



IMAGE SUBMISSION MANUAL

NGM BIOPHARMACEUTICALS, INC.

STUDY TITLE

A Phase 2b, Randomized, Double-blind, Placebo-controlled, Multi-center Study to Evaluate the Efficacy, Safety, and Tolerability of Three Doses of NGM282 Administered for 24 Weeks for the Treatment of Histologically Confirmed Nonalcoholic Steatohepatitis (NASH)

PROTOCOL ID

NGM 18-0108

STUDY PHASE

PHASE 2b

PRODUCT NAME

NGM282

DATE

01-FEB-2019

VERSION

V 2.0



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VERSION HISTORY

VERSION DATE	VERSION NUMBER	SUMMARY
19-SEP-2018	V0.1	Initial Draft
20-SEP-2018	V0.2	Incorporated Sponsor Comments
24-SEP-2018	V0.3	Incorporated Sponsor and CAMRD Comments
24-SEP-2018	V1.0	Final
31-JAN-2019	V1.1	Protocol information updated
01-FEB-2019	V2.0	Final

TABLE OF CONTENTS

1. ARCHIVING AND DE-IDENTIFICATION OF IMAGING DATA	6
1.1 MRI CRF Completion	6
1.2 Image Data Archive Discs	6
2. ELECTRONIC SUBMISSION: DOWNLOADING THE MEDIDATA/INTELEIMAGE PLATFORM.....	7
2.1 Installing the Medidata/Inteleimage Image Management System.....	7
2.1.1 Setup a Windows Workstation Using Internet Explorer (IE) Web Browser	7
2.1.2 Setup a Mac Workstation Using Firefox Web Browser	7
2.1.3 Login to the Medidata/Inteleimage Platform for the First Time.....	7
2.1.4 Navigating the Study Home Screen	8
3. IMAGE UPLOAD VIA MEDIDATA/INTELEIMAGE PLATFORM FOR ELECTRONIC SUBMISSION	9
3.1 Electronic Submission of Images	9
3.2 MRI Identifiers.....	9
3.2.1 Qualification Scans: Site with Single Scanner	9
3.2.2 Qualification Scans: Site with Multiple Scanners	9
3.2.3 Subject Scans: Site with Single Scanner.....	9
3.2.4 Subject Scans: Site with Multiple Scanners.....	10
3.3 Submitting a Site Qualification Scan	11
3.3.1 Software Options for Uploading Images	12
3.3.2 Image Upload	13
3.3.3 Electronic Submission of MRI CRF (Transmittal Form).....	17
3.3.4 Submit a Visit to MCL	20
3.4 Submitting a Subject Scan	21
4. QUERIES.....	21
4.1 Resolving a Query in Medidata/Inteleimage	21
5. MANUAL SUBMISSION.....	22
5.1 Creating CDs and Forms for Archival and Submission	23
6. APPENDIX A: TROUBLESHOOTING JAVA SECURITY ISSUES.....	24
6.1 Add Exceptions to Java Security	24
6.2 Edit Trusted Sites in Internet Explorer	25

LIST OF TABLES

TABLE 1 – QUALIFICATION SCANS WITH A SINGLE SCANNER9

TABLE 2 – QUALIFICATION SCANS WITH MULTIPLE SCANNERS9

TABLE 3 – SUBJECT SCANS WITH SINGLE SCANNER.....9

TABLE 4 – SUBJECT SCANS USING SCANNER A.....10

TABLE 5 – SUBJECT SCANS USING SCANNER B.....10

LIST OF FIGURES

FIGURE 1 – MEDIDATA LOGIN8

FIGURE 2 – STUDY HOME SCREEN IN MEDIDATA.....8

FIGURE 3 – SUBJECT SELECTION FROM HOME SCREEN IN MEDIDATA.....11

FIGURE 4 - VISIT SELECTION FROM HOME SCREEN IN MEDIDATA.....11

FIGURE 5 - SCAN SUMMARY IN MEDIDATA12

FIGURE 6- DOWNLOAD THE TRANSFER AGENT SOFTWARE12

FIGURE 7- INSTALL THE TRANSFER AGENT SOFTWARE.....13

FIGURE 8- UPLOAD EXAMS COMMAND TO START IMAGE TRANSFER13

FIGURE 9 - FIND IMAGE FILES TO UPLOAD USING THE TRANSFER AGENT14

FIGURE 10 - FIND IMAGE FILES TO UPLOAD USING JAVA14

FIGURE 11 - FIND IMAGE FILES TO UPLOAD USING THE MEDIDATA BROWSER AGENT15

FIGURE 12 - SUBMIT IMAGE FILES USING THE TRANSFER AGENT15

FIGURE 13 - SEND IMAGES NOW USING JAVA.....15

FIGURE 14 - UPLOAD SELECTED STUDIES USING THE TRANSFER AGENT16

FIGURE 15 - TRACKING IMAGE UPLOAD PROGRESS USING THE TRANSFER AGENT OR JAVA.....16

FIGURE 16 - TRACKING IMAGE UPLOAD PROGRESS USING THE MEDIDATA BROWSER AGENT16

FIGURE 17- CLICK HERE TO RELOAD VISIT17

FIGURE 18 - PREVIEW / NEXT EXAM REQUIREMENT17

FIGURE 19 - ACCESS ELECTRONIC TRANSMITTAL FORM (E-FORM)18

FIGURE 20 - SUBMIT ELECTRONIC TRANSMITTAL-FORM (E-FORM).....18

FIGURE 21 - EXAMPLE OF INCOMPLETE/ERRONEOUS E-FORM19

FIGURE 22 - CONFIRM CORRECT TRANSMITTAL FORM SUBMISSION.....19

FIGURE 23 - VERIFY VISIT REQUIREMENTS ARE SATISFIED AND SUBMIT DATA TO MCL.....20

FIGURE 24 - CONFIRMATION OF SUCCESSFUL DATA UPLOAD TO MCL21

FIGURE 25 - SELECT DESIRED QUERY FOR RESOLUTION21

FIGURE 26 – QUERY RESPONSE.....22

FIGURE 27 - ADDITION OF SECURITY EXPECTATIONS TO JAVA AND INTERNET EXPLORER (IE)	24
FIGURE 28 - EDIT SITE LIST TO ADD EXCEPTIONS TO JAVA SECURITY	24
FIGURE 29 - ADD WEBSITES AS JAVA SECURITY EXCEPTIONS	25
FIGURE 30 - EDIT INTERNET EXPLORER (IE) TRUSTED SITES.....	25

1. ARCHIVING AND DE-IDENTIFICATION OF IMAGING DATA

Medidata and Inteleimage refer to the same image management system and are used interchangeably. For technical assistance, contact Medidata/Inteleimage: support@inteleimage.com; (+1) 877-464-7473.

