IMACS®

ELIGIBILITY

Any medical center outside the US with an active mechanical circulatory support device program is eligible to participate in IMACS®. Each center must provide the personnel and facilities to record and transmit data to the Data Coordinating Center.

COST

Participation in IMACS® is FREE. The registry is completely funded by ISHLT.

REGISTRATION

To participate in IMACS®, a center must designate a local principal investigator and a data administrator responsible for overseeing data submissions and registry compliance. Additionally, each center must obtain local regulatory approval, sign the IMACS® Memorandum of Agreement and complete web -based data entry training. Please contact us at IMACS@uab.edu to discuss enrolling your center and to obtain enrollment materials.

DATA SUBMISSION

Patient data entry into IMACS® will occur in 2 ways: (1) direct de-identified patient data entry through a Web-based portal, or (2) “collective” (usually countrywide) data provided to IMACS® via a data download.

IMACS® LEADERSHIP

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IMACS® Data Coordinating Center

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IMACS® REGISTRY

Imacs

ISHLT Mechanically Assisted Circulatory Support Registry

http://www.ishlt.org/registries/

IMACS® REGISTRY

In April 2011, the ISHLT Board of Directors approved the implementation of a new mechanical circulatory support registry designed to capture data on MCS devices from any non-US center. The IMACS® (ISHLT Mechanically Assisted Circulatory Support) Registry was launched in January 2013. IMACS® is managed by the University of Alabama at Birmingham, in cooperation with United Network for Organ Sharing (UNOS) in Richmond, VA and the ISHLT MCS Committee. UAB personnel will handle all center interactions, data management, and analyses.

MISSION

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.

WHAT MAKES IMACS UNIQUE?

IMACS® is poised to set the standard for international data collection and cooperation. IMACS® is a high-quality database focused on collecting accurate, complete, and verifiable data from non-US centers. Participants in IMACS® are required to maintain compliance with a 90% follow -up rate, match implants at a hospital with implants from industry records, respond to queries about data inconsistencies or errors, and participate in training sessions. Data obtained from IMACS® will be combined with the INTERMACS® dataset to provide "scientific quality" analyses to seek truths in the global application of durable MCS.

DATA STRUCTURE AND ELEMENTS

- Pre-implant form
- Implant form
- Discharge form
- Follow-up (every 6 months) Form

Major Events

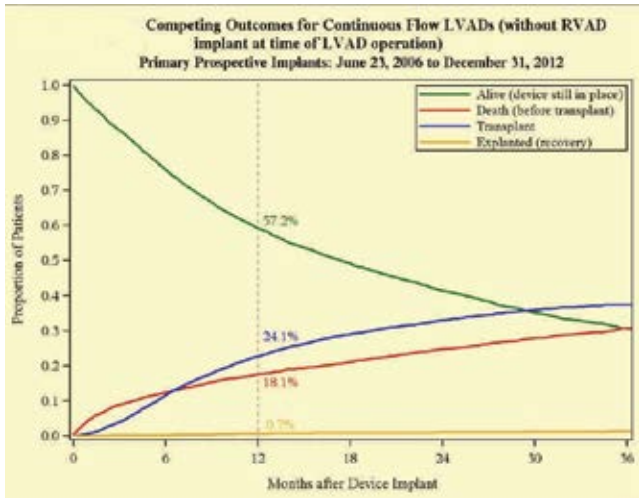
- Death
- Transplant
- Recovery
- Device Exchange

Adverse Events

Adverse Events will be captured in the discharge form and the follow-up forms.

- Device Malfunction
- Infection
- Bleeding
- Neurological Dysfunction
- Respiratory Failure
- Right Heart Failure
- Arterial Non-CNS Thromboembolism

Example of Analysis to be Obtained from IMACS®



WHY PARTICIPATE IN IMACS®?

Benefits to Centers

- Statistical summaries of hospital experience
- Benchmarks for comparison against the international experience
- Description of performance standards for units and practitioners
- Determine resources (personnel, skills, training) needed to meet performance standards
- Participate in device research
- Generate volume and trend data to facilitate short and long term financial planning

Benefits to ISHLT

- Own and direct an international high quality MCSD registry
- Complement the ISHLT transplant registry as ISHLT emphasizes it's role in MCSD research
- Provides Statistical Reports and Research
- Analyses to ISHLT Researchers

Benefits to MCS Community

- Improved outcomes from new techniques and devices
- Facilitate accelerated evaluation of new devices
- Development of international standards for MCS therapy