

PVDOMICS

Chapter 60 & 70 Cardiac Echo & MRI Imaging Core Lab Process



NHLBI Pulmonary Vascular Disease Phenomics Program

Funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health with support from the Pulmonary Hypertension Association

CV Imaging Core



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Cardiac MRI and Echo Topics

- Anonymization Process
- Electronic Transfer of Images
- Data Transmittal Forms 250,251
- Digital Image Transfer – AG Mednet Portal
- Quality Critique System
- Data Clarification Process
- Resubmission of Images
- Safety Preventative maintenance and IAC documentation
- Imaging Core Contact List

Anonymization Process

- The subject coordinator needs to supply the subject ID to the technologist.
- For purposes of confidentiality and to remain compliant with Health Insurance Portability and Accountability Act (HIPAA), all references to a specific subject must be made using the entire Subject ID.
- Site is responsible for correctly de-identifying clinical exams with the correct study assigned Subject ID within the AG Mednet application.
 - Initials, SSN, Medical Record, DOB etc..

Archival Instructions

- Complete the electronic Data Transmittal Form carefully and completely. This is treated as a source document and is subject to audit by regulatory authorities.
- Archive the cardiac MR or Echo study to digital media (DVD) immediately from the imaging system used to acquire the images following the instructions in the MOP. (Images should not be copied directly from the Picture Archiving and Communication System (PACS)).
 - Make one copy of each imaging exam per disc and upload from this media to the AG Mednet website. Retain disc copy of exam with site records.

Digital Image Transfer

AG Mednet

- AG Mednet is a web-based diagnostic imaging network, enabling sites to send diagnostic image exams electronically and securely to the Imaging Core Lab.
 - AG Mednet will provide tools and training to anonymize exams, complete transmittal forms electronically and complete other trial specific tasks.
- Download the Cardiac MRI Transmittal Form #250 or Echo Transmittal Form #251 from the QHS website (<http://qhsapps.ccf.org/pvdomics/>). Completion of the hard copy data transmittal forms will aid in the completion of the AG Mednet Electronic Data Transmittal Form prior to exam upload.
- **Please transfer exams as they are collected.**

Echo Transmittal Form #250

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PVDOMICS Study
Echocardiogram (ECHO) Transmittal Form #250

Instructions: This form is used for both uploading data to AG Mednet for the Imaging Core Lab (ICL) and uploading data to the DCC database. Review AGC Chapter 60 prior to testing.

Study Coordinator Completes Questions 1-5.

110001

-AB

12012015

1. Identification Number 2. Alphacode 3. Date of ECHO (mm/dd/yyyy)

4. Gender (0=Male, 1=Female)..... 0

5. Visit Type 2
1=Qualification, 2=Baseline, 3=Follow-up

Sonographer Completes Questions 6-12.

6. a. Was blood pressure measured at the beginning of ECHO 1
0=No, BP was not collected, 1=Yes

b. If yes, blood pressure measures (mmHg) (systolic/diastolic) 110/070

7. Agitated saline contrast (0=No, 1=Yes)..... 0

8. a. Contrast enhancement for left ventricular opacification (LVO) 1
0=No, contrast agent not collected, 1=Yes

b. If yes, name of contrast agent used 3
1=Optison 2=Definity 3=Lumason 8=Other, specify _____

c. Total contrast volume (mL) 0.2

Comments Technically difficult study.

9. a. Username of ECHO Sonographer who performed echocardiogram..... SMITHCA
b. Name of ECHO Sonographer who performed ECHO Cathy Smith

Revision of 01/15/2016 Pt ID 110001 ACAB Date of ECHO 12/01/2015 Form #250
Page 2 of 2

Ultrasound Equipment Used for this ECHO

10. Ultrasound manufacturer name Philips

11. Model # IE-33

12. Serial # 12345

Transmission Details for ECHO to AG Mednet - Coordinator completes Q13 through end of form.

13. Method of transmission (1=Digital transfer, 8=Other, specify _____)..... 1

14. Date ECHO file transmitted (mm/dd/yyyy)..... 12/01/2015
(Date file transmitted must be greater or equal to the date the form is completed.)

200. Date this form completed (mm/dd/yyyy)..... 12/01/2015

201. Username of person completing/reviewing completeness of this form SMITHCA

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) 1/1/15

Username of person entering this form..... _____

MRI Transmittal Form #251

Revision of 01/15/2016



PVDOMICS Study Cardiac MRI Transmittal Form #251

Form #251
Page 1 of 2

Instructions: This form is used for both uploading data to AG Mednet for the Imaging Core Lab (ICL) and uploading data to the DCC database. Review MOP Chapter 70 prior to testing.

