



Image Transfer Protocol

Agili-C IDE Study (543)

CLN0021

Table of Contents

Image Preparation	3
Subject Identification Code	3
File Naming Conventions for Digital Images	3
Image Transmittal Form.....	4
Image Transfer Options	6
FTP Transfer	6
Courier Transfer.....	9
Logistics Overview & Handling of Images at MMI.....	11
Test Images.....	11
Image Quality Control	11
Discrepancy Handling	11
Image Return.....	11

Instructions for submitting images to MMI are provided below. Any questions regarding the image transfer process for this study should be directed to the study's Project Manager at MMI:

Michal Houston
 Project Manager
 Medical Metrics, Inc.
 +1 (713) 850-7500 x228
mhouston@medicalmetrics.com

Image Preparation

Subject Identification Code

All subject-identifying protected health information (PHI) should be removed from the images and/or metadata before being transferred to MMI. This includes the subject's Name, Birthdate, Age, Weight, Medical Record Number, etc. Sequence-specific details, such as the Series Description, Study Description, Protocol Name, Image Date, etc., must not be removed.

Subjects will be identified using a unique subject identification code consisting of a site number, subject number, and initials. The format of this identification code is provided below:

-

-

Site #
Subject #
Initials

Examples: 001-001-ABC 012-345-E-J

Notes: Include leading zeroes in the site and subject numbers
 Use a hyphen for subjects with two-letter initials

File Naming Conventions for Digital Images

Digital images must be organized in a standard folder structure that clearly and uniquely identifies the subject ID and visit designation.

All images stored in DICOM format must use the following folder structure:

Format: .\[Subject ID] _ [Visit Designation] \ [Modality] \ [* .dcm files]

Example: .\012-345-ABC_Month 6\XR\image.dcm
 .\012-345-ABC_Month 6\MR\image.dcm

In this example, Month 6 images for subject 012-345-ABC are organized within a folder "012-345-ABC_Month 6". The images are stored within a subfolder to identify them by modality, in this case, "XR" and "MR".

If the images themselves are not annotated with the proper image labels, the parent folder must contain the image label so the image is properly identified in MMI's database.

Format: .\[Subject ID] _ [Visit Designation] \ [Modality] \ [**Label**] \ [*].dcm

Example: .\012-345-ABC_PreOp\XR\Lateral\image.dcm
.\012-345-ABC_PreOp\XR\AP\image.dcm

Notes: An underscore should separate the subject ID and visit ID
Use standard visit IDs (PreOp, Month 6, Month 12, etc.)
Include leading zeroes in the subject ID and site number
Use descriptive modality names: XR, MR, etc.

For X-ray images only, Windows® compatible graphics formats are acceptable using the following folder structure:

Windows® compatible graphics formats (X-ray only):

An adequate descriptive file path is described below. Other folder structures and filenames are acceptable provided each image can be uniquely identified by subject ID, visit designation, and view.

Format: .\[Subject ID] _ [Visit Designation] \ XR \ [Filename.ext]

Example: .\012-345-ABC_Month6\XR\Lateral.bmp
.\098-765-B-H_PreOp\XR\AP.jpg

Image Transmittal Form

An **Image Transmittal Form** (ITF) must accompany all images sent to MMI via courier or FTP. The ITF provides an inventory of the images contained within the shipment and a mechanism for documenting the receipt and return of the images. A project-specific ITF template is provided on the following page. An electronic version of the form will also be provided.


For transfers via courier, the ITF must be included in the shipping parcel.
For transfers via FTP, the ITF must be faxed or emailed to MMI.

Enter only one subject/visit designation per row. Multiple subjects can be included on the form. All fields should be completed for each transfer.


Sites must promptly submit all images to MMI to ensure timely receipt and inspection of images. Image receipt and inspections cannot begin until the images arrive at MMI.