1.1 MRI CRF Completion

A paper MRI CRF must be completed for each subject scan and time point submitted to Medpace Core Laboratories (MCL). Please see Section 2.1.4 for details on how to access study-specific materials (including Transmittal Forms) via the Medidata/Inteleimage platform. The information contained on the paper MRI CRF will be transcribed on the electronic MRI CRF in the Medidata/Inteleimage platform at time of upload. **The MRI CRF is considered a source document and should be filed with study documents upon the completion of upload.**

Important reminders:

- Both Date of Birth (DOB) and Scan Date values must be entered in DD/MMM/YYYY format. For example, a DOB of **July 1, 1990** would be written as **01/JUL/1990**.
- If the images are from a replacement scan, please indicate which previous scan it is replacing.
- If the images are from an unscheduled time point, please indicate the time point acquired
- The general comments area is used to provide additional details about the images and/or issues that may potentially impact image analysis, document technical issues that were not capable of being rectified at time of scan, or to clarify subject information not stated above.

Subject identifiers and demographics (e.g. Initials, DOB) should be entered consistently across all study platforms, including Medidata/Inteleimage. This is especially important to note if your site is utilizing anonymized values as opposed to actual subject data. Unless required by law or other official guidelines to only use anonymized values, your site should make all efforts to ensure demographic values are not anonymized within the machine. Certain diagnostic machines are preset to anonymize specific data, which will prompt data queries from MCL to confirm subject information. Site personnel should consult with their respective Information Technology (IT) team to evaluate if machine settings can be adjusted for study parameters.

1.2 Image Data Archive Discs

A study archive CD/DVD is created according to the system manufacturer instructions. Each archive CD/DVD should contain a single subject and single visit. Image data should be de-identified (to the best of your ability) of subject protected health information, and instead contain subject identifiers outlined in the study-specific MRI Manual. The identifiers are typically entered by imaging personnel at the time of scan acquisition. All archive CD/DVDs should minimally be labeled with the study protocol ID, subject ID, and visit time point; it is strongly encouraged to additionally label the CD with the Scan Date. **The archive CD/DVD is considered source image data for a given subject/time point and should be filed with study documents upon the completion of the electronic image upload.**

2. ELECTRONIC SUBMISSION: DOWNLOADING THE MEDIDATA/INTELEMAGE PLATFORM

MCL expects all image files to be submitted electronically via the Medidata/Inteleimage platform, unless indicated otherwise on your site Imaging Feasibility Assessment form, completed during study setup. If electronic submission is not possible, please refer to Section 5 for details.

For additional support on using the Medidata/Inteleimage platform, including articles and video tutorials, please visit <https://learn.mdsol.com/mmi/medidata-medical-imaging-93336474.html>

2.1 Installing the Medidata/Inteleimage Image Management System

The Medidata/Inteleimage platform supports both Windows (the preferred Internet browser is Internet Explorer) and Mac OS (the preferred Internet Browser is Firefox) workstations. A Java-based plugin will allow for uploading of medical images through your Internet Browser without installing any software. If you are using Internet Explorer on a Windows workstation, Medidata/Inteleimage offers an optional piece of software called the Transfer Agent as an alternative to the Java-based upload to optimize upload speeds. The Transfer Agent is the preferred method for image upload, but is not available for Mac OS. This requires a small software installation and separates the actual upload from the browser, allowing you to navigate away from the upload page (or even close the browser) during the transfer process.

2.1.1 Setup a Windows Workstation Using Internet Explorer (IE) Web Browser

Verify the most recent version of IE is installed on your computer by clicking the Settings button (gear icon) in the top right corner of the web browser and selecting "About Internet Explorer". Navigate to <https://www.intelegrid.com/upgrade/transferagent.html> to download the Transfer Agent. If using the Java plug-in verify you have the most recent version of Java by going to <http://java.com/en/download/installed.jsp> and clicking the "Verify Java Version" button.

2.1.2 Setup a Mac Workstation Using Firefox Web Browser

If you do not have Firefox, download it by opening Safari and navigating to www.mozilla.org. If you do have the Firefox web browser, verify that you have the most recent version by clicking the "Firefox" menu (to the left of the "File" at the top of your screen) and selecting "About". Verify you have the most recent version of Java by going to <http://java.com/en/download/installed.jsp> and clicking the "Verify Java Version" button.

2.1.3 Login to the Medidata/Inteleimage Platform for the First Time

Open the Internet Browser and go to www.clinicaltrialimaging.com. Enter your email and password provided to you by Medidata/Inteleimage. If this is the first time logging on, you will be prompted to change your password. **Note:** *Login credentials should be kept in a secure location. The FDA considers a username and password equivalent to an electronic signature under the Code of Federal Regulations (CFR), Title 21 Part 11. All work performed under a login credential is considered to be the work of the account owner. User account information should not be shared with others.*



Figure 1 – Medidata Login

A list of studies your site is participating in will be listed on the main screen. Select the NGM Bio NGM28208 study.

2.1.4 Navigating the Study Home Screen

The home screen is displayed after logging in and selecting the correct study. From this page, you will be able to access enrolled subjects, access study documents, and access any assigned queries.

All pertinent study documents (e.g. MRI Manual, MRI CRF) are available on the Medidata/Inteleimage portal. To access these documents, select the **Documents** tab on the Home Screen and click on the desired document to download it automatically.

For information on accessing and resolving queries relating to submitted image data, see Section 4.

