document is attached to a particular study/series in the submission queue?

You need to click on a particular study/series and expand it to see if there are any attachments.

34. How can users check all the sent studies, irrespective of date and subject ID?

You can see the sent studies / history in by clicking on the “submission history” tab for up to 30 days after the studies are published.

35. What happens when a user tries to submit a study which is already submitted?

During submission, the system will first check whether the same study has already been submitted into TRIAD. If it has, an error and/or warning message will appear.
Depending on the nature of the conflict, specific information for each rule will and appropriate options for the user be provided.

36. Does my TRIAD client login ‘time-out’?
   There is no login time-out in TRIAD windows client and web client.

37. What happens if my windows login times out while submitting via TRIAD?
   The TRIAD submission continues in the background even after windows get locked.

38. I’m having trouble generating a password! What are the password requirements?
   Minimum 8 characters required with a combination of upper & lower case alphabet(s), numeral(s) and special character(s).
   
   Example Password: P@ssword1

39. How can I get the TRIAD application log files?
   You can find the log files by following the below path:

   Open TRIAD application → Go to Task Manager → Processes → right click on Acr.Triad.Client.exe → Open File Location → Check the file Debug_Rolling.log