STS Congenital Audit Instructions

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

Our company is Cardiac Registry Support (CRS). STS has contracted us to conduct the STS Congenital Audit for 2025. 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 educational experience with feedback that will ensure the integrity of collected data.

The audit process includes data abstraction performed on 20 randomly sampled index operations performed between January 1, 2024, and December 31, 2024, and submitted to IQVIA. An audit will also be conducted for all mortalities that occurred within the audit period (January 1, 2024 – December 31, 2024) if the most recent surgery happened within the last 5 year. In addition, there will be a comparison of your site's operating room cardiac surgery log and cases submitted to IQVIA. **Audits results are based upon data your site submitted to IQVIA prior to 4/11/25.**

Your lead congenital auditors are Angela Ebel, RN, MSN, Beth Sherfy, RN, MSN and Diane Hersey, RN BSN. Angela has over 14 years of congenital abstraction experience and has worked with CRS since 2014. Beth is an experienced congenital abstractor and has joined the team as an auditor in training. Diane has over 10 years of congenital abstraction experience. She joined CRS and the audit team in 2022. One of the three congenital heart surgeon auditors will also participate in the audit process. To learn more about the audit process, visit the STS audit website for this year's CHSD audit webinar.

Below you will find the steps required to complete the audit process. We encourage you to print this document and follow the steps in order. If at any time you have questions or concerns, please contact us at angelae@cardiacregistrysupport.com and/or beths@cardiacregistrysupport.com *and/or dianeh@cardiacregistrysupport.com.* ***Please include your STS Participant ID in all communication with CRS.***

Step 1: Select an Audit Date (Due 9/8/2025)

All audits are conducted using an all-day webinar on a specific date you select from the list provided below. The auditing surgeon and CRS will review the previously provided medical records on this date.

The dates below are available for the auditing surgeons to assist with the auditing process. Please select an audit date as soon as possible to secure the date best for your site. The dates are first-come-first-served to all sites being audited, so please select and email CRS with an audit date request.

Monday, September 29, 2025
Wednesday, October 1, 2025
Monday, October 20, 2025
Wednesday, October 22, 2025
Wednesday, October 29, 2025
Wednesday, November 5, 2025
Monday, November 10, 2025
Wednesday, November 12, 2025
Monday, November 17, 2025
Wednesday, November 19, 2025
Monday, December 1, 2025
Wednesday, December 3, 2025

Step 2: Create a Box for Healthcare Account (Due 9/8/2025)

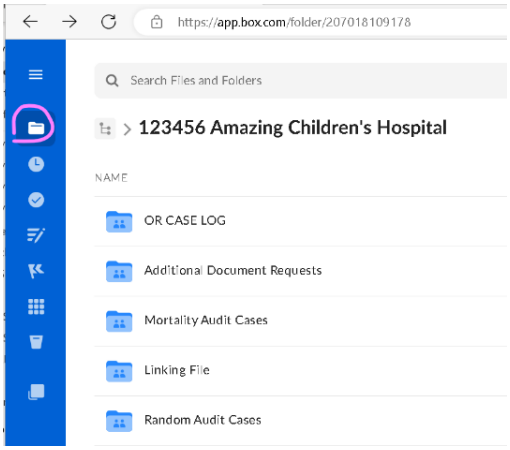
Your site will upload documents into a secure folder location within Box for Healthcare to which only the data manager and CRS have access. For additional information about Box for Healthcare security and compliance, please visit their website at https://www.box.com/security-compliance

It is important to start working early with your HIM and/or IT Department to determine if Box for Healthcare is an acceptable method of file transfer at your facility. If your site already has an approved method of file transfer, we can use that method instead of Box for Healthcare. Box for Healthcare is just one option, and we can accept file transfers of any method if we have the correct site location and any usernames/passwords required.

