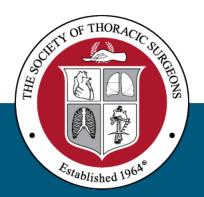
The Society of Thoracic Surgeons

Intermacs & Pedimacs Audit

2025



Purpose of the Audit

- To assure that the data collected at facilities are valid, therefore attesting to the integrity of the STS Intermacs & Pedimacs Databases
- To examine the accuracy, consistency, and completeness of data
- To provide education to the sites

- Affords an opportunity to identify variability in data collection so STS can share best practices, improve data definitions, and enhance training manuals and other educational offerings
 - Audit results drive education for our webinars and content provided at AQO



Site Selection for Audit

- 10% of participating sites are selected for audit
 - 19 Sites for Intermacs, 4 Sites for Pedimacs
- Site Administrator and Physician Representative receives the audit notification via email from STS
 - These two contacts will also receive the results at the end of the audit season

- Participating sites are removed from the audit selection pool for 3 years after completing an audit that meets expectations according to the STS National Database Audit Policy
 - STS reserves the right to utilize various methodologies, including random and targeted selection
 - Targeted audits may be scheduled if requested by a participant or deemed appropriate by STS



Who Will Perform the Audit?

- Healthcare Management Solutions, LLC (HMS) will perform an independent, external audit of the STS Intermacs & Pedimacs Databases
- HMS is HIPAA compliant and will conduct audits adhering to strict security policies in accordance with our Business Associate Agreement (BAA) and Sub-Business Agreement with STS
- HMS is covered as an affiliate under the BAA you entered STS as part of your participation in the Database, so a separate BAA is not needed
- All data files received are stored on an encrypted secure server at HMS



Intermacs Audit

 Healthcare Management Solutions, LLC (HMS) will perform the audit on 10 randomly selected patients entered between 10/1/2023 – 9/30/2024 utilizing version 6.1.

Pedimacs Audit

 Healthcare Management Solutions, LLC (HMS) will perform the audit on 2 randomly selected patients entered between 10/1/2023 – 9/30/2024 utilizing version 5.1.



- A final Summary Report will be emailed by STS to each site. The rate
 of agreement and data completeness will be considered when
 evaluating each site and identifying sites that do not meet the STS
 expectations.
- Your report will show variable accuracy, section accuracy, and overall accuracy.
- Variable accuracy (agreement) will be measured for each audited variable. The denominator will equal the total number of records audited. The numerator will show the number of records where that variable was a mismatch. This will be reported back as a percentage to sites.



- Section accuracy (agreement) will be measured for each section (i.e., Adverse Event (Bleeding), Death Form, Demographics, Pre-Implant (Laboratory), Three Month Follow Up etc.).
- Overall site accuracy (agreement) will be measured for each site as an overall agreement rate. The denominator will equal the total number of records audited. The numerator will show the number of records where that variable was a mismatch. This will be reported back as a percentage to sites.



- For Overall Variables:
- 98.0% or greater is defined as a site that exceeds expectations
- 90.0% to 97.9% is defined as a site that meets expectations
- A site achieving less than 89.9% is defined as a site that does not meet expectations and will require a re-audit within two years



Audit Policy – Overall Variables for Intermacs

Demographics Form	DOB	Date of Birth
	PRIMARY_DGN	Primary Cardiac Diagnosis
	PX_PROFILE	Intermacs Patient Profile
	NYHA_PRE_IMPLANT	NYHA Class
Due touriest Faure	SIX_MIN_WALK_PRE_IMPLANT	6-minute walk
Pre-Implant Form	PRE_IMPLANT_BILI_TOTAL	Total Bilirubin
	PRE_IMPLANT_CREAT	Creatinine
	SGOT_AST	SGOT/AST
	QOL_QUESTION_PRE_IMPLANT	QoL Questionnaire Completed
Implant Form	DEVICE_BRAND	Device Brand
	DEVICE_TY	Device Type
	IMPLANT_DT	Implant Date
Implant Discharge Form	DIS_DISCHARGE_DT	Implant Discharge Date