Study Coordinator Completes Questions 1-5.

1. Identification Number 110002 - 2. Alphacode AB 3. Date of Cardiac MRI (mm/dd/yyyy) 12/01/2015

4. Gender (0=Male, 1=Female)..... 0
5. Visit Type 2
1=Qualification, 2=Baseline, 3=Follow-up

MRI Technologist Completes Questions 6-20.

6. a. Blood pressure measured at the beginning of cardiac MRI?..... 1
0=No, BP measures not collected, 1=Yes
b. If yes, blood pressure measures (mmHg) (systolic/diastolic) 110 / 070
7. a. Was there a cardiac rhythm disturbance during MRI? (0=No, 1=Yes)..... 1
b. If yes, what type of rhythm disturbance? 2
1=Atrial fibrillation 8=Other, specify _____
2=Bradycardia
8. a. Was average heart rate collected during MRI? (0=No, 1=Yes)..... 1
b. If yes, average heart rate during MRI (bpm) 046
9. a. Was contrast agent used? 2
0=No contrast agent used 6=Omniscan (gadodiamide)
1=Abilab (gadofosveset trisodium) 7=ProHance (gadoteridol)
2=Magnevist (gadopentetate dimeglumine) 8=Other, specify _____
3=MultiHance (gadopentetate dimeglumine)
4=OptiMARK (gadoversetamide)
5=Dotarem (gadoterate meglumine)
b. Total contrast volume (mL)..... 40

(continued on next page)

Revision of 01/15/2016 Pt ID 110002 AC AB Date of MRI 12/01/2015

Form #251
Page 2 of 2

10. MRI start time (24-hr clock) (hh:mm) 08:00
11. Injection start time (24-hr clock) (hh:mm)..... 08:15
12. Look-Locker sequence start time (24-hr clock) (hh:mm) 08:28
13. Delayed enhancement sequence start time (24-hr clock) (hh:mm)..... 08:30
14. MOLLI sequence start time (24-hr clock) (hh:mm), if performed 08:35
15. MRI end time (24-hr clock) (hh:mm) 09:00

Comments

16. a. Username of MRI Technologist who performed cardiac MRI SMITHCA
b. Name of MRI Technologist who performed cardiac MRI Cathy Smith

Imaging Equipment Used for this Cardiac MRI

17. MRI manufacturer 3
1=GE 8=Other, specify _____
2=Philips
3=Siemens
18. Model # Avanto
19. Serial Number # 12345
20. Field Strength: Tesla (1=1.5 T, 2=3.0 T) 1

Transmission Details for Cardiac MRI to AG Mednet- Coordinator completes Q21 through end of form.

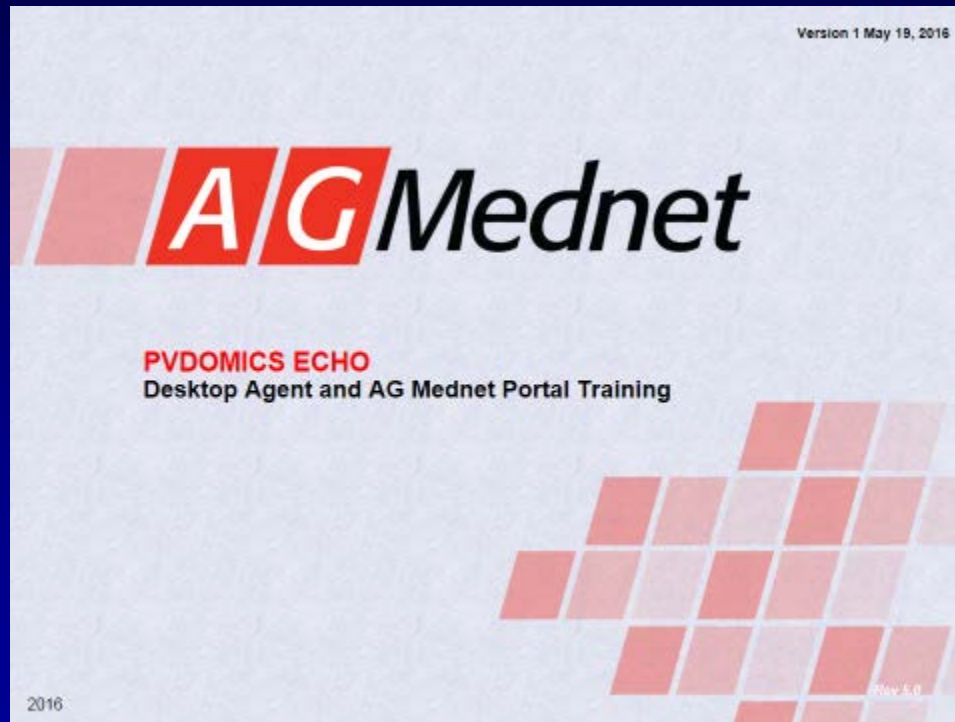
21. Method of transmission (1=Digital transfer, 8=Other, specify 1
22. Date MRI file transmitted to AG Mednet (mm/dd/yyyy) 12/01/2015
(Date file transmitted must be greater or equal to the date the form is completed.)
200. Date this form completed (mm/dd/yyyy)..... 12/01/2015
201. Username of person completing/reviewing completeness of this form SMITHCA