The site's data manager will receive an Intro email from congenital@cardiacregistrysupport.com with a link directing to your hospital's secure Box for Healthcare folder. This folder is where you will eventually upload your site's medical records. Please bookmark this link. If you do not receive this introductory email, please check your hospital's spam. If the email is not there, contact CRS for assistance.

- If you have an existing BOX account, you will be asked to login using your existing password.
- If you do not have an existing BOX account, you will be asked to create a new account. You will use the same email address where you received the invite as the username and create your own password.

When you are ready to upload medical records to Box for Healthcare, login and click on the “All Files” in the left-hand menu bar. Click on the folder labeled with your site’s name (see example to the right). Within your sites folder there will be 5 folders for uploading documents.



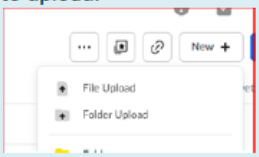
Prior to uploading documents, be sure you are within the correct folder. You will not be able to move files to a different folder once files are uploaded. Using a drag-and-drop method or file upload button, upload files to the appropriate folder.

How to Upload Files and Folders to *BOX*:

Click on the Folder you want to upload to.

- Click on “Upload” here or just drag and drop files and folders directly into the box.

OR Click on the “NEW +” button in the upper right corner to upload file/folder. Clicking on the “upload file or folder” will navigate you to your Windows File Explorer to locate the file to upload.



Step 3: Upload the OR Case Log (Due 9/8/2025)

To evaluate the completeness and comprehensiveness of the database, the auditor completes a comparison of cardiac cases performed by your surgeon(s) and submitted to IQVIA prior to 4/11/25. To complete the comparison, please assemble a **computer-generated operating room log** (list) of all surgical cases performed between **January 1, 2024, and December 31, 2024.** (bedside, OR, non-cardiac, CPB, non-CPB, ECMO, etc.) by all STS surgeons listed on your Schedule A. The file must be an Excel document and include only the date of procedure, procedure description, surgeon’s name, and patient’s medical record number.

SurgDt	Procedure Description	Surgeon	MRN
02/07/2024	VSD repair	Smith	45678
02/14/2024	ASD repair	Jones	23456
02/23/2024	Coarctation Repair	Roberts	12345

After we receive your computer-generated OR Case Log, CRS will begin to match your OR list to the list submitted to IQVIA. Once we match each case, we will send you a secure email highlighted with cases we have questions about. We then ask you to mark each unmatched case with the case type, mortality/non-mortality, and the reason the case does not match. Use the drop-down menu to choose one of the following reasons:

- Our site inadvertently missed this case and did not submit it at harvest time. We will submit this next harvest.
- Our site does not enter this type of case.
- We abstracted the case but did not submit this case type to IQVIA.
- This case was canceled on this date but not removed from the OR schedule.
- We inadvertently entered the incorrect surgical date; will correct the next harvest.
- This case was entered into the adult database. Enter the Adult STS PartID, PatientID, and OpID in the "Other" column.
- Other: Please elaborate in next column

Step 4: Upload a Linking File (Due 9/8/2025)

Prior to the start of the audit, it will be necessary to provide auditors with a file that links the patient medical record number to the STS Operation ID. Attached to this Instruction Letter is an Excel file with a list of your site's Mortality and Random Cases that will be audited. Insert each patient's medical record number into the indicated column (see yellow highlighted MRN column in example below). Upload this file through Box for Healthcare into the folder labeled "Linking File."

Surgical Date	Operation ID	Patient ID	MRN
03/29/2024	V647	V67574	12345
04/20/2024	V653	V57673	67899

Step 5: Upload Mortality Audit Medical Records (Due 9/8/2025)

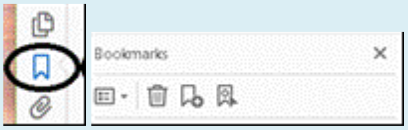
The Mortality cases identified in your excel document (attached to this instruction letter) is a listing of mortalities that occurred within the audit period (**January 1, 2024 – December 31, 2024**) if the most recent surgery happened within the last 5 years. For all site mortalities, the below variables will be re-abstracted by the auditor and compared to the patients' medical records and the data you submitted to IQVIA prior to 4/11/2025. The below data fields will be audited for each mortality on the list.