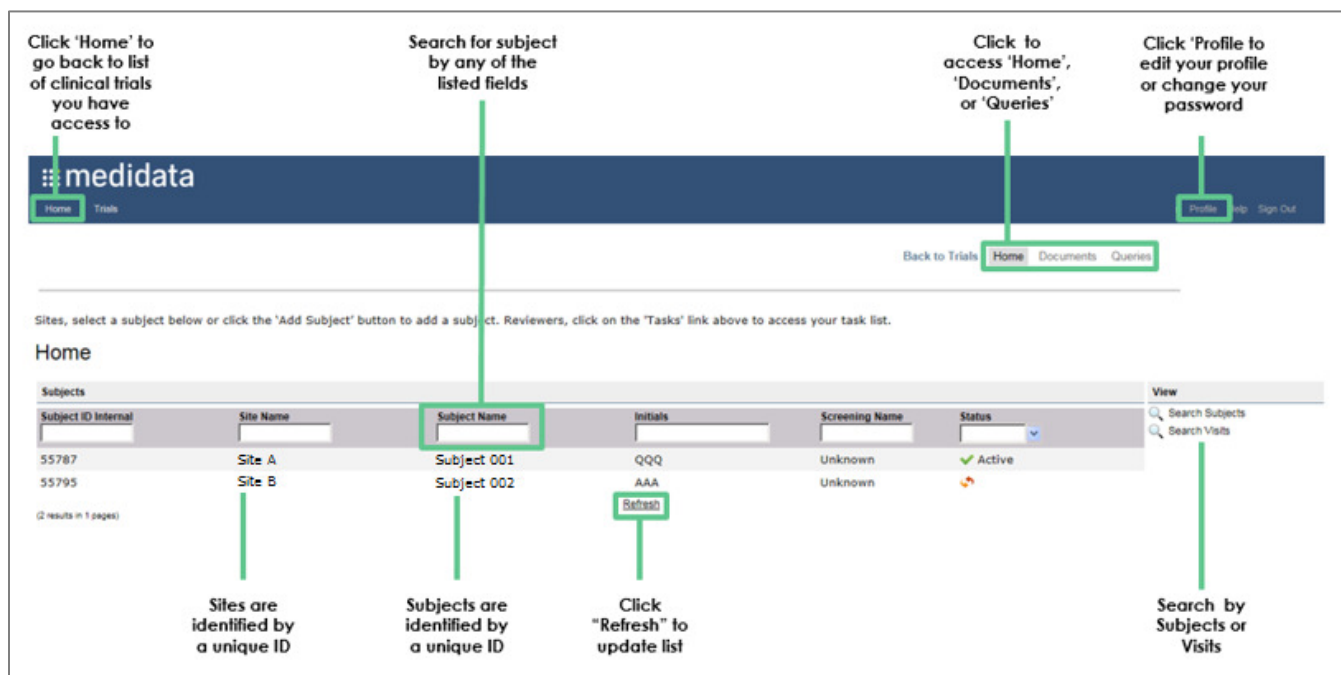


Figure 2 – Study Home Screen in Medidata

3. IMAGE UPLOAD VIA MEDIDATA/INTELMAGE PLATFORM FOR ELECTRONIC SUBMISSION

3.1 Electronic Submission of Images

When a subject is created by MCL in Medidata/Inteleimage, a visit calendar is automatically generated. Each visit contains requirements that must be fulfilled to complete the visit upload. Required tasks are highlighted red; once the required task is complete, it will turn green.

All study images should be in Digital Imaging and Communication in Medicine (DICOM) format. The Medidata/Inteleimage platform will automatically scan your CD/DVD or universal serial bus (USB) drive for DICOM images at time of upload. If no DICOM images are found, you will have the option to navigate to another folder or directory. All images in the scanned directory will be displayed and you can specify which images should be uploaded to the visit requirement.

The same steps are utilized for submission of the qualification scan and submission of subject scans.

3.2 MRI Identifiers

3.2.1 Qualification Scans: Site with Single Scanner

Table 1 – Qualification Scans with a Single Scanner

SITE 801	MRI IDENTIFIER
1 st Qualification Submission	NGM06_801_qq_Q1
2 nd Qualification Submission	NGM06_801_qq_Q2

3.2.2 Qualification Scans: Site with Multiple Scanners

Table 2 – Qualification Scans with Multiple Scanners

SITE 802 SCANNER A AND B	MRI IDENTIFIER
1 st Qualification Submission Scanner A	NGM06_802A_qq_Q1
2 nd Qualification Submission Scanner A	NGM06_802A_qq_Q2
1 st Qualification Submission Scanner B	NGM06_802B_qq_Q1
2 nd Qualification Submission Scanner B	NGM06_802B_qq_Q1

3.2.3 Subject Scans: Site with Single Scanner

Table 3 – Subject Scans with Single Scanner

SITE 801 SUBJECT 201	MRI IDENTIFIER
Baseline	NGM06_801_201_A
Baseline Replacement	NGM06_801_201_A2

SITE 801 SUBJECT 201	MRI IDENTIFIER
Week 12	NGM06_801_201_B
Week 12 Replacement	NGM06_801_201_B2
Week 24	NGM06_801_201_C
Week 24 Replacement	NGM06_801_201_C2
Week 30	NGM06_801_201_D
Week 30 Replacement	NGM06_801_201_D2
Early Withdrawal	NGM06_801_201_EW

3.2.4 Subject Scans: Site with Multiple Scanners

Table 4 – Subject Scans Using Scanner A

SITE 802 SUBJECT 201 – SCANNER A	MRI IDENTIFIER
Baseline	NGM06_802A_201_A
Baseline Replacement	NGM06_802A_201_A2
Week 12	NGM06_802A_201_B
Week 12 Replacement	NGM06_802A_201_B2
Week 24	NGM06_802A_201_C
Week 24 Replacement	NGM06_802A_201_C2
Week 30	NGM06_802A_201_D
Week 30 Replacement	NGM06_802A_201_D2
Early Withdrawal	NGM06_802A_201EW

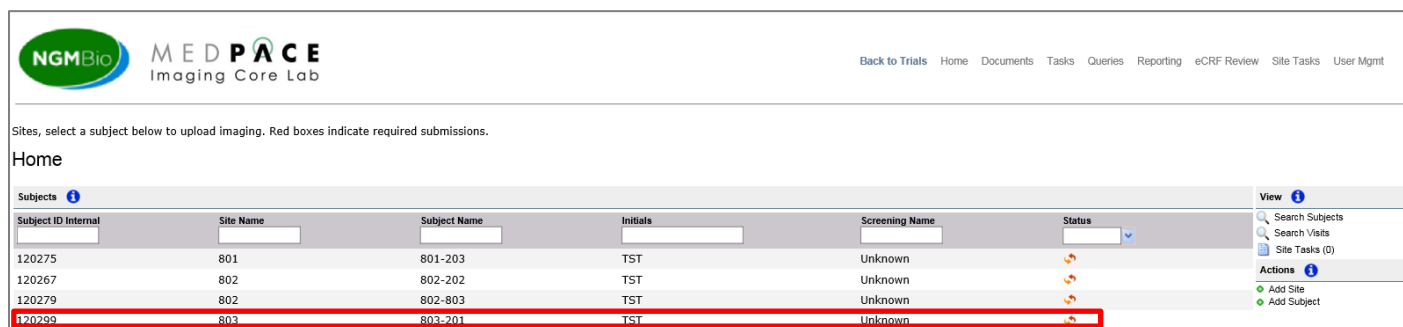
Table 5 – Subject Scans Using Scanner B

SITE 802 SUBJECT 802 – SCANNER B	MRI IDENTIFIER
Baseline	NGM06_802B_202_A
Baseline Replacement	NGM06_802B_202_A2
Week 12	NGM06_802B_202_B
Week 12 Replacement	NGM06_802B_202_B2
Week 24	NGM06_802B_202_C
Week 24 Replacement	NGM06_802B_202_C2
Week 30	NGM06_802B_202_D
Week 30 Replacement	NGM06_802B_202_D2
Early Withdrawal	NGM06_802B_202_EW

3.3 Submitting a Site Qualification Scan

Each site must submit a qualification scan to MCL for review and approval by the Center for Advanced Magnetic Resonance Development (CAMRD) prior to scanning subjects in this study. If the originally submitted qualification scan is not approved by CAMRD, a follow-up submission of a qualification replacement scan will be required for site approval.

- 1 Select the correct subject from the Home Screen.



Sites, select a subject below to upload imaging. Red boxes indicate required submissions.

