

MicroPort– MoM THA Post-Market Study

MMI Project Number: 553

Study Site Initiation

An Overview of Image Acquisition & Transfer Procedures



Purpose & Background

- Ensure that the site begins the project with a clear and shared understanding of the project scope.
- Prospective, Regulated, Multi-Center, Controlled, USA Study
- Imaging Modality: MRI
- This presentation covers:
 - **Image Acquisition Protocol (IAP)**
 - **Image Transfer Protocol (ITP)**

***Each site will receive a copy of this presentation**

Image Acquisition

Imaging Summary

Modality	Study (4-8 Years PostOp)	Post-Study (12 Months after initial visit)
MARS MRI	×	×

1. No imaging will be required for subjects in the 'Non-implanted' study cohort
2. Only implanted, non-revised subjects diagnosed with ALTR at the initial study visit will have an additional MR visit 12 months after the initial MRI exam

Image Acquisition Protocol

MRI Guidelines

- Hardware
 - 1.5 Tesla scanner required, approved for clinical use
 - Phased array body coil
 - Variations in acquisition parameters expected
- Subject and Positioning
 - Administer standard safety screening form
 - Subjects to lie supine, “head first”
 - Legs with 15° rotation, knees with 10° flexion
 - Strap for securing coil, padding under knees OK
 - Instruct subjects to remain still
 - No contrast will be used

Image Acquisition Protocol

MRI Guidelines

- Imaging Anatomy
 - Large FOV (both hips): 34 cm x 34 cm or larger
 - Small FOV (treated hip only): 20 cm x 20 cm
 - Imaging slab to be constant through sequences with same orientation
- Image Acquisition
 - Use Auto Shimming
 - Do NOT use parallel imaging methods (e.g., SENSE, GRAPPA)
 - Center anatomy in FOV
 - Use initial Study visit scans for repositioning on later follow-up scans
 - TR may vary due to scanner hardware limits though should be within specified range.
 - Can use phase oversampling and/or modify # of slices to adjust TR, as needed
 - Standard-of-care sequences may be added
 - **Use highest receiver bandwidth possible**
- Image Format
 - DICOM, include image viewer if possible

Image Acquisition Protocol

MRI Protocol Set-Up

- **Save the Protocol and name it “MMI MicroPort 553” or “MMI MicroPort 553 (Site #)”.**
- **Do not use Research Mode – sequences may not be able to be automatically sorted in database.**
- **Avoid generating secondary DICOM files / other post-processing steps.**
- **Only remove patient identifying information during de-identification.** Do not remove sequence details.
- **Send MMI a copy of the Exam Card for review** prior to scheduling subjects for imaging.
 - Can also review protocol implemented on healthy volunteer.

Image Acquisition Protocol

MRI Protocol Set-Up

PROTOCOL NAME (Exam Card)	“MMI MicroPort 553”
Localizer / Reference / Scout	"Localizer"
Coronal T1 FSE	"Cor T1"
Coronal STIR FSE	"Cor STIR"
Axial T1 FSE	"Ax T1"
Axial T2 FSE	"Ax T2"
Sagittal T2 FSE	"Sag T2"
Axial STIR FSE	"Ax STIR"

Image Quality Monitoring & Feedback

(MMI provides feedback on contrast, resolution, positioning, artifact and acquisition settings)

