

# The Society of Thoracic Surgeons

Intermacs & Pedimacs  
Quality Assurance Report Overview Webinar

January 15, 2026



**STS National Database™**  
Trusted. Transformed. Real-Time.

# Today's Meeting

- Welcome and Introductions
- STS Updates
- Reporting Updates
- Open Discussion



# The STS Team

Nancy Honeycutt, BSN, RN LSSGBH, National Database Manager for the ACSD, Intermacs and Pedimacs

Carole Krohn, MPH, BSN, RN, LSSGB, Director of the STS National Database

Leighann Jones, BS, National Database Manager for the Congenital and General Thoracic Databases

Emily Conrad, MS, National Database Education Manager

# The Intermacs Data Warehouse Team

Brandon Singletary, PhD, Statistician III, Epidemiologist

Ryan Cantor, PhD, Chief Scientific Officer

Rama Rudraraju, PhD, Director of Programming

John Pennington, MSHI, Director of Data Management



# Upcoming Webinars



## Intermacros User Group Call



January 28<sup>th</sup> @ 1PM CT



## Intermacros User Group Call

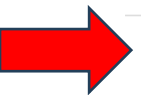


February 25<sup>th</sup> @ 1PM CT



# When Are The Reports Distributed?

Calendar Quarter	Data Entry Deadline	Coverage Stop Date	Distribution Date
Q1	April 30th	March 31st	June 30th
Q2	July 31st	June 30th	September 30th
Q3	October 31st	September 30th	December 31st
Q4	January 31st	December 31st	March 31st



# The INNOVATE Trial and Intermacs

All HM3 patients randomized in the trial *should* be included in Intermacs.

On the Demographics form:

**Is patient involved in a VAD related study?**

☒ Yes  
☐ No  
☐ Unknown

**What is the name of the study?**

The INNOVATE Trial |

**Is this an industry sponsored post approval study?**

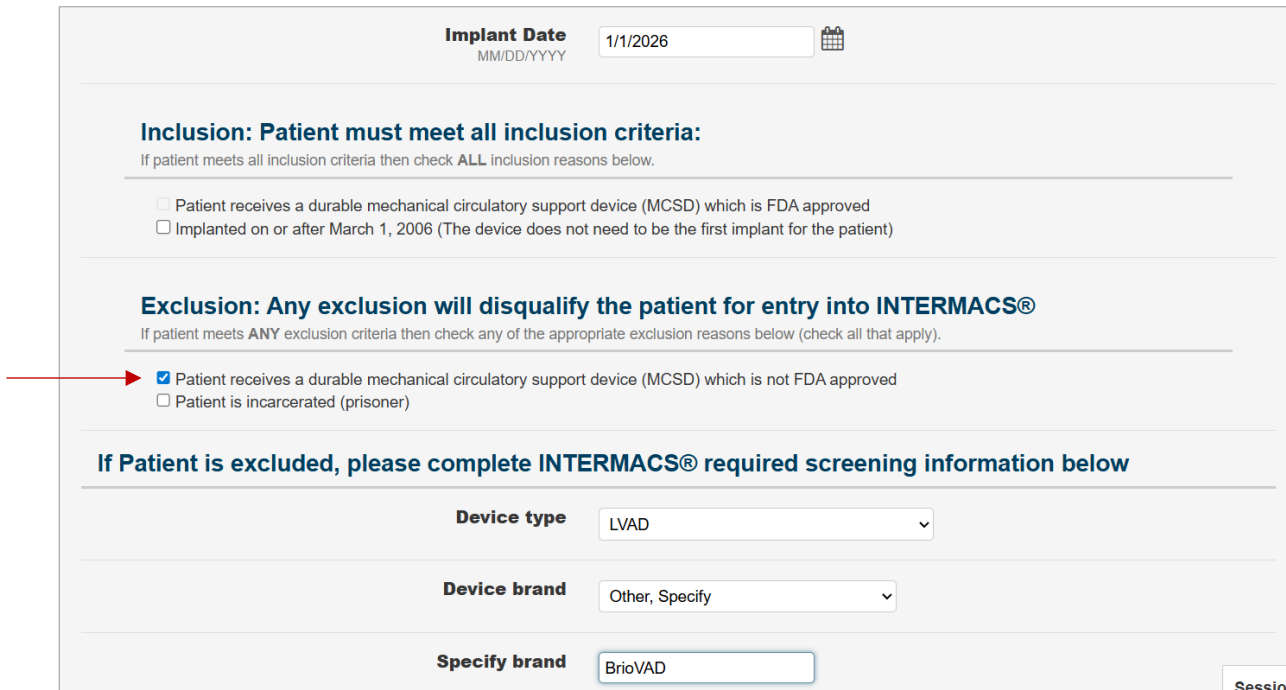
☐ Yes  
☒ No  
☐ Unknown



# The INNOVATE Trial and InterMACs

BrioVAD patients randomized in the INNOVATE trial should *not* be enrolled in InterMACs.