Audit Policy – Overall Variables for Intermacs

Dobo on italiantian Forms	DISCHARGE_DT	Discharge Date
Rehospitalization Form	PRIM_ADMIS_RSN	Primary Reason for Rehospitalization
	AE_INFECTION_ONSET_DT	Driveline Date
	INFECT_LOC_PUMP_DRIVELINE	Driveline Location
	BLEEDING_SOURCE_LOW_GASTRO	Lower GI Bleeding
Adverse Event Form	NEURO_CAT	CVA, TIA Onset Neuro Category
	HEPATIC	Hepatic Dysfunction Post Implant
	RENAL_DYS	Renal Dysfunction Post Implant
	RESP_FAIL	Post Implant Respiratory Failure
	AE_DEV_MALF_EVNT	Device Malfunction
Three Month Follow-Up	HEMOLYSIS	Hemolysis
	RHF	Right Heart Failure
	SIX_MIN_WALK_POST_IMPLANT	6-minute walk
	NYHA_POST_IMPLANT	NYHA Class
	QOL_QUESTION_POST_IMPLANT	QoL Questionnaire Completed
Death Form	DEATH_DATE	Death Date



Audit Policy – Overall Variables for Pedimacs

Demographics Form	DOB	Date of Birth
	PRIMARY_DGN	Primary Cardiac Diagnosis
	PX_PROFILE	Pedimacs Patient Profile
	NYHA_PRE_IMPLANT	NYHA Class
Dre Jeanlant Farms	SIX_MIN_WALK_PRE_IMPLANT	6-minute walk
Pre-Implant Form	PRE_IMPLANT_BILI_TOTAL	Total Bilirubin
	PRE_IMPLANT_CREAT	Creatinine
	SGOT_AST	SGOT/AST
	QOL_QUESTION_PRE_IMPLANT	QoL Questionnaire Completed
Implant Form	DEVICE_BRAND	Device Brand
	DEVICE_TY	Device Type
	IMPLANT_DT	Implant Date
Implant Discharge Form	DIS_DISCHARGE_DT	Implant Discharge Date



Audit Policy – Overall Variables for Pedimacs

Rehospitalization Form	DISCHARGE_DT	Discharge Date
	PRIM_ADMIS_RSN	Primary Reason for Rehospitalization
	AE_INFECTION_ONSET_DT	Driveline Date
	INFECT_LOC_PUMP_DRIVELINE	Driveline Location
	BLEEDING_SOURCE_LOW_GASTRO	Lower GI Bleeding
Adverse Event Form	NEURO_CAT	CVA, TIA Onset Neuro Category
	НЕРАТІС	Hepatic Dysfunction Post Implant
	RENAL_DYS	Renal Dysfunction Post Implant
	RESP_FAIL	Post Implant Respiratory Failure
	AE_DEV_MALF_EVNT	Device Malfunction
Three Month Follow-Up	HEMOLYSIS	Hemolysis Zone Record
	SUBSEQUENT_RVAD	Right Heart Failure Zone Record
	SIX_MIN_WALK_POST_IMPLANT	6-minute walk
	NYHA_POST_IMPLANT	NYHA Class
	QOL_QUESTION_POST_IMPLANT	QoL Questionnaire Completed
Death Form	DEATH_DATE	Death Date



- For the Adverse Events (Appendix B) and Follow-Up (Appendix C) sections:
- 98.0% or greater is defined as a site that meets expectations
- 90% to 97.9% is defined as a site that does not meet expectations and requires further education
- A site achieving 89.9% or less on the Adverse Events or Follow-Up section will require a re-audit within two years



