



STS General Thoracic Audit Instructions

Thank you for participating in The Society of Thoracic Surgeons (STS) General Thoracic Surgery Database (GTSD) audit. The purpose of the audit is to evaluate the consistency in data collection processes and validate the data contained in the database.

Our company is Cardiac Registry Support (CRS). The STS has contracted us to conduct the STS General Thoracic Audit for 2019/2020 cases. CRS has been abstracting and auditing data across various registries since 2009. By adhering to the STS Training Manual and Data Specification Manual, it is CRS's goal to provide an educational experience with feedback that will assure the integrity of collected data.

The audit process includes data abstraction performed on 20 lung cancer or esophageal cancer cases performed for cancer resection between July 1, 2019 and June 30, 2020 and submitted to IQVIA. In addition, there will be a comparison of your site's operating room thoracic surgery log and cases submitted to IQVIA during this timeframe.

Below you will find the steps required to complete the audit process. If at any time you have audit related questions or concerns contact us at GenThoracic@cardiacregistrysupport.com. Please include your STS Participant ID in all communication with CRS.

Step 1: Determine method for delivering Medical Record documents for the audit.

The audit requires that you provide CRS with access to Medical Records for each of the cases being audited. You have two options for providing these records:

- **Option 1:** Direct remote (VPN) access to your facility's EMR is one of the options. You will need to work with your IT department to facilitate access for CRS auditors to remotely access your EMR to audit the identified patients for the data elements listed in Appendix A. If you choose this method, it is important to initiate this process immediately. You will have 3 weeks from the receipt of these instructions to establish access to your EMR. If access has not been established within 3 weeks, you will be required to move to option 2 (upload of PDF data files) for providing Medical Record documents. You will be given an additional 2 weeks to provide the PDF format documentation.
- **Option 2:** Upload of PDF data files is another option to provide medical records. You will be given 4 weeks to upload the required medical records documentation in PDF format with bookmarking or table of contents. More details on this option are included in Step 3.

Note: Email GenThoracic@cardiacregistrysupport.com promptly if you intend to pursue option 1 for the delivery of your EMR documentation.

Step 2: Validate your access to the CRS Secure Portal

CRS uses a Secure Portal for uploading PHI documentation. Instructions on accessing the Secure Portal are found on pages 6-7. In your email you will find your Secure Portal Logon and temporary password. Please logon and reset your password as soon as possible. Email GenThoracic@cardiacregistrysupport.com promptly if you have any issues accessing the secure portal.



Step 3: Upload of Medical Records

Provided in this email is the list of patients that will be audited, in Excel format. Each case is listed by Record ID, which is a de-identified number that links the case to the STS Database and corresponds to a field in your vendor software. The audit variables can be found in Appendix A on page 4-5. Contact your Medical Records and/or IT department to assist with obtaining the required medical record documents. The documents must be provided in PDF format with bookmarks or table of contents denoting each section. Attached is a Sample PDF with bookmarks to use as a guide in creating your medical records document.

Read through the instructions in the Sample PDF carefully. Each section provides guidance on what documents to include for the audit. Work closely with your Medical Records and/or IT departments to assemble this PDF. It is critical to the success of your audit that you provide the information requested in this document. PDFs that do not include the requested information or are not bookmarked in a usable manner will be returned to you and you will be asked to re-create the PDF.

Sites will have 5 business days to make the changes to the PDF files or provide missing documentation and upload to the portal. If CRS does not receive the amended files within 5 business days, the data element will be considered a mismatch. The portal will then be closed.

Instructions on how to access and use the CRS secure portal can be found on pages 6 and 7.

PDF File Security

Your uploaded files will be maintained in designated access control locations that employ encryption to protect data at rest. All access to the designated locations is audited and monitored. Transmission of the data is conducted using compliant encryption algorithms and verified certificates meeting Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards.

Notify CRS via e-mail at GenThoracic@cardiacregistrysupport.com when all files have been uploaded and are ready for audit. Be sure to include your Participant ID.

Step 4: Upload of OR Case Log

Operating Room Case Log Comparison

To evaluate the comprehensiveness of the database, the auditor performs a comparison of surgical cases that were performed between July 1, 2019 and June 30, 2020 to cases that were submitted to IQVIA. Upload the Operating Room generated Case Log (list) of **all primary lobectomy and esophagectomy cases** into the folder titled "OR Case Log" located in the CRS Secure Portal.