- These patients should be entered as **Excluded** in InterMACs
- Reason: **They did not receive an FDA-approved device**



The screenshot shows the InterMACs enrollment form. At the top, the 'Implant Date' is set to 1/1/2026. Below this, the 'Inclusion' section states that the patient must meet all inclusion criteria. The 'Exclusion' section, which is highlighted with a red arrow, states that any exclusion will disqualify the patient. The first exclusion criterion, 'Patient receives a durable mechanical circulatory support device (MCSD) which is not FDA approved', is checked. Below the exclusion section, there is a section for 'If Patient is excluded, please complete INTERMACS® required screening information below'. This section contains three fields: 'Device type' (set to LVAD), 'Device brand' (set to Other, Specify), and 'Specify brand' (set to BrioVAD).

Implant Date  
MM/DD/YYYY 1/1/2026

**Inclusion: Patient must meet all inclusion criteria:**  
If patient meets all inclusion criteria then check ALL inclusion reasons below.

☐ Patient receives a durable mechanical circulatory support device (MCSD) which is FDA approved  
☐ Implanted on or after March 1, 2006 (The device does not need to be the first implant for the patient)

**Exclusion: Any exclusion will disqualify the patient for entry into INTERMACS®**  
If patient meets ANY exclusion criteria then check any of the appropriate exclusion reasons below (check all that apply).

☒ Patient receives a durable mechanical circulatory support device (MCSD) which is not FDA approved  
☐ Patient is incarcerated (prisoner)

**If Patient is excluded, please complete INTERMACS® required screening information below**

Device type LVAD

Device brand Other, Specify

Specify brand BrioVAD



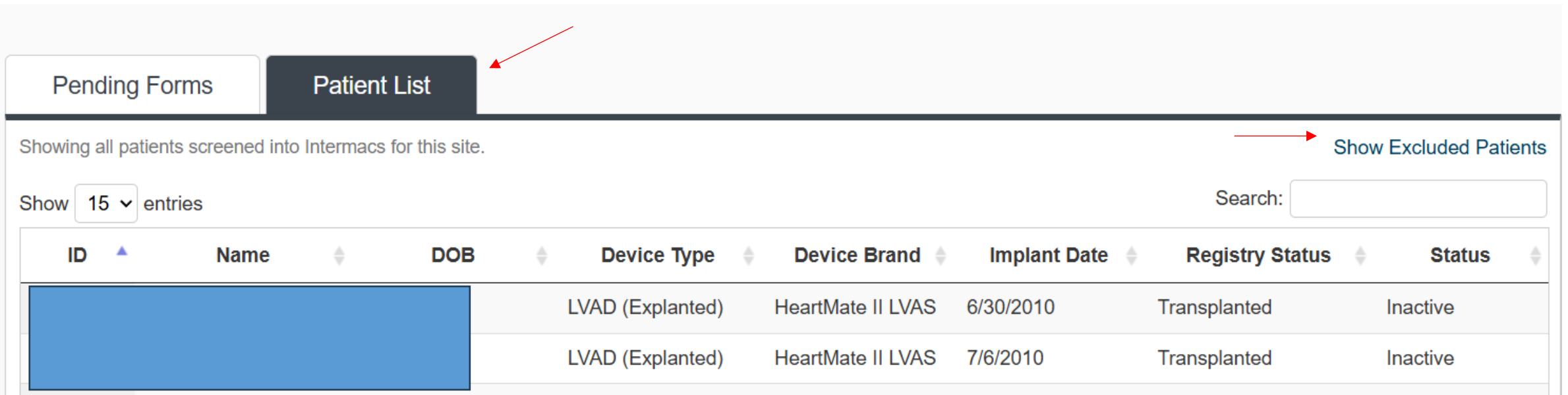
# The INNOVATE Trial and InterMACs

To view excluded patients:

1. Click **Patient List**

2. Select **Show Excluded**

→ All excluded patients at your site will be displayed.



