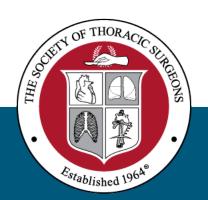
Society of Thoracic Surgeons

General Thoracic Surgery Database User Group Call

February 28, 2024





Agenda

- Welcome and Introduction
- STS Updates
- Neoadjuvant Therapy Module Training Manual
- Harvest Close Review
- Q&A

- February Training Manual posted
 - Bookmarks provided for updates and ease of navigation
- Spring 24 Harvest Close is approaching: Surgery dates 1/1/2021 12/31/2023
 - Harvest Closes March 8th at 11:59pmEastern
 - Opt out deadline is March 12th
 - Pre-Analysis Report Exclusion Warning will be sent approximately one week prior to harvest close.

- GTSD Harvest Pre-Analysis Report Exclusion Warning
 - Goal is to improve data completeness issues and ensure Participants have as many records included in analysis as possible
 - Email will be sent to those Participants 'at risk' for exclusion approx. 1-2 weeks prior to harvest close
 - 2% missing data thresholds are calculated based on the overall composite population eligible for reporting (Esophagectomy, Lobectomy, and Primary Lung Cancer Resection).
 - Specific details can be found in the Analyses Overview
 - Warning Email will include a Participant specific excel spreadsheet containing a list of records that meet the reporting eligibility requirements but are missing one or more of the required fields.
 - Will include ParticID, Patient ID, Record ID, Esoph Cancer, Lung Cancer, Report Year (based on Surgery Date) and flags indicating which field(s) are missing

GTSD						
Harvest	Close	Opt-Out	Includes procedures performed through	Report Posting	Comments	
Spring 2024	March 8	March 12	December 31,2023	Summer 2024	Star Rating	
Fall 2024	September 6	September 10	June 30, 2024	Winter 2024	Star Rating	

2024 Harvest Schedule

STS Temp Fields and REDCap

- Due to an increased use of neoadjuvant therapy, including preoperative immunotherapy and targeted therapy for patients with clinical stage 1b and higher non-small cell lung cancer, the STS began capturing the type and frequency of neoadjuvant therapy being utilized.
- Effective October 1, 2023: Sites began collecting this data using two temporary fields (TempY/N1 and TempText).
 - TempY/N1 (Seq. 4580): Did the patient receive preoperative immunotherapy or a targeted agent directed at the lung cancer of interest?
 - TempText (Seq.4620): If yes, what agent?

Neoadjuvant Therapy Module

- STS Temp Y/N1 (Seq 4580):
 - Did the patient receive preoperative immunotherapy or a targeted agent directed at the lung cancer of interest?
 - If Yes, please complete the module to capture more granular data
 - UPDATED LINK: https://redcap.sts.org/surveys/?s=LFXJTHK4YN8TADK9

- Please note this is a VOLUNTARY MODULE
 - Surgery dates Nov 1, 2023 forward



Neoadjuvant Therapy Module (REDCap) Training Manual

 Supplemental Training Manual will be posted first week of March

- Will be located under v5.21 Data Collection Resources
- These variables will be removed from the current GTSD TM
- Data Collection Form will be posted along with the TM
- Same format as the current GTSD Training Manual
- New FAQ/Clarifications will be added in red
 - Bookmarks will be added each month with the updates

STS Neoadjuvant Therapy Module

Data Collection Variables Updated 3/1/2024

Neoadjuvant Therapy Module (REDCap) LINK: https://redcap.sts.org/surveys/?s=LFXJTHK4YN8TADK9

Data Collection Resources (version specific abstraction documents)

Ask an Abstraction Question

Introduction

This manual is intended to clarify field definition and intent. This document contains the most up to date instructions for data abstraction. Please review this document prior to submitting clinical questions. FAQs will be added to the document in red to provide additional examples and clarification. Comments in green are provided for clarification within prior updates. Please do not print this document since it will change frequently. Using the web version will ensure that you have the most up to date information. Use the Ctrl + F function to search for a number or term of interest. Bookmarks will be added each month with updates.

General Information

If there are duplicate entries into the <u>RedCap</u> database, the STS will delete the prior entry and take the last one entered.



Neoadjuvant Therapy Module (REDCap) Training Manual

SeqNo: 5035

Long Name: Preoperative Invasive Mediastinal Staging Performed

Short Name: preopinvasivemedstag

Format: Text (categorical values specified by STS)

Definition: Indicate whether preoperative mediastinal staging was performed.

Harvest Codes:

Code: Value:

1 Yes 2 No

3 Unknown

Intent/Clarification:

Nov 2023: Indicate if the patient underwent biopsies of mediastinal lymph nodes. If a mediastinoscopy is performed during the same OR trip as a therapeutic lung procedure, it can be captured here.

VATS/thoracotomy mediastinal lymph node dissection performed with lung resection is NOT captured here.

STS Neoadjuvant Therapy Module

SeqNo: 5055

Long Name: Gene Mutations Identified

Short Name: genemutation

Format: Text (categorical values specified by STS)

Definition: Identify any mutations of the geneslisted.