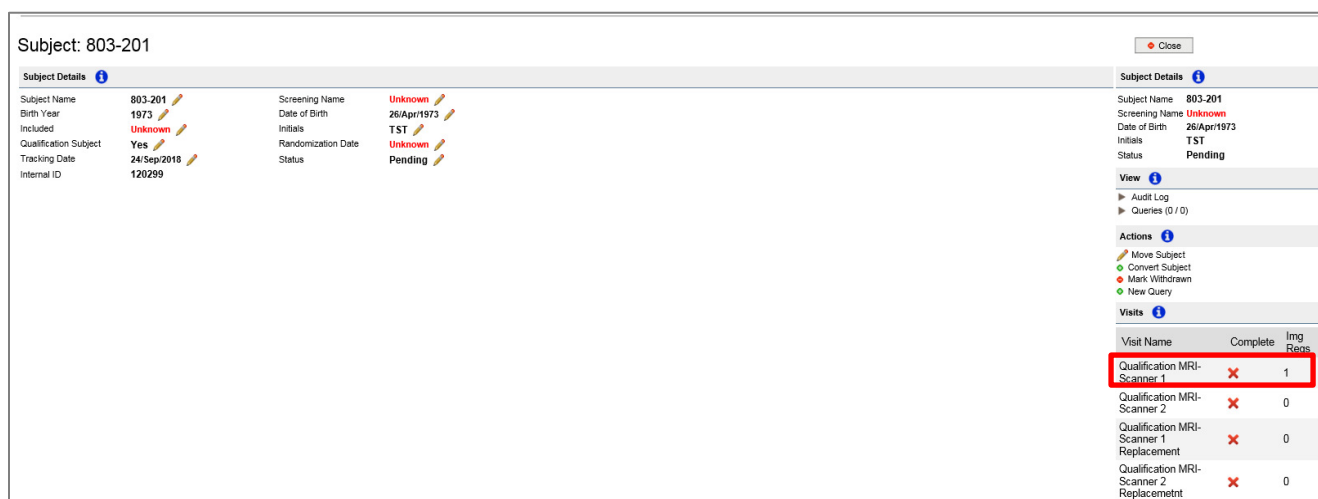
Home

Subject ID Internal	Site Name	Subject Name	Initials	Screening Name	Status	View
120275	801	801-203	TST	Unknown		
120267	802	802-202	TST	Unknown		
120279	802	802-803	TST	Unknown		
120299	803	803-201	TST	Unknown		

Actions: Add Site, Add Subject

Figure 3 – Subject Selection from Home Screen in Medidata

- 2 Select **Qualification** scan.



Subject: 803-201

Subject Details	Subject Details
Subject Name: 803-201	Subject Name: 803-201
Birth Year: 1973	Screening Name: Unknown
Included: Unknown	Date of Birth: 26/Apr/1973
Qualification Subject: Yes	Initials: TST
Tracking Date: 24/Sep/2018	Randomization Date: Unknown
Internal ID: 120299	Status: Pending

Actions: Move Subject, Convert Subject, Mark Withdrawn, New Query

Visits

Visit Name	Complete	Img Reqs
Qualification MRI-Scanner 1	X	1
Qualification MRI-Scanner 2	X	0
Qualification MRI-Scanner 1 Replacement	X	0
Qualification MRI-Scanner 2 Replacement	X	0

Figure 4 - Visit Selection from Home Screen in Medidata

- Subject visit details will outline all requirements (imaging studies and electronic forms for data entry) for the visit.

Subject: 803-201

Qualification MRI-Scanner 1 Visit Details

Visit Name	Qualification MRI-Scanner 1	Visit Date	Unknown
MRI Identifier (NGM06_aaa_2bb_c)	Unknown	MRI Scan Date	Unknown
Status	Active	Internal ID	591511

Qualification MRI-Scanner 1 Visit Requirements

Type	Info	Requirement	Commands
Exam	MR Imaging	1 Exam	Upload Exams
E-Form	Transmittal Form	1 E-Form	E-Form

Submission Problems (4):
Errors:
1. MR Imaging: Requires an upload
2. Transmittal Form: Requires a submission
... (show more)

✖ The Qualification MRI-Scanner 1 visit has not satisfied all required items. Please submit all required exams and files to mark complete!

Figure 5 - Scan Summary in Medidata

3.3.1 Software Options for Uploading Images

Medidata will allow you to upload DICOM images to the Medidata Rave Imaging Platform. While Medidata supports both Windows and Mac OS users and all browser types, MCL recommends uploading images using a Windows computer with the Internet Explorer browser. MCL also recommends installing the Transfer Agent, which is an ActiveX control software used to upload data.

3.3.1.1 Installing the Transfer Agent

Go to the website <https://www.intelegrid.com/upgrade/transferagent.html> and click on the link to install the software. If you need assistance with installation, contact the Medidata/Intelemage support team at support@intelemage.com or +1 (877) 464-7473.

inteleGRID Transfer Agent
TRANSFER AGENT
DIRECTOR
PACS VIEWER

Transfer Agent Installation

[Click here](#) to download the latest version's installer.

Latest Version
Version: 4.0.7.0

Need Help?
Please contact our support department:
• Phone: +1 (877) 464-7473

Figure 6- Download the Transfer Agent Software

If you cannot install software on your computer, Medidata Rave Imaging will attempt to use Java as the upload tool. Java is commonly installed on most computers for use in other applications; if Java version 6 update 26 (or greater) is installed on your computer, you should be able to successfully upload.

If you are a Mac user or do not use Internet Explorer as the default browser, you can still upload images. Using the Firefox browser, you can use Java or the Medidata Browser Agent. The Medidata Browser Agent is an HTML5 plugin that you will be prompted to install prior to upload. Google Chrome does not support the Java plugin but will support the installed Medidata Browser Agent.

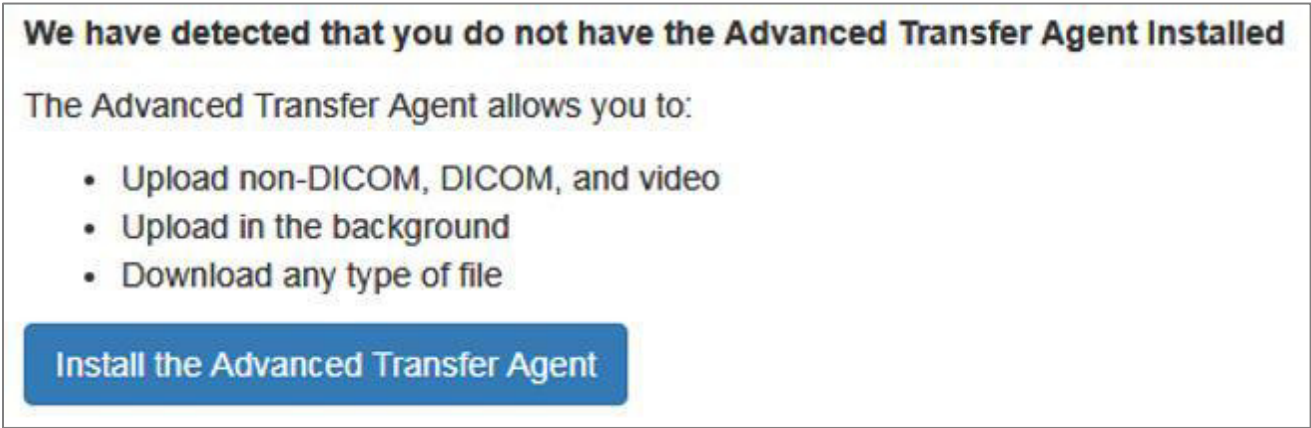


Figure 7- Install the Transfer Agent Software

3.3.2 Image Upload

To begin the upload process, select the Upload Exams link under Commands:

Subject: 803-201

Qualification MRI-Scanner 1 Visit Details

Visit Name	Qualification MRI-Scanner 1	Visit Date	Unknown
MRI Identifier (NGM06_aaa_2bb_c)	Unknown	MRI Scan Date	Unknown
Status	Active	Internal ID	591511

Qualification MRI-Scanner 1 Visit Requirements

Type	Info	Requirement	Commands
Exam	MR Imaging	1 Exam	Upload Exams
E-Form	Transmittal Form	1 E-Form	E-Form

Submission Problems (4):

Errors:

- MR Imaging: Requires an upload
- Transmittal Form: Requires a submission

... (show more)

✖

The Qualification MRI-Scanner 1 visit has not satisfied all required items. Please submit all required exams and files to mark complete!