ID	Name	DOB	Device Type	Device Brand	Implant Date	Registry Status	Status
[Redacted]	[Redacted]	[Redacted]	LVAD (Explanted)	HeartMate II LVAS	6/30/2010	Transplanted	Inactive
[Redacted]	[Redacted]	[Redacted]	LVAD (Explanted)	HeartMate II LVAS	7/6/2010	Transplanted	Inactive






# The INNOVATE Trial and InterMACs

## Excluded Patients

Show 15 ▾ entries

Search:

Screen Log ID ▲	Hospital	Device Type	Device Brand	Implant Date
		LVAD	HeartMateIIILVAS	4/26/2011
		LVAD	HeartMateIIILVAS	11/4/2011
		LVAD	OtherSpecifyHeartWare	12/5/2011
		LVAD	OtherSpecifyHeartWare	12/13/2011



# PHI Security Reminder

## Protected Health Information (PHI)



To protect patient privacy, PHI should only be shared via **secure** or **encrypted** email.



Do not send PHI through regular email



If you do not have a way to send a secure email, please reach out to me and I will send you a Neo Certified email that you can respond to



# Contact Us

## Nancy Honeycutt, BSN, RN

- *STS National Database Manager, Intermacs and Pedimacs*  
 nhoneycutt@sts.org

## Patricia Potter, BSN, RN

- *Intermacs Data Warehouse Director of Clinical Affairs*  
 patricia.potter@kirso.net

## Brandon Singletary, PhD

- *Intermacs Data Warehouse Director of Data Reporting and Visualization; Epidemiologist*  
 brandon.singletary@kirso.net



# Open Discussion

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Please use the Q&A Function.



We will answer as many questions as possible.



We encourage your feedback and want to hear from you!

# THANK YOU FOR JOINING!



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# **Intermacs & Pedimacs Quality Assurance Reporting and Dashboard Quarterly Webinar**

**January 15, 2026**

# Quarterly Webinar

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- 2025 Q3 Reports
  - Available for download until 3/31/2025
- New Dashboard
  - Launching late this month
  - Users
- Report Questions



# Quarterly Reports

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1. Download .zip file
2. Right click and select 'Extract All'
3. Save to preferred folder
4. Use site password when prompted
  - If password needed, we can provide but then save in secure location (ex. Bitwarden)
5. Files included:
  - Readme.doc (this file)
  - Cover letter for the reports
  - STS INTERMACS Data Quality Report (2025-12)
  - STS INTERMACS - QAR (2025 Q3) - Cumulative – All Patients
  - STS INTERMACS - QAR (2025 Q3) - Cumulative – Primary VAD Patients
  - STS INTERMACS - QAR (2025 Q3) - Cumulative – Prior Durable LVAD Patients
  - STS INTERMACS - QAR (2025 Q3) - Recent – All Patients
  - STS INTERMACS - QAR (2025 Q3) - Recent – Primary VAD Patients
  - STS INTERMACS - QAR (2025 Q3) - Recent – Prior Durable LVAD Patients

**\*\*Next Cycle 2025 Q4 will be available 3/31/2026**





# New Dashboard

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- Current Version
  - Tables and figures of counts/rates/benchmarking
  - Comparing site vs aggregate registry data
  - Real time/monthly data updates
  - Filter by select registry specific characteristics
  - Dashboard embedded in WBDE for access by users
- New Dashboard (Jan 2026)
  - **\*Keeps all the above features.**
  - Plus:
    - More flexibility for multiple users per site
    - Enhanced features:
      - Access to multiple years of patient-level data
      - Interactive filters
      - Secure Excel exports
    - Faster development: Custom enhancements already implemented; new features deployed rapidly.
    - Pathway to more enhanced embedded analytics

# Report Questions

- Exhibit 1:
  - Why does my patient's device exchange not show up in the 2021-2025 time period?

## *Exhibit 1: Device Counts for Patients in this Report*

The following tables list the number of implants received by patients meeting the inclusion criteria for this report. Subsequent exhibits are based on a patient level analysis. Characteristics are reported at the time of first implant. Unless noted otherwise, outcomes and follow-up include all information reported to INTERMACS for the patient.

NOTE: For most patients a second device indicates a device exchange. However, this count also includes the patients who receive a subsequent RVAD.

**GROUP=HOSPX-9999**

Device	IMPLANT DATE PERIOD			TOTAL
	< 2015	2016 - 2019	2020 - 2024 (Jan-Mar)	
	n	n	n	n
Primary Device	400	323	330	1053
2nd Device	58	21	9	88
3rd Device	7	3	0	10
4th Device	0	0	0	0
5th Device	0	0	0	0

# Report Questions

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- AE Counts:
  - What is the difference between exhibits 22a and 22c?

