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
Research Data Workshop
May 15, 2015
9:00 am – 2:00 pm

Room: Salons 3A and 3B
Space is limited – Contact Grant Studdard at gkst@uab.edu

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
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
- 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
INTERMACS Ninth Annual Meeting
MCSDs in 2015: Evolution, Expansion, and Evaluation
May 15-16, 2015
Room: Salons 1 and 2

Saturday May 16, 2015

7:00 am  Registration

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

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

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

9:00 am  Session 5: New Pump Updates
- MVAD / Circulite Update  Robert Kormos, MD
- HeartMate III Update  Katrin Leadley, MD
- SynCardia 50mL  David Farrar, PhD
- Jarvik Infant 2000  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  Kathy Grady, PhD, APN
- Patient Selection and Estimation of Prognosis after LVAD Implant: Use of Health Status Measures  Kathy Grady, PhD, APN
- Predicting Patients at Risk for Poor Global Outcomes after DT MCS Therapy  Kelsey Flint, MD
- Suzanne Arnold, MD
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<tr>
<th>Time</th>
<th>Session</th>
<th>Title</th>
<th>Presenters</th>
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<tbody>
<tr>
<td>11:00 am</td>
<td>Session 7</td>
<td>New Surgical Strategies</td>
<td>James Kirklin, MD; Simon Maltais, MD, PhD</td>
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<td>• Non-sternotomy Surgical Approaches for Implantation of Continuous Flow VADS</td>
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<td>• Size Limitations for Current Continuous Flow Pumps: How young can we go?</td>
<td>Iki Adachi, MD</td>
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<td>11:30 am</td>
<td>Session 8</td>
<td>Hospital / Quality Assurance / Joint Commission</td>
<td>Robert Kormos, MD</td>
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<td>• Using QA Data to Guide a Successful VAD Program</td>
<td>Barbara A. Elias, RN, CCRN</td>
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<td>• Joint Commission View on MCS QA</td>
<td>Tonya Elliott, PHR</td>
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<td>• Hospital Challenges in MCS Utilization</td>
<td>Pavan Atluri, MD</td>
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<td>12:15 pm</td>
<td>Lunch</td>
<td>Lunch &amp; Awards Ceremony</td>
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<td>1:15 pm</td>
<td>Session 9</td>
<td>Pump Thrombosis Update</td>
<td>James Kirklin, MD</td>
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<td>• Anticoagulation: Review of Best Practices</td>
<td>Salpy Pamboukian, MD, MSPH</td>
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<td>• Continuous Flow Pump Thrombosis Update</td>
<td>James Kirklin, MD</td>
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<td>1:45 pm</td>
<td>Session 10</td>
<td>Decision Making Challenges</td>
<td>Lynne Warner Stevenson, MD</td>
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<td>• Presenting Choices to Patients</td>
<td>Larry Allen, MD, MHS</td>
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<td>• The Roadmap for Medical Patients</td>
<td>Joseph Rogers, MD</td>
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<td>• Medamacs: Who Gets to the End of Medical Therapy</td>
<td>Garrick Stewart, MD, MPH</td>
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<td>• Are BTT / DT Designations Still Relevant to VAD Outcomes</td>
<td>Josef Stehlik, MD, MPH</td>
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<td>• Panel Discussion: Projecting Outcomes for Ambulatory Patients without VAD</td>
<td>Joseph Rogers, MD; Josef Stehlik, MD, MPH;</td>
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<td>• INTERMACS Risk Model for MCS Outcomes in Ambulatory Profiles 4-6</td>
<td>Larry Allen, MD, MHS; MedaMACS Representative</td>
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<td>• Questions</td>
<td>James Kirklin, MD; David Naftel, PhD</td>
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<td>3:00 pm</td>
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