Audit Policy – Adverse Events Section for Intermacs

WBDE Form	Short Name	Variable
Rehospitalization Form	PRIM_ADMIS_RSN	Primary Reason for Rehospitalization
Adverse Event Form	AE_INFECTION_ONSET_DT	Driveline Date
Adverse Event Form	INFECT_LOC_PUMP_DRIVELINE	Driveline Location
Adverse Event Form	BLEEDING_SOURCE_LOW_GASTRO	Lower GI Bleeding
Adverse Event Form	NEURO_CAT	CVA, TIA Onset Neuro Category
Adverse Event Form	HEPATIC	Hepatic Dysfunction Post Implant
Adverse Event Form	RENAL_DYS	Renal Dysfunction Post Implant
Adverse Event Form	RESP_FAIL	Post Implant Respiratory Failure
Adverse Event Form	AE_DEV_MALF_EVNT	Device Malfunction
Adverse Event Form	HEMOLYSIS	Hemolysis
Adverse Event Form	RHF	Right Heart Failure



Audit Policy – Follow-Up Section for Intermacs

WBDE Form	Variable
Death Form	Death Date
Death Form	Completed
One Month Follow-Up Form	Completed
Three Month Follow-Up Form	QoL Questionnaire Completed
Three Month Follow-Up Form	6-minute walk
Three Month Follow-Up Form	NYHA Class



Audit Policy – Adverse Events Section for Pedimacs

WBDE Form	Short Name	Variable
Rehospitalization Form	PRIM_ADMIS_RSN	Primary Reason for Rehospitalization
Adverse Event Form	AE_INFECTION_ONSET_DT	Driveline Date
Adverse Event Form	INFECT_LOC_PUMP_DRIVELINE	Driveline Location
Adverse Event Form	BLEEDING_SOURCE_LOW_GASTRO	Lower GI Bleeding
Adverse Event Form	NEURO_CAT	CVA, TIA Onset Neuro Category
Adverse Event Form	HEPATIC	Hepatic Dysfunction Post Implant
Adverse Event Form	RENAL_DYS	Renal Dysfunction Post Implant
Adverse Event Form	RESP_FAIL	Post Implant Respiratory Failure
Adverse Event Form	AE_DEV_MALF_EVNT	Device Malfunction



Audit Policy – Follow-Up Section for Pedimacs

WBDE Form	Variable
Death Form	Death Date
Death Form	Completed
One Month Follow-Up Form	Completed
Three Month Follow-Up Form	QoL Questionnaire Completed
Three Month Follow-Up Form	Hemolysis Zone Record
Three Month Follow-Up Form	Right Heart Failure Zone Record
Three Month Follow-Up Form	6-minute walk
Three Month Follow-Up Form	NYHA Class



- **Verification of post-procedure status** is required to be submitted to the audit company. This includes any tracking logs, electronic health records, or other documentation to support coding of those variables listed in Appendix D.
- 100.0% accuracy is defined as meeting expectations
- 99.9% or less for accuracy is defined as not meeting expectations and will require re-audit within two years



Audit Policy – Post-Procedure Verification for Intermacs & Pedimacs

Short Name	Notes
Three Month Follow-Up Form	Check that it was completed
Death Form	Check that it was completed



- If your site meets expectations for the adverse events section, follow-up section, post-procedure verification and overall data variables then your site will receive an audit completion certificate and the site will be removed from the audit pool for the next 3 years
- If your site does not meet expectations and requires reaudit within 2 years, your site will be selected for audit in 2 years and STS will provide further information at that time
- Contact: Emily Conrad, STS
 National Database Education
 Manager, at <u>econrad@sts.org</u>



First Steps

- A link to the <u>STS Intermacs Database Data Collection Questionnaire</u> or <u>STS Pedimacs Database Data Collection Questionnaire</u> is in the audit notification letter that was sent to the Site Administrator and Physician Representative for your site.
- Fill out this questionnaire and provide the lead contact for the audit
- HMS staff will take over from there...