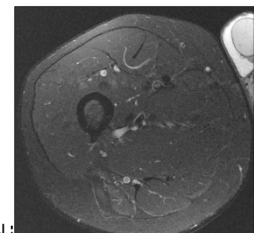
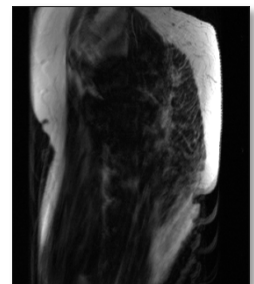
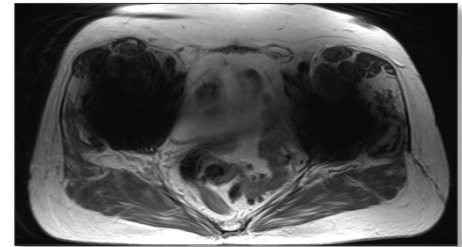
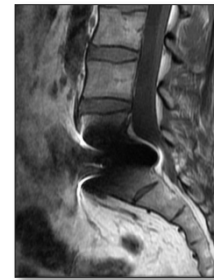
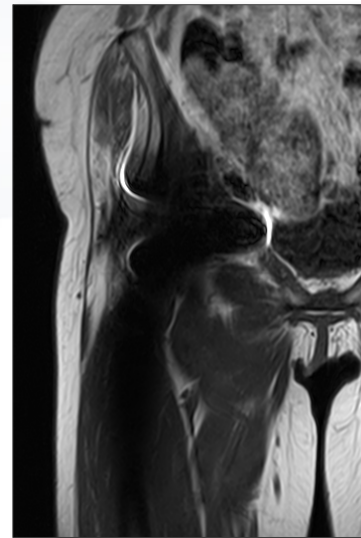
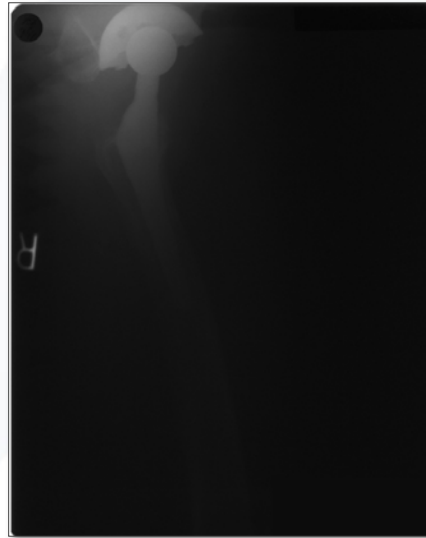
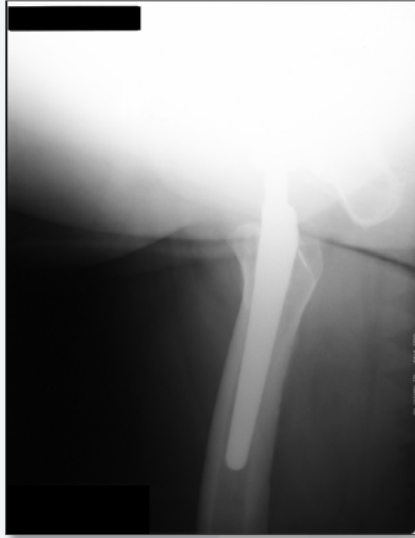


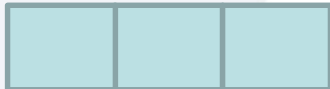
Image Acquisition Protocol

General Guidelines

- **Follow all imaging safety requirements specified by your institutional guidelines.**
- **When possible, review prior scans while planning and acquiring images at later follow-up visits.**

Image Transmittal to Core Lab & Logistics

Subject Identification Code



3-digit
Site Number

—



3-digit
Subject Number



Right (R) or Left (L)

- Include leading zeros in site and subject numbers
- Subject initials will not be collected.

Examples: 001-001R 011-013L

Image Quality Control

All images go through QC steps:

1. **Image Labeling Inspection (ILI):** conducted to ensure there are no discrepancies in the subject ID, visit designation, visit date, or any other study information.
2. **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.
3. **Review by Project Manager/Technical Project Manager** if needed, depending on the complexity of the issue.

Image Quality Control

QC & Discrepancies

- Discrepancies are identified and relayed in real time via email notification sent to the site with a CC to sponsor.
- All discrepancies are tracked internally by a Discrepancy number.
- Email notification of a discrepancy will always include a Discrepancy number.
- Response to discrepancies should always reference the Discrepancy number.

Image Quality Control

Sample Discrepancy Notification

- Discrepancy#: 12345
- Subject ID: 001-011R
- Visit Date: 05-May-16
- Visit Designation: Pre-Op
- Issue: The CD received did not contain any images.
- Action Requested: Please send the image(s) with a new transmittal form.