Visit Designations:

- Screening
- Week 2
- Month 6
- Month 12
- Month 18
- Month 24
- Additional Annual Visit
- Unscheduled Visit

CartiHeal Agili-C IDE Study (543)	Sent Date: _____ <small>(dd-mmm-yyyy)</small>		Site Number: _____	
	Method of Transfer: <input type="checkbox"/> FTP <input type="checkbox"/> Courier		Tracking #: _____	
Person Preparing Shipment/Transfer: _____				
Email: _____	Phone: _____	Fax: _____		

Subject ID <small>Site Subject Initials</small>	Visit Designation	Visit Date <small>(DD-MMM-YY)</small>	Treatment Side
			<input type="checkbox"/> Right <input type="checkbox"/> Left
			<input type="checkbox"/> Right <input type="checkbox"/> Left
			<input type="checkbox"/> Right <input type="checkbox"/> Left
			<input type="checkbox"/> Right <input type="checkbox"/> Left
			<input type="checkbox"/> Right <input type="checkbox"/> Left
			<input type="checkbox"/> Right <input type="checkbox"/> Left
			<input type="checkbox"/> Right <input type="checkbox"/> Left
			<input type="checkbox"/> Right <input type="checkbox"/> Left
			<input type="checkbox"/> Right <input type="checkbox"/> Left
			<input type="checkbox"/> Right <input type="checkbox"/> Left

<p>Courier Transfer (Discs and Films):</p>  <p>Insight from Imaging</p> <p>Medical Metrics, Inc. 2121 Sage Road, Suite 300 Houston, Texas 77056 P 713-850-7500 www.medicalmetrics.com</p> <p>Attn: CartiHeal Agili-C IDE Study (543)</p>	<p>FTP Transfer:</p> <p>Click the "Send to MMI" button below to submit the transmittal form.</p> <p>Alternatively, send this form to either of the following:</p> <p style="text-align: right;">Fax: +1 (713) 850-9996 Email: tf@medicalmetrics.com</p>
<p>Address to Return Discs and/or Films:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

(To Be Completed by Medical Metrics Personnel)

Date of Return: _____ - _____ - _____ (dd-mmm-yyyy) Fax #: _____ Return Prepared By: _____

Image Transfer Options

The following image transfer options are available for this study:

- FTP
- Courier
 - CD/DVD

FTP Transfer

Sites that prefer to upload images via FTP will receive a file transfer account that is specific to the site and project, along with the username and password. A completed ITF must be faxed or emailed to MMI once the images have been uploaded.

The fax number is: +1 (713) 850-9996

The email address is: tf@medicalmetrics.com

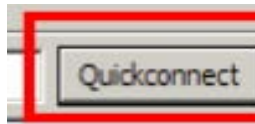
When MMI receives the transmittal form by fax or email, the images identified on the form will be moved off of the FTP site to indicate that they have been processed. The transmittal form will then be verified and faxed or emailed back to the site for their records. Any gaps or discrepancies will be marked on the transmittal form.

MMI recommends FileZilla for FTP file transfers, which is freely available from the website below. FileZilla is a free FTP transfer client and is recommended, though not required if your facility has an existing FTP client available for use.

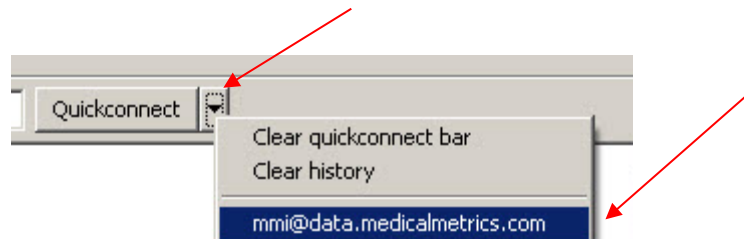
NOTE: If FileZilla is not available to the site, or if installation / use of the client software is not permitted, an alternative software-based client should be used. Web-based FTP transfers are not recommended (ex. using Internet Explorer). The software used for FTP transfer should support the following features: unattended transfers, resuming interrupted / paused transfers (without restarting), multiple concurrent transfer sessions, and support for slow and / or lengthy transfers.

