

Accessing Intermacs Data by Industry for FDA Post Market Studies

Procedures and Policies

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Introduction

From the beginning of Intermacs, a stated goal has been to facilitate the evolution of MCSDs. Specifically, the goals of INTERMACS are:

Intermacs

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..**
- **Utilize Registry information to guide improvements in technology, clinical application and evolution of next generation devices.**
- **Provide hospital specific Quality Assurance Reports. (added 2010)**

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In collaboration with industry and the FDA, Intermacs has worked towards these goals. Intermacs has assisted in pre-market approval studies and post market approval studies by providing data and, in some cases, statistical expertise. This document establishes the policies for sharing data among manufacturers for FDA post market studies.

Intermacs is interested in assisting companies within a context of fairness. The Intermacs Executive Committee has oversight for these efforts. The purpose of this document is to put a formal structure on these efforts by Intermacs, especially when Intermacs is asked to provide data to Company A that includes data from patients who receive devices made by Company B.

FDA Post Market Studies

Company A only requires data on patients who receive their devices

If Company A only requires data from patients who receive devices that are made by company A, then the process will be handled totally between Company A and the Intermacs DCC. The specifications of the study protocol will guide the process. The assumption is being made that the FDA has approved the protocol.

1. All interactions between Company A and Intermacs will be guided per the signed Project Agreement between Intermacs and Company A and via the approved FDA protocol.
2. The data will be subject to the general Intermacs policies for data quality and secure transfer of de-identified data.
Data transfers from Intermacs to Company A will be made per the Project Agreement on a pre-specified basis.
3. Unless otherwise specified in the Project Agreement or as necessary to meet regulatory requirements, Company A will not be given access to patient-level de-identified outcome data until the data collection phase of the study is complete.
4. Any patient-level de-identified data will be transmitted by secured encrypted means and the recipient will be held to data confidentiality and protections per NHLBI policies.
5. After each data transfer, including transfers with de-identified outcome data, company A may request clarifications on any data element that appears to be incorrect or inconsistent. Intermacs will provide clarifications as needed, and, when necessary, contact the local coordinator for corrections to the data entered into the web based data entry system.

Company A requires data from patients who receive a device from Company B

If Company A requires data from patients who receive a device from Company B, then an equitable process will be employed that considers the interests of both companies.

1. The data will be subject to the general Intermacs policies and procedures for data quality and secure transfer of de-identified data.
2. Company A will receive de-identified data from patients with their device as specified in the protocol and the Project Agreement. This will likely be an ongoing periodic transfer as patients are enrolled in the study.
3. Company A will receive de-identified data from patients who receive a device from Company B as described in the protocol and the Project Agreement. This may also be an ongoing periodic transfer based on the specifications in the protocol.
4. Patient outcomes de-identified data will be transferred to both companies per the Project Agreement. Under most circumstances this will occur after patient enrollment is complete and the minimal follow-up period is complete.

5. Company B will receive de-identified data from patients from both Company A and Company B. This will occur after the final data transfer for all patients has been sent to Company A and Company A has had sufficient time to review all of the data and has worked with the Intermacs DCC to correct any data inconsistencies.
6. The Intermacs DCC will work with Company B to correct any data inconsistencies identified by Company B.

Publications Policy for FDA Post-Market Approval Studies using Intermacs Data

In the event Company A wishes to use the Registry Data in a publication or presentation, Company A shall submit all proposed publications or disclosures to Intermacs (through the Executive Committee) at least thirty (30) days prior to submission for publications or disclosures to allow Intermacs through the EC, to review the matter for disclosure of information from the Registry. Intermacs, through the EC, shall have thirty (30) days from its receipt of such proposed publications or disclosures to review and to provide written notice to Company A requiring the removal of the Registry Data or any other information relating to the Registry Policies and Procedures that is proprietary. All proposals submitted for publications or presentation should reference the Renewal Contract as follows, "Intermacs has been funded whole or in part with Federal Funds from the National Heart, Lung and Blood Institute, National Institutes of Health, Department of Health and Human Services, under contract Number HHSN268201100025C."

Company A shall have first rights to any publication or presentation of the data received from Intermacs for their Post-Market Approval Study for one (1) year following conclusion of the study as defined in the Project Agreement. At the end of one (1) year, Company B and/or Intermacs will have the right to publish or present the data.

If Company B wishes to use the Registry Data in a publication or presentation, Company B shall submit all proposed publications or disclosures to Intermacs (through the Executive Committee) at least thirty (30) days prior to submission for publications or disclosures to allow Intermacs through the EC, to review the matter for disclosure of information from the Registry. Intermacs, through the EC, shall have thirty (30) days from its receipt of such proposed publications or disclosures to review and to provide written notice to Company B requiring the removal of the Registry Data or any other information relating to the Registry Policies and Procedures that is proprietary. All proposals submitted for publications or presentation should reference the Renewal Contract as follows, "Intermacs has been funded whole or in part with Federal Funds from the National Heart, Lung and Blood Institute, National Institutes of Health, Department of Health and Human Services, under contract Number HHSN268201100025C."

Failure to follow this policy could jeopardize future access to Intermacs data.

Considerations

1. Data inconsistencies that are discovered by either company will be investigated and corrected as necessary by the INTERMACS DCC.
2. Each company is not required to share their analyses with the other company.
3. Disputes in analyses performed by Company A and Company B will not be managed by the Intermacs DCC. However, the Intermacs DCC will help facilitate any necessary conference calls and/or meetings in regard to any dispute.