Image Quality Control

Labeling

- All subject-identifying protected health information (PHI) should be removed from the images/metadata before transfer to MMI:
 - Name, Birthdate, Medical Record Number, etc.
- Do not remove sequence or image details:
 - Image Date, Study Description, Protocol Name, etc.

Image Quality Control

Out-of-Scope Imaging

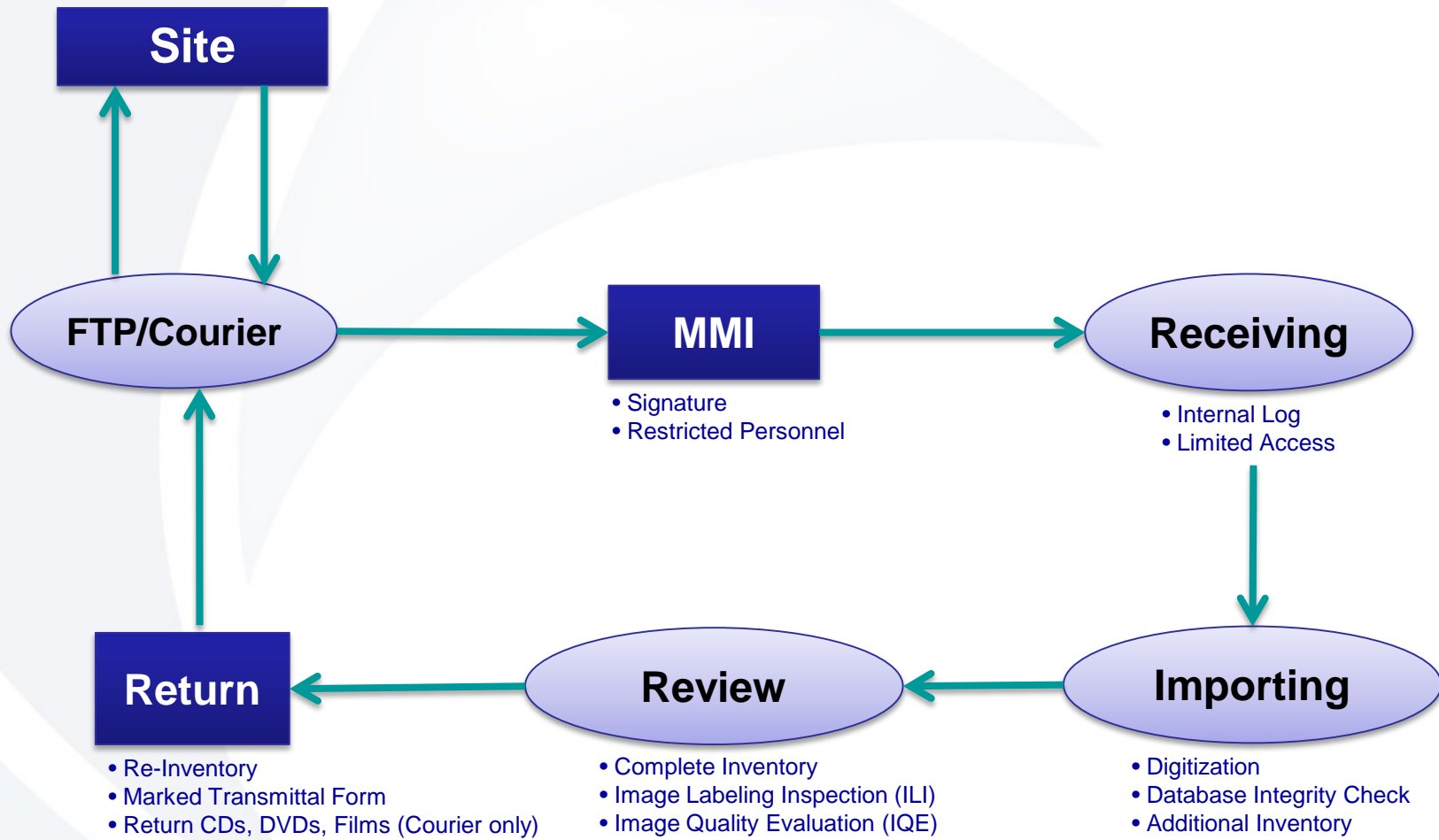
- Out-of-Scope Images could be:
 - Receipt of non-required modalities
 - ex: CT received in a MR study
 - Receipt of imaging not relevant to treatment site
 - ex: Shoulder images received for a hip study
 - Receipt of non-required visits
 - ex: Week 30 imaging received
- MMI will contact the sponsor on preferred method of handling out-of-scope images