Figure 8- Upload Exams Command to Start Image Transfer

If study images for upload are stored on your computer, network drive, or USB, navigate to the folder using the **Find Image Files** button. If the study images for upload are stored on a CD/DVD inserted into your computer's disc drive, Medidata/Inteleimage will automatically recognize a CD/DVD in the drive.

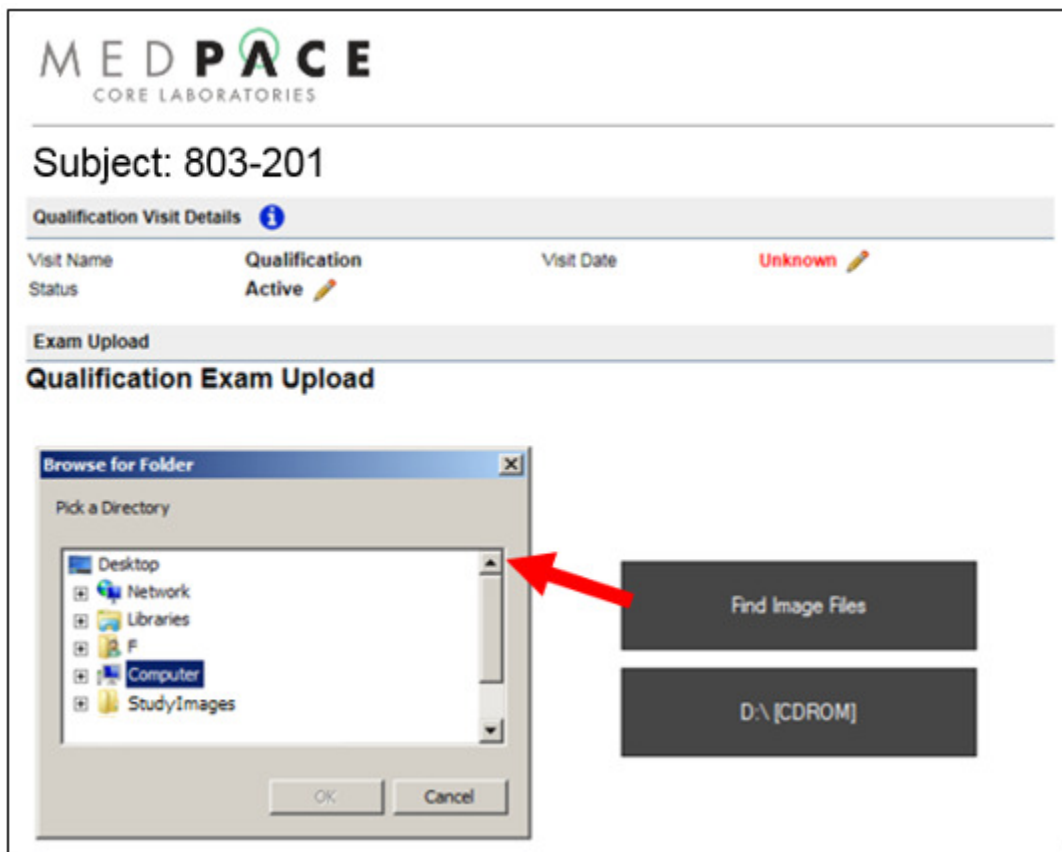


Figure 9 - Find Image Files to Upload Using the Transfer Agent



Figure 10 - Find Image Files to Upload Using Java



Figure 11 - Find Image Files to Upload Using the Medidata Browser Agent

Once an image source is selected, Medidata/Inteleimage will automatically begin searching for images. Once the exam has been located, check the box in the **Send** column, and press the correct button for your upload method: **Submit Image Files** (Transfer Agent), **Send Images Now** (Java), or **Upload Selected Studies** (Medidata Browser Agent).

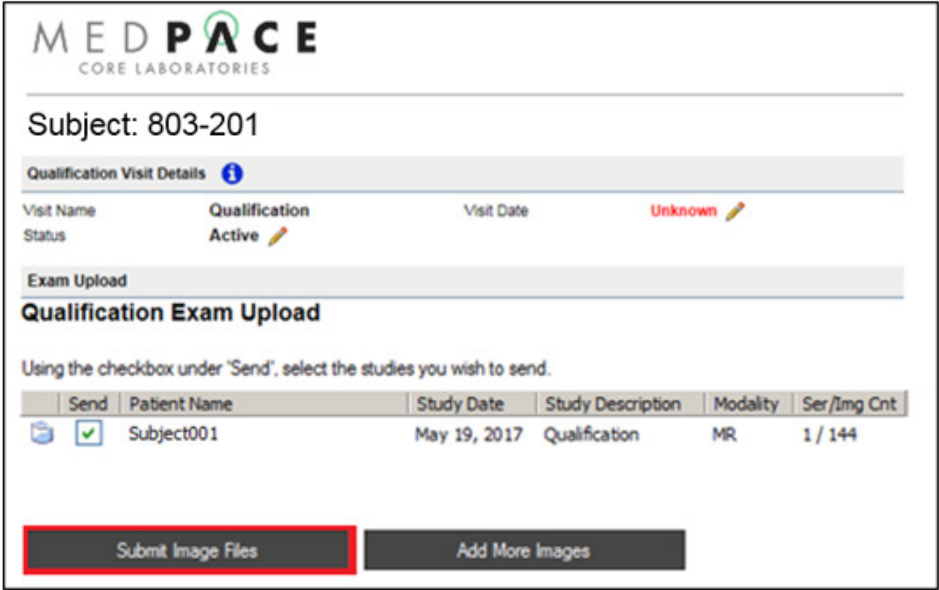


Figure 12 - Submit Image Files Using the Transfer Agent

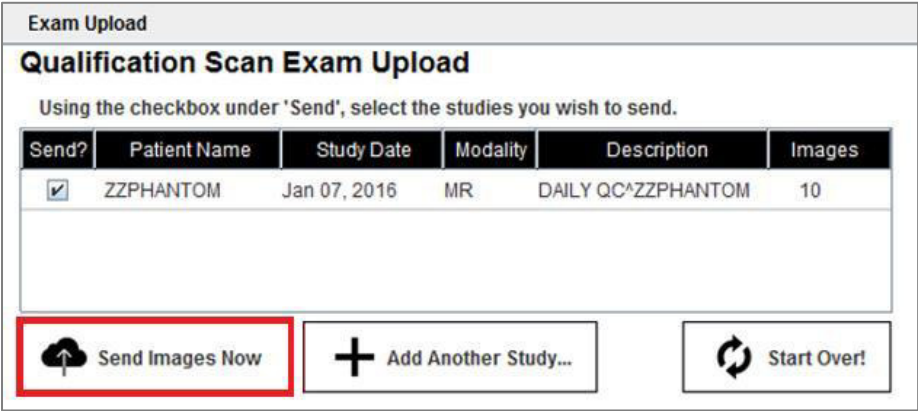


Figure 13 - Send Images Now Using Java

IntelGRID Account

PACS/Modality

Upload

	Patient Name	Study Date	Modality	Description	Ser/Img
<input checked="" type="checkbox"/>	Subject 001	8/21/15 12:56 AM	MR	Qualification	1 / 5

Customer Service Call 1-866-MEDIDATA (633-4328)

Upload Selected Studies

Add More Studies

Figure 14 - Upload Selected Studies Using the Transfer Agent

Medidata/Inteleimage will prepare the images for upload. The exam is uploaded in the background; check icons in your system tray to view upload progress.