## *Exhibit 22a. Patient Percent Experiencing Each Adverse Event Type*

For each adverse event type, the percent of patients with a least one event of that type reported is presented at for your site and STS-INTERMACS overall.

Patient percent experiencing a specific adverse event = number of unique patients with reported event / number of patients at your site \* 100

While useful, this measure does not take into consideration the varying amount of time on support for each patient (exposure time) or the timing of the adverse events. Subsequent exhibits use adverse event rates that more accurately compare adverse events reported at your site to the overall cohort.

## *Exhibit 22c. Adverse Event Counts*

The following table includes overall counts and percentages for each type of adverse event reported at your site and STS Intermacs overall. These totals are based on adverse events reported for primary prospective patients.

# Report Questions

- AE Counts:
  - What is the difference between exhibits 22a and 22c?

*Exhibit 22a. Patient Percent Experiencing Each Adverse Event Type*

	HOSPX-9999			STS Intermacs		
	Events	Patients	Patient Percent	Events	Patients	Patient Percent
Arterial Non-CNS Thromboembolism	9	9	0.9%	654	594	1.4%
Bleeding	479	275	26.1%	41751	17637	42.3%
Cardiac Arrhythmia	302	227	21.6%	21637	12705	30.4%
Device Malfunction and/or Pump Thrombosis	193	148	14.1%	15516	9298	22.3%
Hepatic Dysfunction	23	21	2.0%	2399	2169	5.2%
Hypertension	251	150	14.2%	9989	6004	14.4%
Infection	938	491	46.6%	54544	22799	54.6%
Myocardial Infarction	4	4	0.4%	303	278	0.7%
Neurological Dysfunction	274	218	20.7%	15243	10790	25.9%
Other Serious Adverse Event	295	178	16.9%	25507	12671	30.4%
Pericardial Drainage	23	21	2.0%	1822	1630	3.9%
Psychiatric Episode	24	17	1.6%	4059	3127	7.5%
Rehospitalization	3138	762	72.4%	162084	31267	74.9%
Renal Dysfunction	127	117	11.1%	9914	7967	19.1%
Respiratory Failure	184	145	13.8%	12531	9459	22.7%
Right Heart Failure	234	179	17.0%	14847	9903	23.7%
Venous Thromboembolism	28	27	2.6%	1679	1554	3.7%
Wound Dehiscence	18	12	1.1%	796	711	1.7%

*Exhibit 22c. Adverse Event Counts*

Adverse Events	HOSPX-9999		STS Intermacs	
	Episodes	%	Episodes	%
Arterial Non-CNS Thromboembolism	9	0.1 %	654	0.1 %
Bleeding	479	7.3 %	41751	10.5 %
Cardiac Arrhythmia	302	4.6 %	21637	5.4 %
Device Malfunction and/or Pump Thrombosis	193	2.9 %	15516	3.9 %
Hepatic Dysfunction	23	0.3 %	2399	0.6 %
Hypertension	251	3.8 %	9989	2.5 %
Infection	938	14.3 %	54544	13.7 %
Myocardial Infarction	4	0.0 %	303	0.0 %
Neurological Dysfunction	274	4.1 %	15243	3.8 %
Other Serious Adverse Event	295	4.5 %	25507	6.4 %
Pericardial Drainage	23	0.3 %	1822	0.4 %
Psychiatric Episode	24	0.3 %	4059	1.0 %
Rehospitalization	3138	47.9 %	162084	41.0 %
Renal Dysfunction	127	1.9 %	9914	2.5 %
Respiratory Failure	184	2.8 %	12531	3.1 %
Right Heart Failure	234	3.5 %	14847	3.7 %
Venous Thromboembolism	28	0.4 %	1679	0.4 %
Wound Dehiscence	18	0.2 %	796	0.2 %
Total Events	6544	100.0 %	395275	100.0 %

# Report Questions

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- Death following cessation of support.
  - I have a patient that was implanted and died within the first year after implant. The patient died 2 days after his LVAD was disabled. The death is then captured on the 1 Year post cessation form. However, does this death still count as a mortality for less than 1 year post LVAD insertion?

Yes.

The patient will be censored for follow-up at the time of cessation of support, however if the patient subsequently dies **within 30 days** of the cessation of support, then the registry endpoint for this patient will be counted as a death.

