A National (International) Resource
What is INTERMACS?

INTERMACS is the United States national registry for patients who are receiving durable, FDA approved mechanical circulatory support device therapy to treat advanced heart failure. This registry was devised as a joint effort of the National Heart, Lung and Blood Institute (NHLBI), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), clinicians, scientists and industry representatives.
**INTERMACS STRUCTURE (2010 – 2015)**

- **NHLBI**
- **Observational Safety Monitoring Board (OSMB)**
- **Operations Committee**
  - NIH, FDA, CMS, UAB, UNOS, Co-PIs, Hospital Coordinators
  - Advice
  - Oversight
  - Reports

- **Executive Committee**
  - NIH, PI, Chair, Co-PI’s & Exec Director

- **Business Advisory Committee**
  - NIH, PI, DCC Director, Chair, Exec Director, Industry & Selected Hospitals

- **Co-PI’s and Chair**
  - Pittsburgh
  - Cleveland Clinic
  - Brigham & Women’s
  - Michigan

- **UNOS (DCR)**
  - Data

- **Participating Hospitals**
  - Data

- **UAB (DCC)**
  - Deliverables
  - Subcontracts ($)
  - Deliverables (Including Data)

- **FDA**
- **CMS**
  - Reports
  - Advice
  - Deliverables

- **INTERMACS Committees**
  - Coordinators Council
  - Industry
  - Pediatric
  - Hospital Standards
  - Medical Event Review
  - Data Access, Analysis & Publications

- **MEDAMACS**
  - Data Entry (MEDAMACS)
  - Data & Reports
  - Data & Reports
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Goals of the Registry

• Facilitate the refinement of patient selection to maximize outcomes with current and new device options.
• Identify predictors of good outcomes as well as risk factors for adverse events after device implantation.
• Develop consensus “best practice” guidelines to improve clinical management by reducing short and long term complications of MCSD therapy.
• Guide clinical application and evolution of next generation devices.
• Utilize Registry information to guide improvements in technology, particularly as next generation devices evolve.
Original Contract

Contract Extension
May 31, 2010 – November 30, 2010

Second Contract
December 1, 2010 – November 30, 2015
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<tr>
<th>114</th>
<th>Activated Sites</th>
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<td>6855</td>
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INTERMACS Hospital Enrollment

Hospital and Patient Accrual
June 2006 - September 2011

Year 1
(new patients: 274) Year 2
(new patients: 441) Year 3
(new patients: 950) Year 4
(new patients: 1262) Year 5
(new patients: 1557)

Activated Hospitals
Launch date (6/23/06)

Protocol Amendment 2.2
Protocol Amendment 2.3

Heartmate II BTT approval (4/21/08)

Hospital
Patient

Month

Jul06 Jan07 Jul07 Jan08 Jul08 Jan09 Jul09 Jan10 Jul10 Jan11 Jul11 Jan12
Intermacs: June 2006 – December 2011

Primary Implant Enrollment: n=5407

- Continuous Flow Intracorporeal LVAD Pump
- Pulsatile Flow Intracorporeal TAH
- Pulsatile Flow Intracorporeal LVAD Pump
- Pulsatile Flow Paracorporeal LVAD Pump

<table>
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The ‘MACS’ Family
pediMACS Launch Status

- pediMACS will follow the structure of INTERMACS
- A few important changes from INTERMACS:
  - Pediatric patients (< 19 yrs. at time of implant)
  - Includes both durable and temporary support
    MCSDs
  - Modifications of AE definitions
  - Possible expansion of quality of life instruments
MedaMACS

- To provide parallel information about medical outcomes for survival, function, and quality of life
- within INTERMACS profiles 4-7
- to help refine patient selection in the crucial range of ambulatory HF
- where the greatest benefit of VAD is anticipated.
Mission Statement

ISHLT Mechanically Assisted Circulatory Support (IMACS) Registry

The specific mission of IMACS is the promotion of scientific investigations and publications based on analyses of this multinational database, providing the opportunity for an international array of authors to collaborate in Registry investigations, presentations, and publications.