The OR Case Log should list all primary lobectomy and esophagectomy cases and include the STS Record ID for each procedure. The OR Case Log should be provided in an Excel spreadsheet format and include the following fields: STS Record ID, Surgery Date, Primary Procedure (CPT Code), Procedure Description, Discharge Date, and Date of Birth for each procedure. It is not necessary to upload medical records for these cases, only a list of all surgical cases performed. Do not include procedures other than primary lobectomy and esophagectomy cases.



OR Case Log Format Example

RecordID	SurgDt	PrimProc	ProcDesc	DischDt	DOB
V111111	7/7/2019	32480	Lobectomy	7/11/2019	1/5/1952
V111112	3/14/2020	43107	Esophagectomy	3/28/2020	12/8/1948
V111113	4/15/2020	32663	Lobectomy	4/23/2020	5/15/1963

Instructions on how to access and use our secure portal can be found on pages 6 and 7.

Step 5: Audit is Performed

Once CRS has received all required medical record documents, the audit will be performed. During this time, you may be contacted regarding any questions or missing information to ensure a thorough and accurate audit.

Step 6: Audit Adjudication and Follow up Webinar

Once CRS has completed the audit, a preliminary copy of the results will be sent to the Primary Data and File Contact(s). At that time, the facility can choose to participate in a Web conference to discuss the results of the audit and provide additional information regarding any mismatches that were found during the audit process.

Step 7: Final Report

STS will send the final audit report to your Primary Data and File Contact and Surgeon Representative.



Appendix A: General Thoracic 2021 Audit Variables

For Lung Cases

<u>V 2.41 Seq #</u>	<u>Field</u>
10	RecordID
80	PatID
290	AdmitDt
370	HospName
750	PriorCTS
700	PreopChemoCur
720	PreopXRT
650	Diabetes
660	DiabCtrl
970	CigSmoking
910	PFT
940	FEVPred
960	DLCOPred
1070	ECOG
1580	LungCancer
1680	PET or PET/CT
1880	ClinStageLungTumor
1890	ClinStageLungN
1250	CategoryPrim
1310	SurgDt
1360	ProcStartT
1370	ProcEndT
1490	Proc
1920	PathStageLungT
1940	PathStageLungN
1990	LungCANodes
2000	LungCANodStat
2010	LungCAPathMarg
3330	PostOpInvProc
3460	Pneumonia
3560	AtrialArryth
3520	Vent
3470	ARDS
3480	RespFail
3580	MI
3870	DischDt
3880	MtDCStat
3890	DisLoctn
3900	CTubeDis
3930	Readm30Dis
3950	Mt30Stat
4030	SmokCoun
4080	TempCode – COVID Diagnosis
4070	TempDt – COVID Date



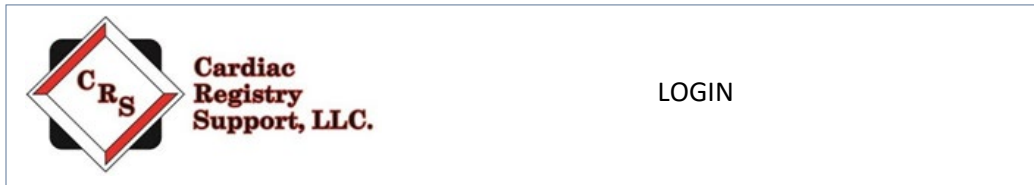
For Esophageal Cases

<u>V 2.41 Seq</u>	<u>Field</u>
10	RecordID
80	PatID
290	AdmitDt
370	HospName
750	PriorCTS
700	PreopChemoCur
720	PreopXRT
970	CigSmoking
960	DLCOPred
1070	ECOG Zubrod
1590	EsophCancer
2090	ClinStagEsophEUS
2150	ClinStageEsophT
2160	ClinStageEsophNode
1250	CategoryPrim
1310	SurgDt
1360	ProcStartT
1370	ProcEndT
1490	Proc
2230	PathStageEsophT
2240	PathStageEsophN
2280	EsophCANodes
2290	EsophCAPathMarg
3330	PostOpInvProc
3460	Pneumonia
3520	Vent
3560	AtrialArryth
3650	DelayCondEmp Delayed conduit emptying requiring intervention
3780	LaryngealNerve Recurrent Laryngeal Nerve Paresis
3870	DischDt
3880	MtDCStat
3890	DisLoctn
3900	CTubeDis
3930	Readm30Dis
3950	Mt30Stat
3480	RespFail
4030	SmokCoun
4080	TempCode – COVID Diagnosis
4070	TempDt – COVID Date