ParentLongName: Molecular Testing Performed Prior To Initiation of Therapy

ParentShortName: moltest
ParentValue: = "Yes"
ParentHarvestCodes: 1

Harvest Codes:

Code: Value:

1 EGFR exon 19 deletion

2 EGFR L858R insertion

3 ALK rearrangement

4 KRAS 5 RET

6 ROS-1

7 Other

8 None

Intent/Clarification:

Nov 2023: This is not an exhaustive list of all potential mutations – it is the most common. Please choose 'none of the above' if a mutation is present but is not on this list.



The Society of Thoracic Surgeons General Thoracic Surgery Database Neoadjuvant Therapy Supplemental Data Collection Form v1.0



Abstraction Question?

- Submit questions via the <u>STS</u>
 Clinical Question Request Form | <u>STS</u>
- Please use the appropriate Sequence number/short name as provided on the data collection form.

STS National Database

February 2024

Patient Information						
Participant ID:		Patient ID:				
ParticID (5010)		PatID (5015)				
Record ID:		Date of Surgery:				
RecordID (5020)		SurgDt (5025)				
Neoadjuvant Therapy						
Was preoperative invasive mediastinal staging performed: ☐ Yes ☐ No ☐ Unknown						
Preopinvasivemedstag (5035)						
(If <u>Yes</u> →) Who	performed the biopsy:	□ Pulmonology □ Thoracic Surgery				
Perfo	rmedbiopsy (5040)	□ Both □ Unknown				
PD-L%: %						
pdl1 (5045)						
Was molecular testing performed prior to initiation of therapy: ☐ Yes ☐ No ☐ Unknown						
Moltest (5050)						
(If <u>Yes</u> →)	Were mutations in any of the	following genes identified:				
Genemutation (5055)						
	□ EGFR exon 19 deletion					
	□ EGFR L858R insertion					
	□ ALK rearrangement					
	□ KRAS					
	□ RET					
	□ ROS-1					
	□ Other					
	L Other					



End of Harvest Review Checklist

Library

Other Resources

National Report Analyses Overview UPDATED NOV 17 2023

Fall 2023 Harvest Composite Quality Ratings Summary

Spring 2023 Harvest Composite Quality Ratings Summary

Fall 2022 Harvest Composite Quality Ratings Summary_12.17.2022

Spring 2022 Harvest Composite Quality Ratings Summary

Fall 2021 Harvest Composite Quality Ratings Summary 03082022

Spring 2021 Harvest Composite Quality Ratings Summary_9.28.2021

Fall 2020 Harvest Composite Quality Ratings Summary.9.28.2021

Spring 2020 Harvest Composite Quality Ratings Summary_9.28.2021

Risk Adjusted Dashboard Report Overview (GTSD) Updated 06042021

Contact List Report Overview (NEW)

COVID-Positive Patients Included in Risk-Adjusted Analysis

Critical Errors, Errors and Warnings List (Updated 8/25/2021)

Database Data Collection Resources (GTSD)

Database Transition Resources

Direct Data Entry FAQ

End of Harvest Review Checklist (GTSD)

Known Issues - February 2023

Missing Variable Report Overview (GTSD)

Participant Dashboard Non-Analyzed Report Overview (GTSD)

STS Harvest Opt-Out Request Form

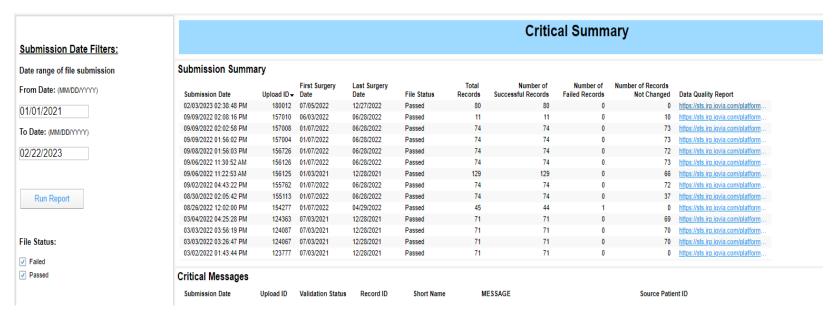
STS Database IQVIA Role Mapping

Uploader Instructions



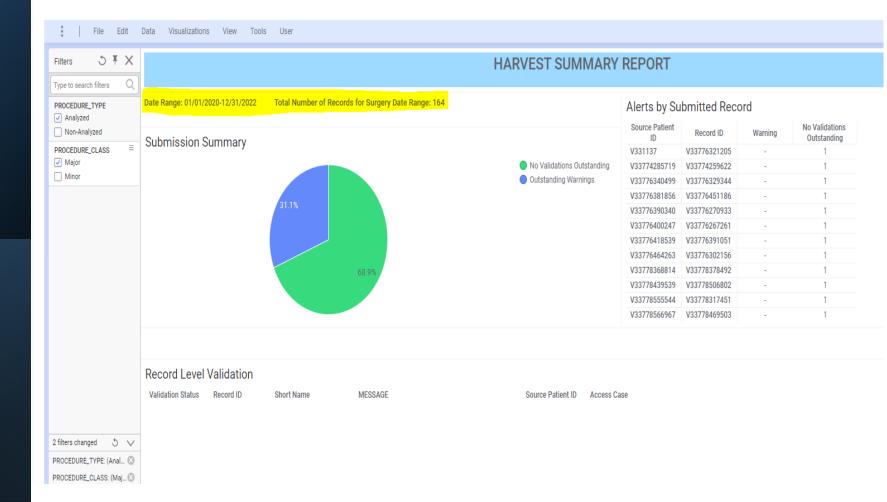
Spring 24 Harvest Close Checklist (resource in IQVIA Library)