Audit Process and Timeline

- 1. Audit Request Email- within 10 days of STS Intermacs/Pedimacs Database Data Questionnaire Response
- 2. Documentation Due Date- 30 business days from Audit Request Email
 **Due to the response period expansion from 30 calendar days, extensions will be limited to extreme circumstances
- 3. Review Period- 2-3 months from documentation submission
- 4. Interim Mismatch Report Issued- upon review period completion
- **5. Interim Mismatch Report Response** response due 5 business days after site receives Interim Mismatch Report
- 6. Adjudication- upon receipt of Interim Mismatch Report response
- 7. Final Reporting- sent by STS to Site Administrator and Physician Representative



Audit Request Email

- Within 10 business days of submitting the STS Intermacs or Pedimacs Data Collection Questionnaire, the listed contact(s) will receive an audit request email from the STS Mailbox (STS@hcmsllc.com).
- This Audit Request Email will contain information about the audit and any deadlines.
 - The email will include:
 - A secure link to the case sample for your site
 - The list of variables to be audited
 - Documentation Process Instructions

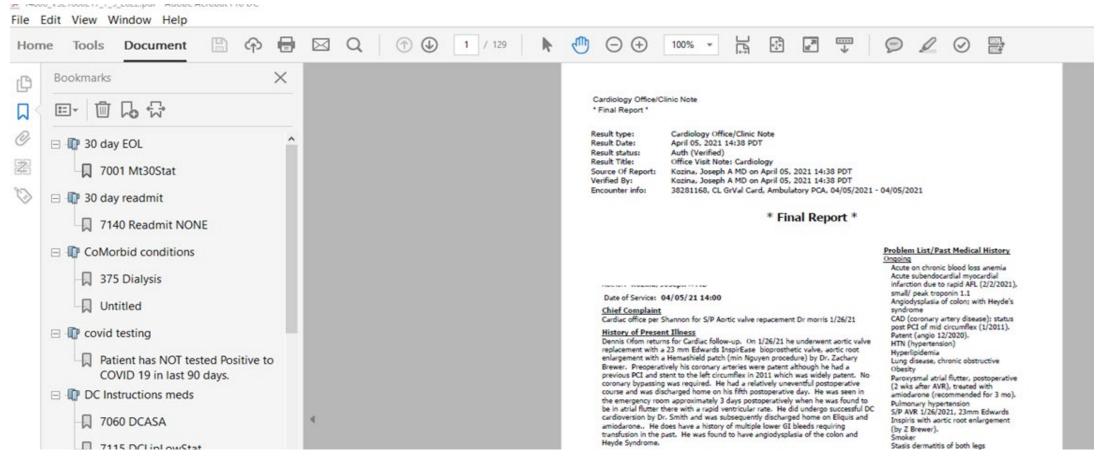


Documentation Collection

- Documentation should be submitted in PDF format.
- One PDF file for each Case.
- Bookmarks or other electronic flags must be used to identify each section of the record.
- Use the following naming convention for each individual PDF file: "PatientID_EventID_SiteCode".
- All cases can be zipped into one zip file for submission.
- Additional information will be provided in your Audit Request Email.



Document Collection: Bookmarking





Documentation Collection: Bookmarking Demo



Documentation Tips

- All submissions should be reviewed by your data abstractor for completeness.
- Submit only documentation relevant to the specific implant case do not include the entire patient record.
- Screenshots or snips are acceptable as long as they include enough surrounding detail to identify the patient and encounter.
- All submitted documentation must include patient identifiers and encounter dates, including screenshots or snips.
- Missing or irrelevant documentation may lead to mismatches during the audit.
- Submit documentation before the due date to avoid delays from unforeseen submission issues.

Submission of Documentation

- Documents will be uploaded using a file submission link that will be provided in your Audit Request Email.
- Submission is secure and encrypted.
- Submissions will not be accepted via email.
- If you experience any issues with submission, reach out to the STS Audit Team at STS@hcmsllc.com.



Clinical Lead Submission Tips

- All submissions should be reviewed by your data abstractor for completeness. Please include only documentation that was used by your site for case abstraction. DO NOT include the entire patient record/encounter.
- Records may include outpatient visits/testing as well as inpatient records.
- Prior to sending your data, please review your responses in the STS
 Database for each audited case. This allows you the opportunity to
 review the data entered/submitted and provide the auditing team the
 correct documents used for abstraction.
- Most mismatches result from missing records or overly large documentation, which makes it difficult to pinpoint the correct variables.



Questions & Answers



Contacting HMS

If you experience any issues with submitting your documentation, please contact the HMS Audit Team at STS@hcmsllc.com.

Be sure to include your STS Site Code in all communications