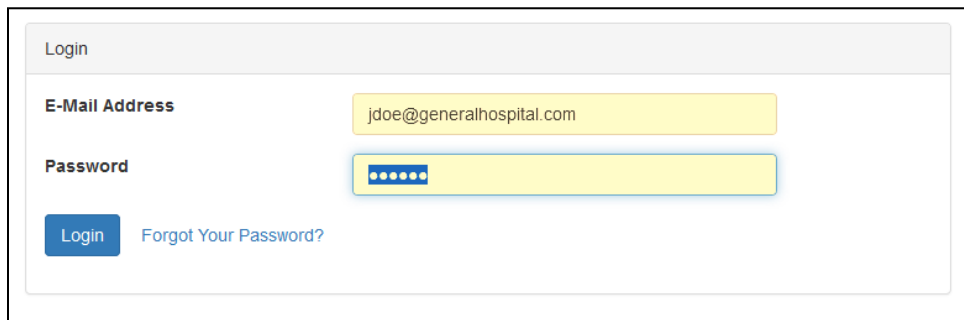
CRS Portal Instructions

Go to: www.crshome.net

Click "LOGIN" in the upper right-hand corner.




Enter your email address and the supplied password. **Your email address is case sensitive. Be sure to use only lower-case letters as shown in the provided username from CRS.**



The screenshot shows a login form with the following fields and elements:

- Header: Login
- E-Mail Address: A text input field containing 'jdoe@generalhospital.com'.
- Password: A password input field with six dots representing the password.
- Buttons: A blue 'Login' button and a blue link 'Forgot Your Password?'.

After your 1st login, you will be required to change your password.



The screenshot shows a password reset form with the following fields and elements:

- Header: Welcome General Hospital
- Reset Password: A sub-header for the form.
- E-Mail Address: A text input field containing 'jdoe@GeneralHospital.com'.
- Password: An empty password input field.
- Confirm Password: An empty confirm password input field.
- Buttons: A blue 'Reset Password' button.

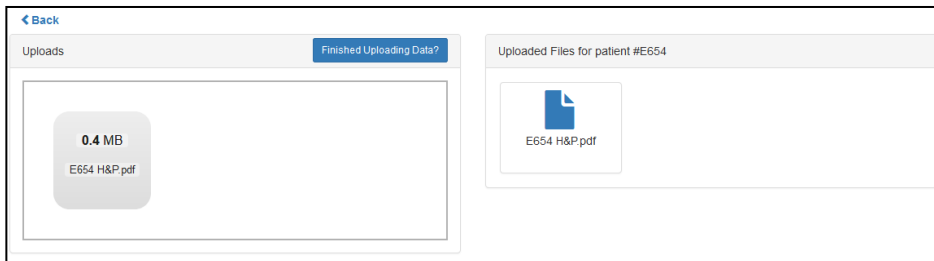
After updating your password, log in again with your new password.

On the main page click on the Unique ID folder that you wish to upload data to.



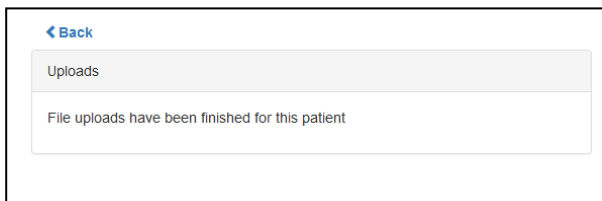
On the Patient detail page, drag the files you wish to upload to the upload area. You can drag and drop as many files as needed into this area.

You can leave this Portal detail page and re-enter at any time to upload more files.



You will see all the file names you have uploaded on the right-hand side of the patient detail page.

Once you have finished uploading data for this patient, click the "Finished Uploading Data?" button to close uploads.



When file upload for all patients is complete notify CRS at: Genthoracic@cardiacregistrysupport.com

Thank you for your participation in the ongoing independent audit of the STS General Thoracic Surgery Database. We look forward to working with you.