INTERMACS Ninth Annual Meeting Program
MCSDs in 2015: Evolution, Expansion, and Evaluation

Friday, May 15 2015 and Saturday, May 16 2015

Research Data Workshop  Friday, May 15, 9:00 am – 2:00 pm
Space limited – Contact Grant Studdard at gkst@uab.edu

Coordinator’s Meeting  Friday, May 15, 3:00 – 4:30 pm

Interact: A Social and Networking Event  Friday, May 15, 4:30 – 5:30 pm

Annual Meeting & Scientific Sessions  Friday, May 15, 6:30 – 8:30 pm and
Saturday, May 16, 7:30 am – 3:00 pm

Continuing Medical Education credits (CME) and Continuing
Education Units (CEU) are available for guest attending the
Friday and Saturday Meeting & Scientific Sessions

The Westin Baltimore Washington Airport
1110 Old Elkridge Landing Road, Linthicum Heights, MD 21090
Phone 443-577-2300

Version Date: 02/011/2015
Course Description:

- The purpose of this workshop is to give the attendees a basic understanding of research methodology, i.e. hypothesis formulation, steps of a research project, use and management of research datasets, and basic analyses as they pertain to INTERMACS. The emphasis will be on the pragmatic programming and statistical steps necessary to produce clinically relevant research. These applied steps will be illustrated via four research examples from INTERMACS.

Intended Audience:

- Data managers and statisticians who are part of a research team that has or will receive data from INTERMACS (project Principle Investigator is welcome)

Prerequisites:

- Basic statistical methods
- Statistical programming language (Note: INTERMACS uses SAS)
- Basic data management skills (merging/linking datasets, variable derivations, and cohort identification)

Instructors:

- David C. Naftel, PhD, Director
- Susan L. Myers, Data Base Administrator
- Ryan S. Cantor, MSPH, Statistician
- Kathryn A. Hollifield, BSN, RN, Director of Clinical Affairs

Agenda/Outline

8:30 am Registration

9:00 am INTERMACS and Research

- What is INTERMACS? Description, Goals
- Patient timeline for data acquisition
- Research Plan (3 examples)
  A. Hypothesis Formulation
    i. Survival by after MCSD implant
    ii. Factors associated with bleeding
    iii. Quality of Life across time
  B. Descriptive, Data Mining
**Data Structure**

1. Review of Documentation
   A. Protocol Evolution
   B. Users’ Guide 3.0
   C. Web Based Data Entry
   D. Printable Forms 3.0
   E. Data Element Changes Over Time

2. Research Datasets (SAS format)
   A. Patient (each record is a patient)
   B. Device (each record is a device operation)
   C. Follow-up (each record is a follow-up visit)
   D. Events (each record is an adverse event)
   E. Management
      i. Cohort identification
      ii. Sub-setting
      iii. Merging datasets
      iv. Interval calculation

**Analysis**

1. Descriptive Statistics
2. Missing Data
3. Kaplan Meier (time related outcomes)
   A. Overall
   B. Stratify
   C. Time to first bleeding adverse event
4. Follow-up Data
   A. Comparison across time
   B. Paired Comparisons
5. Multivariable Analysis (introduction)
6. Presenting the Results
7. Available Resources

2:00 pm Adjourn
Coordinator’s Meeting  
May 15, 2015  
3:00 – 4:30 pm  
Room: Salons 1 and 2

Purpose:  
• To educate Intermacs and Pedimacs Coordinators on data entry and adverse event definitions.

Audience:  
• Site Coordinators

For the 2015 Coordinators meeting we will have a question and answer session regarding:

1. 4.0 Web Based Data Entry (WBDE) and Adverse Event definitions

2. How can Intermacs help you with Joint Commission reporting

3. Quality Assurance Reports for the coordinator? How the coordinators can benefit from them, too.

4. Research Opportunities for the coordinator, I understand this data and I want to write an abstract too.

5. Networking: We appreciate you, the coordinator!

6. Preparing for audits / understanding the audit process.
Interact: A Social and Networking Event
May 15, 2015
4:30 – 5:30 pm