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ____/____/_____
Username of person entering this form _____

Sites will enter required demographic data in electronic transfer system 8

AG Mednet Home Screen



Example of Signature Log



C5Research
Cleveland Clinic, Coordinating Center for Clinical Research

PVDOMICS

AG Mednet Digital Image Transfer Training Completion Signature Page

AG Mednet WebEx: Recorded Session

Site Number: Site #: _____

Site Name: _____

Training Session Date: _____

<i>Print Name and Role:</i>	<i>Signature:</i>	<i>Date:</i>

ORDS     

AG Mednet Steps

- 1. Complete account authorization**
- 2. Register for an account on the AG Mednet Portal**
- 3. Launch the Desktop Agent and log-in with your Username/Password**
- 4. Submit an exam**
 - a) Import an image exam**
 - b) Review images (optional)**
 - c) Assign the exam to the trial**
 - d) De-identify the Pixel Data**
 - e) De-identify the DICOM data**
 - f) Complete the Data Transmittal Form**
 - g) Upload the exam**
 - h) Confirm successful exam submission**

CMR & Echo Quality Control

- **CMR and Echo Critiques**

- All images will be monitored for quality and adherence to the PVDOMICS imaging protocol.
- The Imaging Core will provide feedback in the form of a critique to sites and the DCC via email for each study submitted.
- The critique is a tool intended to standardize the collection of research quality data and to capture mistakes, if any, before they are repeated.
- The critique should be shared with the technologist performing the imaging exam to ensure the acquisition of research quality data and to help prevent the possibility of missing data.

Site Name:

Site Code:

Operator:

Subject:

Exam Date:

Equipment:

Visit:

Modality: ECHO

Exam Type: TTE

Criteria To Meet	Completed Correctly	Additional Comments
Was the study de-identified?	Yes	
Was there a good quality EKG tracing?	Yes	
Were adequate frame rates captured?	NA	
Was the LVOT from PLAX measurable?	Yes	
Were zoomed views of the Aortic Valve and the LVOT without color Doppler acquired?	Yes	
Were zoomed views of the Aortic Valve and LVOT with color Doppler acquired?	Yes	
Was the Aortic Root from PLAX measurable?	No	Suggest repositioning the subject and/or moving the transducer to a higher intercostal space.
Was the Left Ventricle measurable?	No	Biplane LVEF not possible due to loss of endocardial definition. Recommend use of contrast in technically difficult studies.
Was the Right Ventricle measurable?	Yes	
Was the Right Atrium measurable?	Yes	
Was the Left Atrium measurable?	Yes	
Was the LVOT pulse wave Doppler peak velocity measurable?	No	Site used Doppler steering angle of greater than 10 degrees, could not analyze PW of LVOT
Was the Aortic Valve Stent pulse wave Doppler peak measurable?	No	
Was the Aortic Valve continuous wave Doppler peak velocity measurable?	Yes	
Was the Pedoff probe used in three views (APEX/Subcostal, RSB, SSN)?	Yes	
Was Aortic Valve color Doppler acquired?	Yes	
Was Mitral color Doppler acquired?	Yes	
Was Pulmonary Vein pulse wave Doppler velocity acquired?	Yes	
Was Mitral inflow pulse wave Doppler acquired?	Yes	
Was Tricuspid Regurgitation color Doppler acquired?	Yes	
Was Tricuspid Regurgitation continuous wave Doppler velocity measurable?	Yes	
Was Tissue Doppler Imaging (TDI) acquired?	Yes	
Was Subcostal imaging of IVC with sniff acquired?	Yes	
Was this a technically difficult study?	Yes	

Criteria To Meet	Core Lab Response / Comments
Study Quality	Few measurements possible
Conclusion	Biplane LVEF not possible due to loss of endocardial definition. Recommend use of contrast in technically difficult studies. Site used Doppler steering angle of greater than 10 degrees, could not analyze PW of LVOT. Do NOT use Doppler angle correct in Echocardiography.