FTP and Courier Transfers

Overview of Image Transfer Process

- Obtain image(s) from radiology workstations/ PACS.
- De-identify all subject-related PHI.
- Label images/Name files with subject ID and visit designation.
- Complete the image transmittal form .
- Submit image(s) to MMI w/image transmittal form.
- Resolve any discrepancies.
- Returned to the site: image transmittal forms and images (if media were submitted).

Workflow & Image Lifecycle



MMI does not store nor destroy media, all images are returned to the site.

Image Transmittal Form

- A transmittal form must accompany all images!
 - Provides:
 - Inventory of all images in shipment
 - Documents:
 - Shipment, Receipt, Return
- For Courier Images:
 - Transmittal form must be in parcel
- For FTP Images:
 - Transmittal form must be faxed/mailed
- Use **one** row per subject, per visit.
 - Can have multiple subjects on one form.

Image Transfer Protocol MoM Post-Market Study MicroPort Orthopedics, Inc.

MicroPort MoM Post-Market Study	Sent Date: (dd-mm-yyyy)	Site Number:
	Method of Transfer: <input type="checkbox"/> FTP <input type="checkbox"/> Courier	Tracking #:
Person Preparing Shipment/Transfer:		
Email:	Phone:	Fax:

Subject ID	Visit Designation	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

Courier Transfer (Disks and Films):

medicalmetrics INC.
Insight from Imaging
Medical Metrics, Inc.
2121 Sage Road, Suite 300
Houston, Texas 77056
P: 713-850-7500
www.medicalmetrics.com

Attn: MicroPort MoM Post-Market Study

Address to Return Disks and/or Films:

FTP Transfer:
Click the "Send to MMI" button below to submit the transmittal form.

Alternatively, send this form to either of the following:
Fax: +1 (713) 850-9996
Email: tf@medicalmetrics.com

(To Be Completed by Medical Metrics Personnel)
Date of Return: ____ - ____ - ____ (dd-mm-yyyy) Fax #: ____ Return Prepared By: ____

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Completing the Transmittal Form

- All items indicated in yellow must be completed on the transmittal form:

Image Transfer Protocol MoM Post-Market Study MicroPort Orthopedics, Inc.

MicroPort MoM Post-Market Study	Sent Date: (dd-mm-yyyy)	Site Number:	
	Method of Transfer: <input type="checkbox"/> FTP <input type="checkbox"/> Courier	Tracking #:	
Person Preparing Shipment/Transfer:			
Email:	Phone:	Fax:	

Subject ID (dd-mm-yy)	Visit Designation	Visit Date (dd-mm-yy)	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

Courier Transfer (Discs and Films):  Insight from Imaging Medical Metrics, Inc. 2121 Sage Road, Suite 300 Houston, Texas 77056 P 713-850-7500 www.medicalmetrics.com	Address to Return Discs and/or Films: _____ _____ _____ _____	FTP Transfer: Click the "Send to MM" button below to submit the transmittal form. Alternatively, send this form to either of the following: Fax: +1 (713) 850-9998 Email: tf@medicalmetrics.com
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Attn: MicroPort MoM Post-Market Study

(To Be Completed by Medical Metrics Personnel)

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

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- ✓ Sent Date
- ✓ Method of Transfer
- ✓ Site Number
- ✓ Tracking Number (if courier)
- ✓ Name/Email/Phone/Fax of person preparing shipment
- ✓ Subject ID, Visit Designation, Visit Date, and Treatment Side
- ✓ Address for returning films, CDs, DVDs (Not needed for FTP transfers)
- ✓ If you are sending replacement images, indicate that on the transmittal form. (avoids creation of discrepancy)