# Report Questions

- My heart failure MD would like for me to share our 1, 2, & 3 year LVAD survival to date. Where can I find this information?

1. Cumulative Report – All Patients Exhibit 34
2. If looking for more flexibility in the patient population. Outcome Analytics tool in WBDE site.

\*Coming Soon: Dashboard

## Outcome Analytics

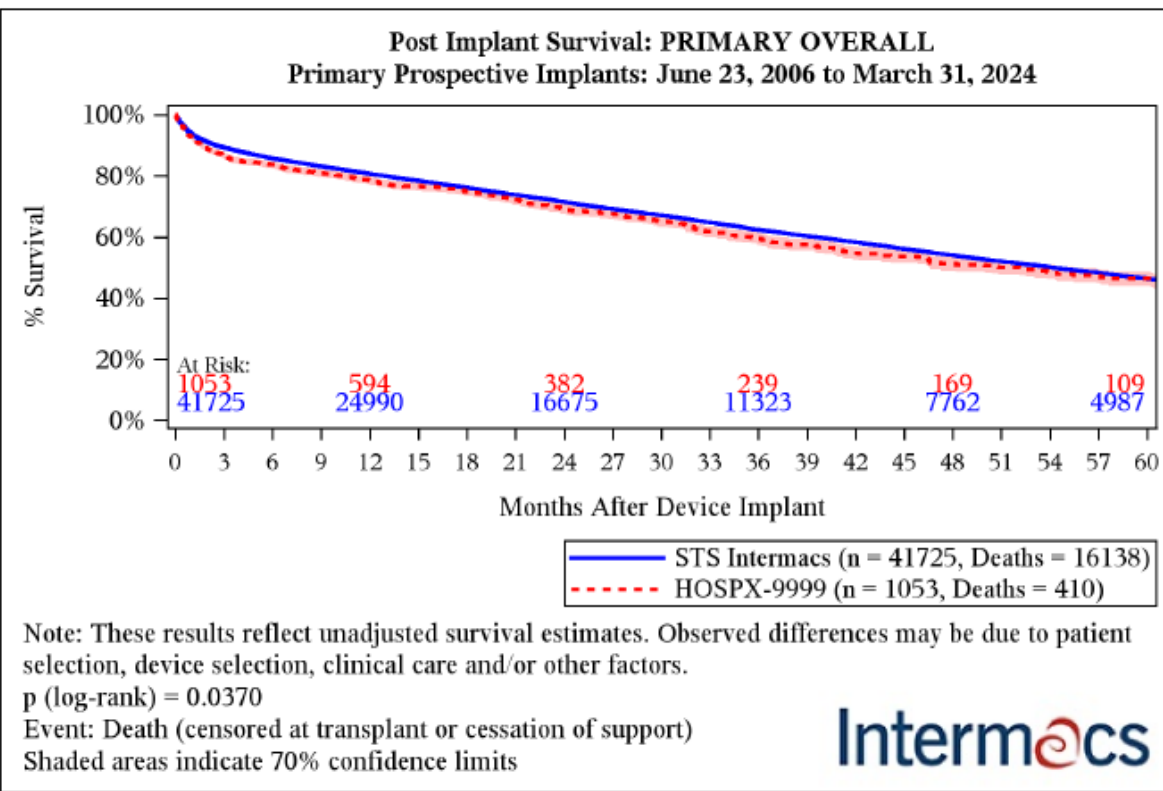
Available 

Click the above link to generate Kaplan-Meier curves for your selected event on your selected cohort.

# Report Questions

- My heart failure MD would like for me to share our 1, 2, & 3 year LVAD survival to date. Where can I find this information?

**Exhibit 34. Post Implant Survival - PRIMARY OVERALL**



Months after Device Implant	STS Intermacs	HOSPX-9999
1	93.7% (93.6%-93.9%)	92.7% (91.9%-93.5%)
3	89.2% (89.1%-89.4%)	86.5% (85.4%-87.6%)
6	85.7% (85.5%-85.9%)	83.6% (82.4%-84.7%)
9	83.1% (82.9%-83.3%)	80.9% (79.7%-82.2%)
12	80.6% (80.4%-80.8%)	78.4% (77.0%-79.7%)
24	71.5% (71.2%-71.7%)	69.3% (67.6%-70.9%)
36	62.4% (62.1%-62.7%)	59.4% (57.4%-61.3%)
48	54.0% (53.7%-54.4%)	51.3% (49.0%-53.4%)
60	46.3% (46.0%-46.7%)	46.4% (44.0%-48.7%)