- Utilize your Resources
 - Review the Data Quality Report for each upload submission
 - · Resolve any critical errors and review errors or warnings and correct as needed
 - Review the Critical Summary Report
 - Enter data file **SUBMISSION** dates (not surgical date range)
 - Review uploads to verify surgery dates and total number of records submitted for each upload



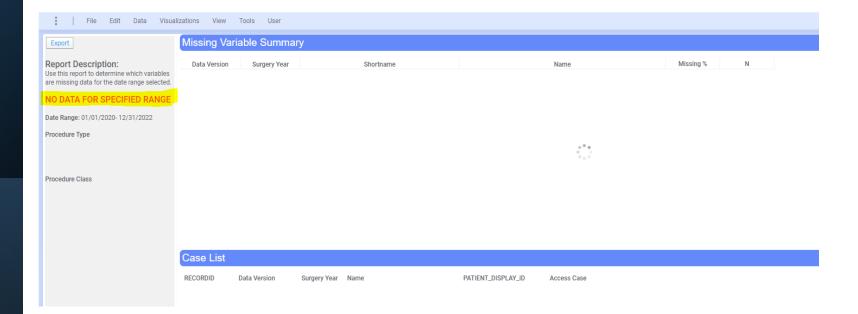
Spring 24 Harvest Close Checklist (resource in IQVIA Library)

- Utilize your Resources
 - Review Harvest Summary Report (located under Operational Reports)
 - Allows you to look at all critical errors, errors and warnings for a specified date range (analysis reporting period)
 - · Verify total number of records submitted for specified date range



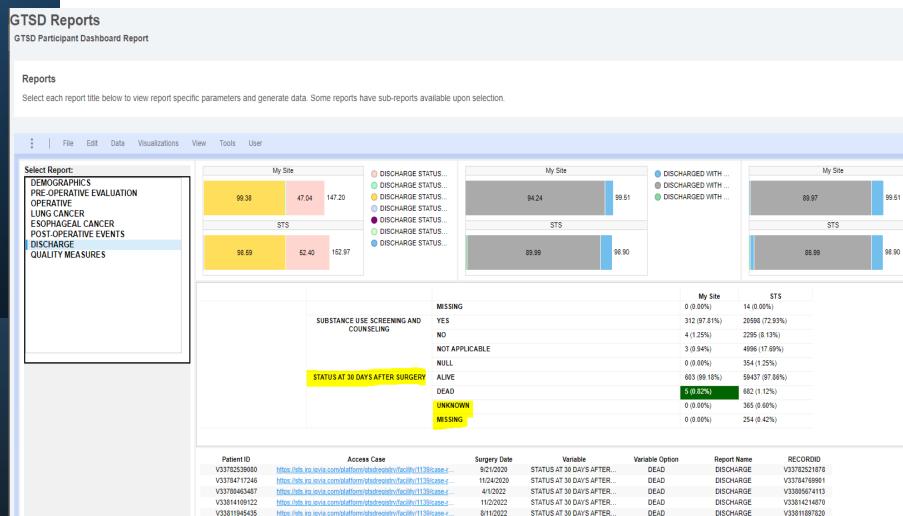
Spring 24 Harvest Close Checklist (resource in IQVIA Library)

- Utilize your Resources
 - Review the Missing Variable Report (located under Operational Reports)
 - · Allows you to pinpoint any records that contain missing data
 - Important to ensure Mortality Variables (MtDCStat; Mt30Stat) are complete. "Unknown" is considered as missing data in analysis



Spring 24 Harvest Close Checklist (resource in IQVIA Library)

- Utilize your Resources
 - Review the Participant Dashboard
 - Allows you to confirm record counts, mortalities, identifies records with missing or "unknown" data



STS Updates

Upcoming GTSD Webinars

Monthly Webinars

- March 13 @ 1:30pmCT/2:30pmET
- April 10 @ 1:30pmCT/2:30ET



Open Discussion



Please use the Q&A Function.



We will answer as many questions as possible.



We encourage your feedback and want to hear from you!

Contact Information

Leigh Ann Jones, STS National Database Manager, Congenital and General Thoracic

- Ljones@sts.org
- 312-202-5822

Helpdesk Support
(Harvest Questions/Analysis
Report Questions)

STSDB_helpdesk@sts.org

Database Operational Questions

(Database Participation, Contracts, etc.)

• STSDB@sts.org



THANK YOU FOR JOINING!