1. Load / Install FileZilla (<http://filezilla-project.org>)
 - Follow instructions to download FileZilla > “**Download FileZilla Client**”
 - Select the proper download file according to your operating system (e.g., Windows 7, Windows 10, Mac OSX, etc.)
2. Once FileZilla is installed, there are a few configuration changes that need to be made first. Go to **Edit > Settings**
 - **Connection**: Increase the timeout in seconds from **120** to at least **600**. This will help prevent a quick disconnect if stepping away for a moment.

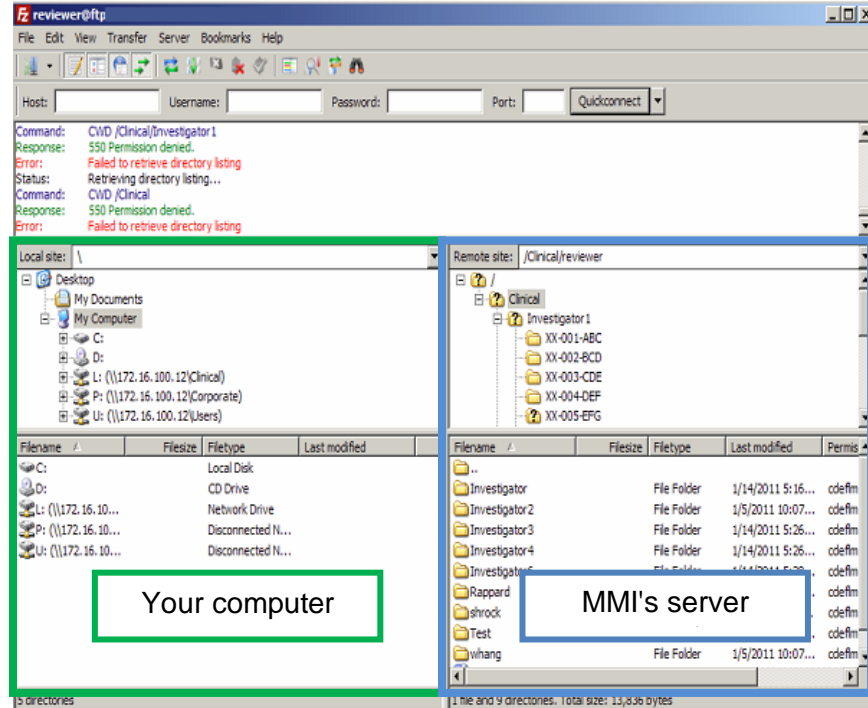
- **Transfer** > **Settings**: Change the value from **Auto** to **Binary**.
 - (Optional) **Logging** > **Log to file**: Enable a logging record for your audit account trail. Click **Browse** and select a location for saving the log.
 - Click **OK**.
3. In the FileZilla Quickconnect fields, enter the following information:
- **Host**: data.medicalmetrics.com
- or -
 - **Secure Host**: ftpes:\\data.medicalmetrics.com
 - **Username**: assigned by MMI (your project-specific FTP username)
 - **Password**: assigned by MMI (your project-specific FTP password)
 - **Port**: <empty>
4. Select "Quickconnect"



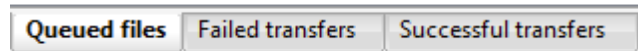
5. After you have connected once, use the Quickconnect arrow & select your project for future attempts.



6. The files on **your** computer are in the 'Local Site' pane (left panel; **green**). The files on **MMI's FTP** site are in the 'Remote site' pane (right panel; **blue**).



- Place a copy of the images you wish to transfer to MMI in descriptively-named folders using the folder-naming conventions described above.
- Navigate to the new image folder in the left pane. Double-click (or right click and select Upload) on the folder of images to transfer. Check the bottom tabs for the status of the files in queue or transferred:



- If successful, you will now see the file in the right pane (copied onto the FTP site). Large files (CT or MRI) may take several minutes to transfer.
- Fax the completed transmittal form to: +1 (713) 850-9996 or email the completed form to: tf@medicalmetrics.com

For questions regarding installation or internet connection issues, please contact your IT support resources.