Figure 15 - Tracking Image Upload Progress Using the Transfer Agent or Java

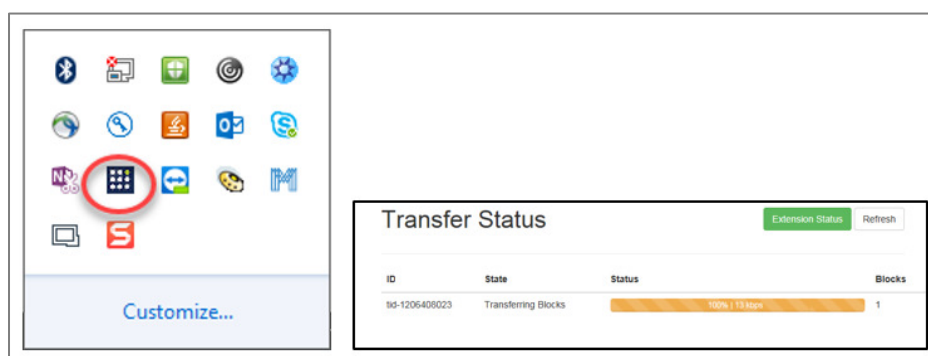


Figure 16 - Tracking Image Upload Progress Using the Medidata Browser Agent

Once the upload is complete, navigate back to the visit requirements screen by selecting the **Click here to reload visit** link.

Figure 17- Click Here to Reload Visit

The visit requirement has been fulfilled and is now green. Any outstanding requirements will remain red until fulfilled. All images can be reviewed prior to submission by selecting **Preview** next to the exam requirement.

Subject: 803-201

Qualification MRI-Scanner 1 Visit Details

Visit Name	Qualification MRI-Scanner 1	Visit Date	Unknown
MRI Identifier (NGM06_aaa_2bb_c)	NGM06_803_qq_Q1	MRI Scan Date	Unknown
Status	Active	Internal ID	591511

Qualification MRI-Scanner 1 Visit Requirements

Type	Info	Requirement	Commands
Exam	MR Imaging	1 Exam	Upload Exams
E-Form	Transmittal Form	1 E-Form	E-Form

Submission Problems (2):

Errors:

- Transmittal Form: Requires a submission
- Tracked item [MRI Scan Date]: Requires a value

✗ The Qualification MRI-Scanner 1 visit has not satisfied all required items. Please submit all required exams and files to mark complete!

Exam

Preview	Requirement	Modality	Study Date	Images / Series	Upload Date	Upload By	Actions
	MR Imaging	MR	22/Aug/2018 10:43 AM	25 / 1	24/Sep/2018 7:27 AM	t.davis2@medpace.com	Preview Remove Study Send Study Download Study Open In Pacs Edit DICOM Headers

Figure 18 - Preview / Next Exam Requirement

3.3.3 Electronic Submission of MRI CRF (Transmittal Form)

After all files have been uploaded for the subject and visit, an electronic MRI CRF must be completed. The Medidata/Inteleimage platform will periodically save your progress in the event that the form is not completed during a session. Access the MRI CRF by clicking **E-Form**.

Subject: 803-201

Qualification MRI-Scanner 1 Visit Details ⓘ

Visit Name	Qualification MRI-Scanner 1	Visit Date	Unknown ⓘ
MRI Identifier (NGM06_aaa_2bb_c)	NGM06_803_qq_Q1 ⓘ	MRI Scan Date	Unknown ⓘ
Status	Active ⓘ	Internal ID	591511

Qualification MRI-Scanner 1 Visit Requirements ⓘ

Type	Info	Requirement	Commands
Exam	MR Imaging	1 Exam	Upload Exams
E-Form	Transmittal Form	1 E-Form	E-Form

Submission Problems (2):
Errors:
 1. Transmittal Form: Requires a submission
 2. Tracked item [MRI Scan Date]: Requires a value

✗ The Qualification MRI-Scanner 1 visit has not satisfied all required items. Please submit all required exams and files to mark complete!

Exam ⓘ


Preview	Requirement	Modality	Study Date	Images / Series	Upload Date	Upload By	Actions
	MR Imaging	MR	22/Aug/2018 10:43 AM	25 / 1	24/Sep/2018 7:27 AM	t.davis2@medpace.com	Preview Remove Study Send Study Download Study Open In Pacs Edit DICOM Headers

Figure 19 - Access Electronic Transmittal Form (E-Form)

- 1 Fill out the MRI CRF completely and press the **Sign Form** button to submit.

Medpace Imaging Core Lab
Data Transmittal

Sponsor: NGM Bio
Study Protocol ID: NGM28208

Site Name	<input type="text"/>
MRI Identifier (NGM06_aaa_2bb_c) ;	<input type="text"/>
Scan Date	<input type="text"/> Eg 01/Jan/2000
Name of MRI System	<input type="text"/>
Initials of MRI technologist/operator	<input type="text"/>
Did any adverse events occur during the MRI?	<input type="radio"/> Yes <input type="radio"/> No
If Yes, please describe in detail:	<div><input type="text"/></div>
Are any PHI (except scan date) present within the image data or DICOM headers? If Yes, please remove PHI prior to data transmission.	<input type="radio"/> Yes <input type="radio"/> No
Have all image data been uploaded via electronic data transfer system?	<input type="radio"/> Yes <input type="radio"/> No

Figure 20 - Submit Electronic Transmittal-Form (E-Form)

- Any incorrect fields will turn solid red and a message will appear detailing the error(s). Click **Return to Form** to close the message and correct the errors. The field(s) will remain red and until **Sign Form** button is pressed again. When corrected, green checkmarks will appear next to the field(s).

Subject: 803-201

Qualification MRI-Scanner 1 Visit Details ⓘ

Visit Name	Qualification MRI-Scanner 1	Visit Date	Unknown
MRI Identifier (NGM06_aaa_2bb_c)	NGM06_803_qq_Q1	MRI Scan Date	Unknown
Status	Active	Internal ID	591511

**Medpace Imaging Core Lab
Data Transmittal**

Sponsor: NGM Bio
Study Protocol ID: NGM28208

Site Name	
MRI Identifier (NGM06_aaa_2bb_c) ;	
Scan Date	Eg 01/Jan/2000
Name of MRI System	
Initials of MRI technologist/operator	
Did any adverse events occur during the MRI?	<input checked="" type="radio"/> Yes <input type="radio"/> No
If Yes, please describe in detail:	
Are any PHI (except scan date) present within the image data or DICOM headers? If Yes, please remove PHI prior to data transmission.	<input checked="" type="radio"/> Yes <input type="radio"/> No
Have all image data been uploaded via electronic data transfer system?	<input checked="" type="radio"/> Yes <input type="radio"/> No

Save Sign Form Cancel

Form Entry Errors

The following problems were found, these problems must be fixed in order to continue:

- Site Name is required is required. The field must be at least 1 characters (Tab: null)
- MRI Identifier is required is required. The field must be at least 1 characters (Tab: null)
- Valid date is required in the format DD/MMM/YYYY is required (Tab: null)
- Name of MRI System is required is required. The field must be at least 1 characters (Tab: null)
- MRI technologist/operator initials is required in the format AAA or A-A (Tab: null)
- Did any adverse events occur during the MRI? is required. You must make a selection (Tab: null)
- Are any PHI present? is required. You must make a selection (Tab: null)
- Have all image data been uploaded? is required. You must make a selection (Tab: null)

Return to Form

Figure 21 - Example of Incomplete/Erroneous E-Form

- Click the **Sign Form** button, input your credentials, and click the **Ok** button to complete.