Data Clarification Process

- **Query Notification**
 - The study coordinator and the DCC will receive an email from the Imaging Core asking for resolution of any issues discovered during the quality control (QC) process. Prompt response is required from the study coordinator.
 - Query Data Clarification Form
 - Review the variable name, reported value and comments/suggestions
 - Record the corrected information in the resolution box

Data Clarification Form



Data Clarification

Imaging Core Lab
9500 Euclid Avenue JJ-65
Cleveland, OH 44195
Fax: 216-445-4419

PVDOMICS

Site Name: Brigham and Women's Hospital

Site Code: 11

Operator:

Subject: 110001-AB

Exam Date: 12/1/2015

Modality: ECHO

Visit: Baseline

Equipment: Philips IE-33

Exam Types: TTE

Media Critique

Digital Data stored in correct format?

Comment: The exam contains minimal images for this study. (29 images only).

Please re-upload the complete echo exam and forward to the Imaging Core Lab.

Sign and Date this DCF and return fax this query to the Imaging Core Lab as soon as possible for echo processing to be continued.

Response: _____

Signature: _____

Date: _____

Print Name: _____

Data Clarification Form



Data Clarification

Imaging Core Lab
9500 Euclid Avenue JJ-65
Cleveland, OH 44195
Fax: 216-445-4419

PVDOMICS

Site Name: Brigham and Women's Hospital

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Comment: The exam contains minimal images for this study. (29 images only).

Please re-upload the complete echo exam and forward to the Imaging Core Lab.

Sign and Date this DCF and return fax this query to the Imaging Core Lab as soon as possible for echo processing to be continued.

Response: _____

Signature: _____

Date: _____

Print Name: _____

Data Clarification Process Continued

- Media Queries

- Review the issue and comments/suggestions
- Record the corrected information and/or comments of action taken (Example: Sent Imaging Core new images via AG Mednet)
- Please print your name, sign and date (DD/MMM/YYYY) in the space provided. The Core Lab will not consider corrections recorded on the DCF unless signed and dated by site personnel completing the form. A signature indicates agreement that the data should be changed as indicated on the DCF.

- Questions ?

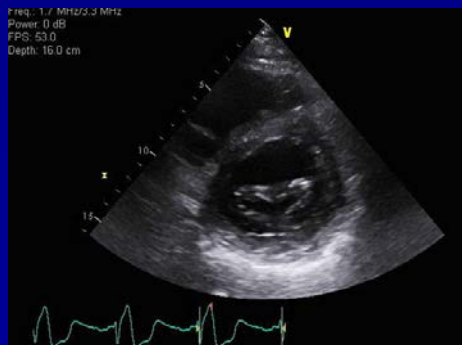
- Contact an Imaging Core Team Member for assistance

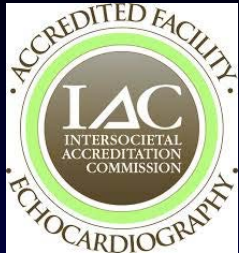
CMR Data Clarification Process Continued

- **Resolution and Return of DCF**
 - The site contact person (coordinator) must fax the completed DCF to the Imaging Core within five business days at 1-216-445-4419. The site will keep a copy of the DCF with corresponding study files.
- **Unresolved Query Process**
 - If the Imaging Core does not receive the faxed resolution, a follow up email will be sent to the site study coordinator, and the DCC will be copied, for immediate attention/resolution of the DCF.

Replacement Study Submission

- Image transfer incomplete
- Images not moving
- ID and Image set mismatch
- Identification correction clarified through DCF
- Core needs to remove old study
- Notification sent to site to resubmit image study





ACR Safety Standards



- Preventive Maintenance (PM) Document
- IAC (Intersocietal Accreditation Commission)
- MRI and Echo
 - Prior to qualification, a copy of the current annual PM document for each CMR scanner planned for use in the PVDOMICS trial, including serial number, must be submitted to the Imaging Core.
 - Submit again upon renewal date

Quick Print Imaging Core Contact Information

Margaret(Koko) Park	Lead Imaging Specialist	parkm@ccf.org	216-445-5175
Jeanne Drinko	Imaging Specialist	drinkoj@ccf.org	216-445-5274
Annitta Flinn	Core Lab Manager	flinna@ccf.org	216-445-5274
Cathy McDowell	Research Coordinator	mcdowec@ccf.org	216-445-7842
Michelle Baksar	Project Specialist	baksarm@ccf.org	216-444-9872
Jill Rusticelli	Project Specialist	rusticj@ccf.org	216-442-5231

AG Mednet Support	support@agmednet.com	1-888-9246336
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PVDOMICS DCC Website	http://qhsapps.ccf.org/pvdomics/
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Thank You!



Cleveland Clinic

Every life deserves world class care.