Room: Prefunction

Hors d’oeuvres

Cash Bar
Friday May 15, 2015

5:30 pm  Registration

6:00 pm  Dinner

6:30 pm  Session 1: MCS In Special Populations

- Chemotherapy (Adriamycin
- HIV
- The Use of Mechanical Support in Adults with Congenital Heart Disease
- Peri Partum
- Restrictive and Obstructive Cardiomyopathies
- Acute Myocardial Infarction
- Debate: Who Should Not Receive a VAD: Pragmatism and FUTILITY in Patient Selection

Frank Pagani, MD, PhD
Guilherme Oliveira, MD
Salpy Pamboukian, MD, MSPH
Christina VanderPluym, MD
Renzo Loyaga-Rendon, MD, PhD
John Stulak, MD
Deepak Acharya, MD
Joseph Rogers, MD
Saturday May 16, 2015

7:00 am  Registration

7:30 am  Session 2: INTERMACS Overview / Update
- Enrollment
- 4.0 Update / Relaunch / Waiver of Consent / WBDE
  James K. Kirklin, MD
  David C. Naftel, PhD

7:40 am  Session 3: Patterns of MCS Utilization
- Impact of MCS Complications on Transplant Status
- Temporary Devices as a Bridge to More Permanent MCS
- RVAD Utilization
  James Young, MD
  Todd Dardas, MD, MS
  Eduardo Rame, MD, MPhil, MS
  Michael Kiernan, MD, MS

8:30 am  Session 4: Pediatric Device Issues
- First 100 Patients (or 200 Patients)
- Impact of MCS Therapy on Pediatric Transplantation
  David Rosenthal, MD
  Elizabeth Blume, MD
  Chris Almond, MD

9:00 am  Session 5: New Pump Updates
- MVAD / Circulite Update
- HeartMate III Update
- SynCardia 50mL
- Jarvik Infant 2000
  Robert Kormos, MD
  Katrin Leadley, MD
  Thoratec Representative
  Francisco Arabia, MD, MBA
  Robert Jarvik, MD

9:45 am  Break

10:15 am  Session 6: Quality of Life
- Quantifying the Impact of Adverse Events on Health-related Quality of Life Early after Implant
- Patient Selection and Estimation of Prognosis after LVAD Implant: Use of Health Status Measures
- Predicting Patients at Risk for Poor Global Outcomes after DT MCS Therapy
  Kathy Grady, PhD, APN
  Kelsey Flint, MD
  Suzanne Arnold, MD
11:00 am  Session 7: New Surgical Strategies
- Non-sternotomy Surgical Approaches for Implantation of Continuous Flow VADS
- Size Limitations for Current Continuous Flow Pumps: How young can we go?
  James Kirklin, MD
  Simon Maltais, MD, PhD
  Iki Adachi, MD

11:30 am  Session 8: Hospital / Quality Assurance / Joint Commission
- Using QA Data to Guide a Successful VAD Program
- Joint Commission View on MCS QA
- Hospital Challenges in MCS Utilization
  Robert Kormos, MD
  Barbara A. Elias RN, CCRN
  Joint Commission Representative
  Pavan Atluri, MD

12:15 pm  Lunch & Awards Ceremony

1:15 pm  Session 9: Pump Thrombosis Update
- Anticoagulation: Review of Best Practices
- Continuous Flow Pump Thrombosis Update
  James Kirklin, MD
  Salpy Pamboukian, MD, MSPH
  James Kirklin, MD

1:45 pm  Session 10: Decision Making Challenges
- Presenting Choices to Patients
- The Roadmap for Medical Patients
- Revive-IT Registers Life without VAD
- Medamacs: Who Gets to the End of Medical Therapy
- Panel Discussion: Projecting Outcomes for Ambulatory Patients without VAD
  Lynne Warner Stevenson, MD
  Larry Allen, MD, MHS
  Joseph Rogers, MD
  Josef Stehlik, MD, MPH
  Garrick Stewart, MD, MPH
  Joseph Rogers, MD; Josef Stehlik, MD, MPH; Larry Allen, MD, MHS; MedaMACS Representative
  James Kirklin, MD
  David Naftel, PhD
  Garrick Stewart, MD, MPH

3:00 pm  Adjourn