Subject: 803-201

Qualification MRI-Scanner 1 Visit Details ⓘ

Visit Name	Qualification MRI-Scanner 1	Visit Date	Unknown
MRI Identifier (NGM06_aaa_2bb_c)	NGM06_803_qq_Q1	MRI Scan Date	Unknown
Status	Active	Internal ID	591511

**Medpace Imaging Core Lab
Data Transmittal**

Sponsor: NGM Bio
Study Protocol ID: NGM28208

Site Name	TEST
MRI Identifier (NGM06_aaa_2bb_c) ;	NGM_803_qq_Q1
Scan Date	22/AUG/2018
Name of MRI System	Siemens
Initials of MRI technologist/operator	TLD
Did any adverse events occur during the MRI?	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, please describe in detail:	
Are any PHI (except scan date) present within the image data or DICOM headers? If Yes, please remove PHI prior to data transmission.	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have all image data been uploaded via electronic data transfer system?	<input checked="" type="radio"/> Yes <input type="radio"/> No

Save Sign Form Cancel

Signature

Username:

Password:

☒ Ok ☐ Cancel

User Information:
First Name: Tamara
Middle Name:
Last Name: Davis

Figure 22 - Confirm Correct Transmittal Form Submission

3.3.4 Submit a Visit to MCL

Once all requirements have been satisfied, Medidata will display a Visit Completion message. Clear the message by entering your credentials and pressing the **Ok** button.

Note: MRI Scan Date and MRI Identifier must be completed in order to submit the visit.

Press the **Submit Visit** button to submit the images and Transmittal Form to MCL for review, processing, and quality control (QC).

Subject: 803-201

Qualification MRI-Scanner 1 Visit Details

Visit Name	Qualification MRI-Scanner 1	Visit Date	Unknown
MRI Identifier (NGM06_aaa_2bb_c)	NGM06_803_qq_Q1	MRI Scan Date	22/Aug/2018
Status	Active	Internal ID	591511

Qualification MRI-Scanner 1 Visit Requirements

Type	Info	Requirement	Commands
Exam	MR Imaging	1 Exam	Upload Exams
E-Form	Transmittal Form	1 E-Form	E-Form

SUBMIT VISIT

Signature

Username:

Password:

User Information:
First Name: Tamara
Middle Name:
Last Name: Davis

By electronically signing here you accept that your electronic signature is the legally binding equivalent of your handwritten signatures and that it is prohibited to share your username and password or any other components of your signature (21 CFR Part 11.100) and are submitting the visit.

☒ Ok ☐ Cancel

Exam

Preview	Requirement
	MR Imaging

Figure 23 - Verify Visit Requirements Are Satisfied and Submit Data to MCL

The exam status will update to **Visit will be reviewed - thank you!** Select the **Close** button in the top right corner of the page to return to the Study Home Screen. **Do not click the internet browser's Back button, as this will return you to the login screen.** The visit will now display as Complete with a green check when reviewing the subject history.

Once MCL receives the images, they will be reviewed for quality and completeness. The images will then be transferred to CAMRD via Box.com for review and analysis.

Subject: 803-201

Close

Qualification MRI-Scanner 1 Visit Details

Visit Name

Qualification MRI-Scanner 1

Visit Date

Unknown

MRI Identifier

NGM06_803_qq_Q1

MRI Scan Date

22/Aug/2018

Status

Pending QC

Internal ID

591511

Subject Details

Subject Name

803-201

Screening Name

Unknown

Date of Birth

26/Apr/1973

Initials

TST

Status

Pending QC

View

View Subject

Audit Log

Queries (0 / 0)

Actions

New Query

Reset Visit

Visits

Visit Name

Complete

Img Reqs

Qualification MRI-Scanner 1

✓

1

Qualification MRI-Scanner 2

✗

0

Qualification MRI-Scanner 1 Replacement

✗

0

Qualification MRI-Scanner 2 Replacement

✗

0

Qualification MRI-Scanner 1 Visit Requirements

Type

Info

Requirement

Commands

Exam

MR Imaging

1 Exam

Upload Exams

E-Form

Transmittal Form

1 E-Form

E-Form

Exam

Preview

Requirement

Modality

Study Date

Images / Series

Upload Date

Upload By

Actions

MR Imaging

MR

22/Aug/2018 10:43 AM

25 / 1

24/Sep/2018 7:27 AM

t.davis2@medpace.com

Preview

Remove Study

Send Study

Download Study

Open in PICS

Edit DICOM Headers

Files

File Name

Requirement

Size

Signed

Upload Date

Actions

Data Transmittal

Transmittal Form

N/A

✓

24/Sep/2018 7:42 AM

Remove Edit

Figure 24 - Confirmation of Successful Data Upload to MCL

3.4 Submitting a Subject Scan

The same steps utilized for submission of the site qualification scan will be followed for submission of the subject scan. If an unscheduled or replacement scan is required, the same steps used for qualification scans will be followed. Below are screen shots that show how the screens differ.

The main difference between site qualification and subject scans is the list of available study visits. The site qualification scan submission only displays Qualification and Qualification Replacement visit, whereas subject scan submission displays study-related imaging time points as visit options

4. QUERIES

During image quality control (QC), MCL or CAMRD may identify data discrepancies that will result in a query to the site. If a query has been assigned to the site, a notification email will be automatically generated by the Medidata/Inteleimage system. The user will need to log into Medidata/Inteleimage to access or respond to the query; a reminder email is sent every three (3) days until the query is resolved.

4.1 Resolving a Query in Medidata/Inteleimage

- Click on **Queries** tab from the Home Screen. Select the desired query.

MEDPACE

CORE LABORATORIES

[Back to Trials](#)
[Home](#)
[Documents](#)
[Queries](#)

Queries

Q ID

Site Name

Subject Name

Visit Name

Title

Assigned To

Status

Category

Created

12919

Site A

Subject 001

Screening

Upload Missing Images

a.user@example.com

Open

Missing Images

27/Jul/2017

Figure 25 - Select Desired Query for Resolution

- 5 Click **Comment** to respond. Type response in **Details** box and click **Save** to resolve the query.