For questions regarding FTP transfer process, please contact the study Project Manager at MMI or MMI Support at support@medicalmetrics.com

Courier Transfer

Sites that prefer to transfer images to MMI via courier must send them to the following address using a courier service (e.g. FedEx, UPS or DHL) that support electronic tracking of shipments:

Medical Metrics, Inc.
Attn: CartiHeal Agili-C IDE Study (543)
2121 Sage Road, Ste 300
Houston, TX 77056, USA

Phone: +1 (713) 850-7500
Fax: +1 (713) 850-9996

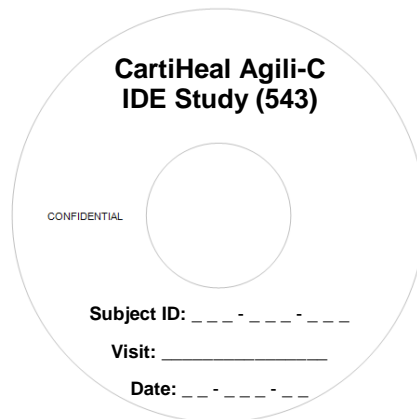
An **Image Transmittal Form** (ITF) must accompany each shipment. The ITF provides an inventory of all images in the shipment and must be placed within the packing container. The study ITF can be found in the section above.

CD / DVD Discs

Images for a specific subject visit should be stored on a single CD or DVD. **If possible, a single CD/DVD should contain only the images obtained during a single visit for a single subject.** Placing digital images for multiple subjects and/or multiple visits on a single CD or DVD should be avoided.

CD/DVD Disc Label

If needed, sites will be provided round disc labels that can be placed directly on the disc. The CD/DVD Disc Label is a permanent-adhesive label with pre-printed fill-in-the-blank and check-box information. The label is used to identify the subject ID, visit designation, and visit date of images on the CD or DVD. A ball-point pen should not be used on the label after it has been affixed to the disc, as this may corrupt the disc.



Disc Sleeve Label

CDs and DVDs must be contained within a sleeve or jewel case to protect the disc during shipment. A **Disc Sleeve Label** must be affixed to the CD/DVD sleeve or jewel case. The label should not be attached to the CD or DVD itself, which will obstruct the center hole, and render the disk unusable. The Disc Sleeve Label is a permanent-adhesive label with pre-printed fill-in-the-blank and check-box information. The label is used to identify the subject ID, visit designation, visit date, and type(s) of images on the CD or DVD.

An example **Disc Sleeve Label** is provided below:

CartiHeal Agili-C IDE Study (543) – Disc Sleeve Label					
Subject ID:	____	–	____	–	____
	Site #		Subject #		Initials
Visit Designation:	_____				
Visit Date:	____	–	____	–	____
	dd		mmm		yy
Contents:	<input type="checkbox"/> X-Ray <input type="checkbox"/> MRI				

Notes: Include leading zeroes in the site and subject numbers
Use DD-MMM-YY date format (e.g. '01-Jan-14)

Logistics Overview & Handling of Images at MMI

Test Images

MMI will accept test images for quality review and transfer testing and provide feedback to the site. Test images should be labeled as "Test" as the subject ID of all forms, labels, and data fields.

Image Quality Control

Upon receipt at MMI, the images will be reviewed for the following:

- **Image Labeling Inspection (ILI):** conducted to ensure there are no discrepancies in the subject ID, visit designation, visit date, or any other study information.
- **Image Quality Evaluation (IQE):** conducted to ensure the imaging parameters are compliant with the Image Acquisition Protocol and that the image quality is sufficient for use in the study.

Additional review may be required depending on the complexity of any noted issues.

Discrepancy Handling

All discrepancies identified during the image quality control process will be relayed promptly after identification via email notification to the site. CARTIHEAL will be carbon-copied (CC'd) on the email.

Each discrepancy will be tracked using a Discrepancy ID number which will be included in the discrepancy notification email. The Discrepancy ID number should always be referenced when responding to discrepancy notifications.

Image Return

MMI does not store or destroy any image media. All films and CDs/DVDs will be returned to the site once discrepancies are resolved, along with the marked-up transmittal form(s). Images transferred via FTP will *not* be returned to the site, only the associated transmittal form(s) will be returned.