Image Transmittal Form

- All images should be sent/transferred to MMI as soon as possible.
- If extra images were acquired outside of the stated visit windows due to clinical concerns, they will be imported into the database as “Unscheduled Visits”.
 - Identify extra images on Transmittal Form

Digitization & DICOM

- Digitization requirements:
 - At least 150 dpi (dots per inch).
 - No photocopies
 - File format:
 - DICOM
- DICOM Images
 - File Name: text string (*format is unrestricted; e.g. image0001.dcm*)
 - File Type: *.dcm or DICOMDIR
 - Directories / Labeling must contain:
 - Site #, Subject ID, Visit Designation
 - Directories / Labeling should/may contain:
 - Exam view, Treatment Side, Visit Date

Filename is typically
automatically generated
by workstation

Folder Structure



[Subject ID]_[Visit Designation]



MARS MRI



DICOM



image0001.dcm
image0002.dcm
image0003.dcm

...

Digital FTP Transfer

File Transfer Protocol (FTP)

- Instructions located in Image Transfer Protocol
- Each site will receive a user ID and password for FTP transfers.
 - Contact the Project Manager for details.
- Image file names should be formatted with:
 - Subject ID
 - Visit Designation
 - Absolutely **NO SUBJECT NAMES** in filename
- Fax or email image transmittal form to MMI:
 - Fax: +1 (713) 850-9996
 - Email: tf@medicalmetrics.com
 - Do **not** transfer image transmittal form using FTP

FTP Instructions

- download/install FileZilla (or other FTP client)
 - Free at <https://filezilla-project.org>
 - Recommended, not required → other clients can be used

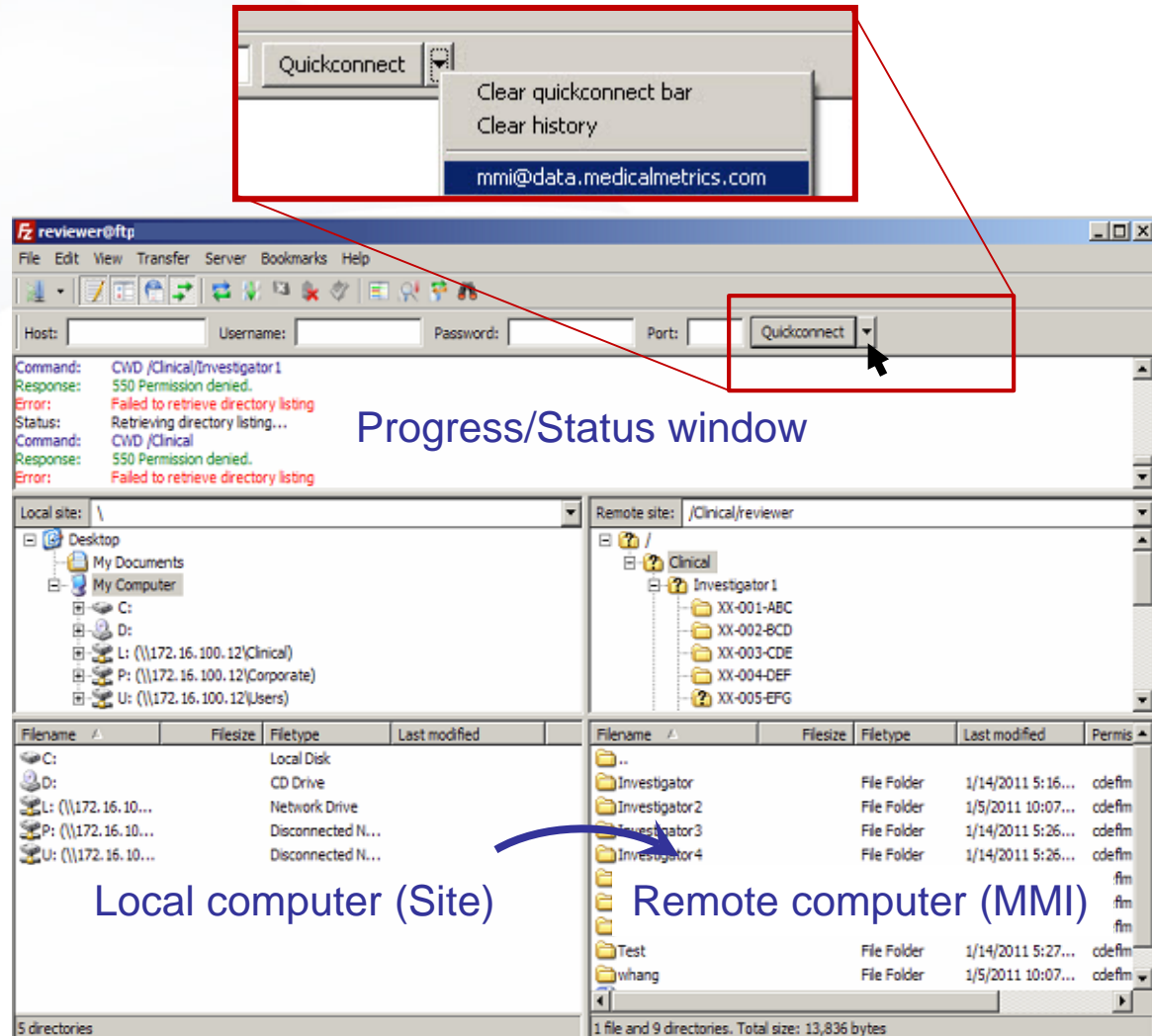
- Run FileZilla:



- **Host:** data.medicalmetrics.com
- **Secure Host:** ftpes:\\data.medicalmetrics.com
- **Username:** assigned by MMI (project-specific)
- **Password:** assigned by MMI (project-specific)
- **Port:** (empty)
- Click “Quickconnect”

FTP Instructions

- In the future, you can select MMI's server from the dropdown list under the Quickconnect button.
- Local drive is on left.
- Remote server (MMI) is on right.
- Transfer images from local drive to remote server:
 - “Drag and drop”
 - Right click → “Upload Files”



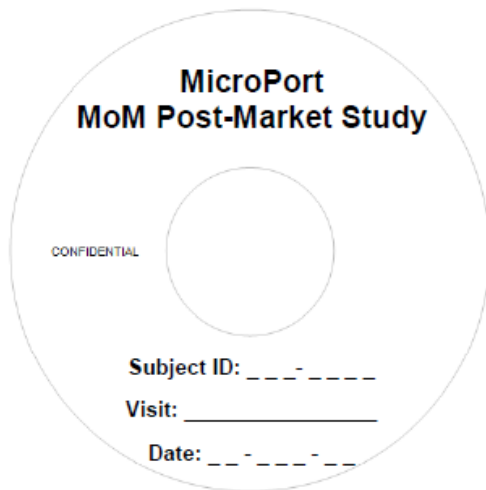
FTP Summary

1. Most likely to occur directly after a patient visit.
2. FTP reduces the potential for labeling errors.
 - (i.e. CD labels, Sleeve labels, etc.).
3. Transmittal form is required.
4. Do **NOT** upload transmittal form to FTP.
5. Submit transmittal form either via fax or email.
6. No need for MMI to return images back to the site.
 - Only the marked up transmittal form by fax.

COURIER TRANSFERS

Courier Labels

- CD Label



MicroPort
MoM Post-Market Study

CONFIDENTIAL

Subject ID: ____-____-____

Visit: _____

Date: ____-____-____

- CD Sleeve/Case Label

MicroPort MoM Post-Market Study – Disc Sleeve Label			
Subject ID:	____-____-____	____-____-____	
	Site #		Subject #
Visit Designation:	_____		
Visit Date:	____-____-____	____-____-____	____-____-____
	dd	mmm	yy

Only to be placed on the sleeve or jewel case.
Do **NOT** place directly on disc as the center hole may be obstructed.

Courier Summary

- All labels and forms are supplied to the site by MMI.
- Both CD and CD sleeve/case labels will be needed.
- All CDs received by MMI will be returned after images are imported into database, and all discrepancies are resolved.
- Do not mark on the discs with a ball point pen. Permanent marker is permitted.
- Send CD/DVD via courier.
- Include Transmittal form in shipment.

Thanks For Your Attention!

Questions ????



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