The screenshot displays a web application interface for managing queries. The main window is titled 'Query-12919' and contains a 'Query Details' section with the following information: Title 'Upload Missing Images', Open Date '27/Jul/2017 04:03 PM EDT', Creator 'MCL Team Member', Assignee 'a.user@example.com', Category 'Missing Images', Last Action Date '27/Jul/2017 04:03 PM EDT', Status 'Open', and Close Date 'N/A'. A 'View' button is located in the top right corner. Overlaid on this is an 'Add Comment' dialog box. This dialog box includes an 'Assignee' dropdown menu set to 'a.user@example.com', a 'Details' text area containing the text 'Missing images have been submitted.', and a 'Commands' section with 'Save' and 'Cancel' buttons. The 'Save' button is highlighted with a red box. In the background, a 'Query History' table is partially visible, showing a single entry for '27/Jul/2017 04:03 PM EDT'.

Figure 26 – Query Response

5. MANUAL SUBMISSION

In the event a site cannot access the Medidata/Inteleimage platform for electronic data submission, a paper Transmittal Form and an image CD/DVD should be submitted following the below process. Fully complete a paper MRI CRF following the guidelines in Section 1.1. **All fields must be completed; any incorrect/missing data on the MRI CRF will result in a site query.**

GUIDELINES:	
Use a black ballpoint pen.	Use block capital letters.
Avoid writing outside of the provided space.	Avoid abbreviations.
Use an "X" or checkmark for checkbox fields.	Date format: DD/MMM/YYYY (e.g. 04/APR/2018).
Correct errors by drawing a single line through the error, writing the correct value nearby, and initialing/dating the correction.	

5.1 Creating CDs and Forms for Archival and Submission

- 1 Copy the images to two (2) CDs. Do not include non-image files on the CD if at all possible. Label the CD with the study protocol ID, subject ID, and visit time point; it is strongly encouraged to additionally label the CD with the Scan Date.
- 2 Complete a paper MRI CRF, and make a photocopy. File the photocopied Transmittal Form and one of the labeled CDs in the appropriate study file and/or binder.
- 3 Mail the original MRI CRF and the labeled CD to MCL. Shipping instructions for your study are provided to the Clinical Research Coordinator at the main site, and are available electronically in the study Documents tab in Medidata (See Section 2.1.4).

6. APPENDIX A: TROUBLESHOOTING JAVA SECURITY ISSUES

If you encounter Java errors while attempting to upload images, security expectations will need to be added to Java and Internet Explorer.



Figure 27 - Addition of Security Expectations to Java and Internet Explorer (IE)

6.1 Add Exceptions to Java Security

Open the Start Menu and click **Control Panel**. Select **Programs > Java**. Click the Security tab at the top, then select **Edit Site List...** button.

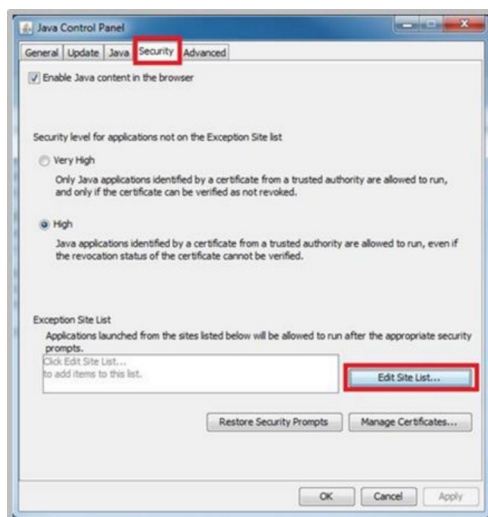


Figure 28 - Edit Site List to Add Exceptions to Java Security

Select the **Add** button and enter the following addresses, pressing the **OK** button once finished:

- <https://intelegrid.com>
- <https://web.intelegrid.com>
- <https://endo.intelegrid.com>

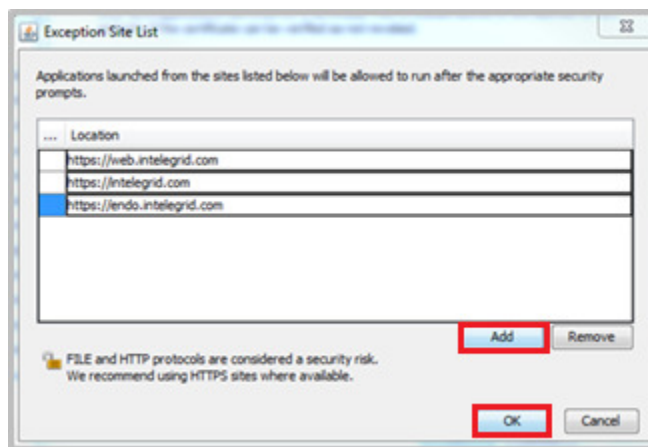


Figure 29 - Add Websites as Java Security Exceptions

6.2 Edit Trusted Sites in Internet Explorer

In Internet Explorer, open the Internet Options by either clicking on the gear icon in the upper right-hand corner or clicking "Tools" menu, then click "Internet Options". Click the "Security" tab, then click "Trusted Sites", then click "Sites".

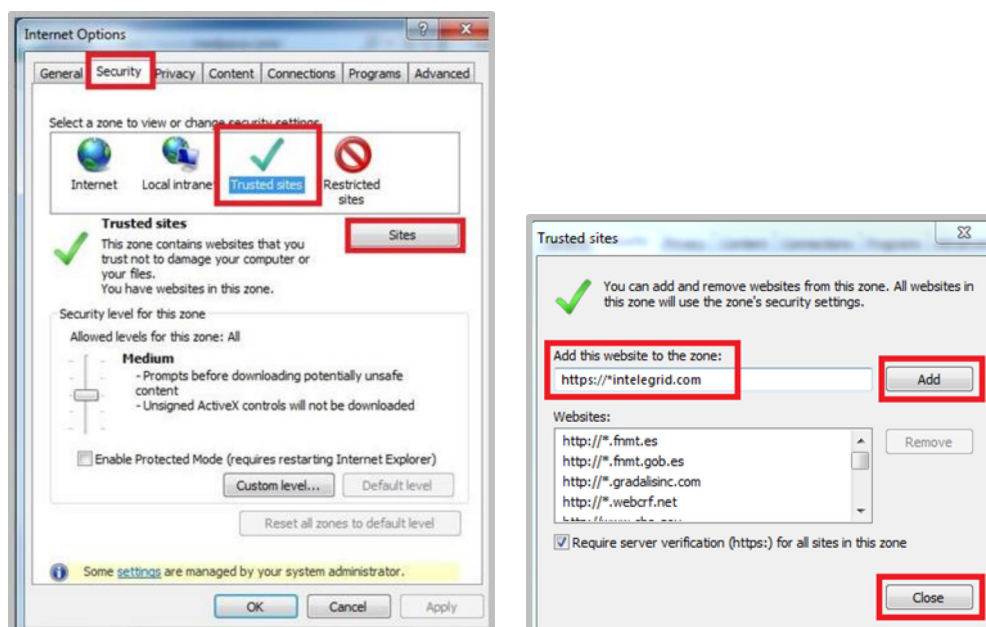


Figure 30 - Edit Internet Explorer (IE) Trusted Sites

Enter https://*.intelegrid.com and click **Add** then click **Close**. Close Internet Explorer before trying to upload again. Contact Medidata/Intelegimage for support at support@intelegimage.com or +1 (877) 464-7473.