Mortality Audit Case Data Elements

Variable Name	SeqNo.	Short Name
Date of Surgery	580	SurgDt
Date of Admission	570	AdmitDT
Date of Hospital Discharge	4875	HospDischDt
Operation Type	1755	OpType
Date of Database Discharge	4935	DBDischDt
Mortality Status at Hospital Discharge	4880	MtHospDisStat
Mortality Status at Database Discharge	4940	MtDBDisStat
Mortality-30-day Status	4945	Mt30Stat
Mortality Date	5005	MtDate

How to add Bookmarks:

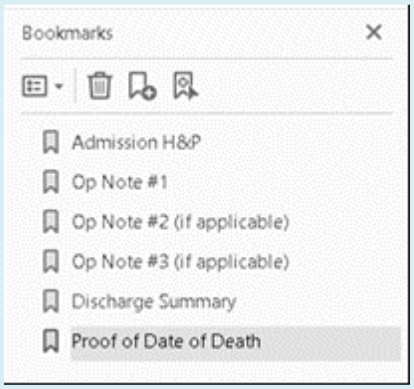
- Add the specific bookmarks using an upgraded version of pdf software such as Acrobat DC
- Make sure you are on the page you would like to bookmark. Open the left arrow in your pdf to view the Bookmarks area.
- Click on the bookmark symbol with the (+) sign. Then name the bookmark and click enter. (You may need to use an upgraded version of the pdf software to see the bookmark symbol and complete this task.)



- PDFs that do not include the requested information or are not bookmarked in a usable manner will be returned and you will be asked to re-create the PDF. If documentation is missing, the site data manager will be notified and asked to upload the requested documents.

How to Obtain, Bookmark and Label your Mortality Case Files:

- Contact your Medical Records to assist with obtaining all mortality cases medical record documents.
- Each case needs to be provided in a separate document, PDF format, with specific bookmarks denoting areas of the audit.
- If your Medical Records department automatically adds standard bookmarking (standard bookmarking is not preferred by the auditing surgeon), it will still be necessary for your site to add the specific bookmarks using an upgraded version of pdf software such as Acrobat DC.
- Below are the specific required bookmarks requested by your auditing surgeon for the mortality audit.



- It is critical to the success of your audit that the bookmarks requested be available in each document.
- Rename your files using the file naming system – OpIDVxxxxxx. If you have more than one file related to that case, name it – OpIDVxxxxx_B.
- Upload all mortality pdf files to the *BOX* folder labeled "Mortality Audit Cases."

Step 6: Upload Random Audit Medical Records (Due 3 Weeks Prior to Audit)

Also attached to the email is a list of cases randomly selected for audit by STS for data period **January 1, 2024, and December 31, 2024**. The below variables will be re-abstracted by the auditor and compared to the patients' medical records and the data you submitted to IQVIA prior to 4/11/25. The below data fields will be audited for each Random Audit on the list. There are 25 cases listed, however only the first 20 have been selected for audit. The last 5 cases are reserved as oversampling in the event a case is deemed ineligible.

Random Audit Case Data Elements

Variable Long Name	SEQUENCE NUMBER	SHORT NAME
Birth Information Known	300	BirthInfoKnown
Premature Birth	315	Premature
Gestational Age At Birth Known	320	GestAgeKnown
Gestational Age (if < 1 year)	325	GestAgeWeeks
Noncardiac Congenital Anatomic Abnormality	420	NCAAMulti
Chromosomal Abnormality	455	ChromAbMulti
Syndromes	490	SyndromeMulti
Date of Admission	570	AdmitDt
Date of Surgery	580	SurgDt
Height	585	HeightCm
Weight	590	WeightKg
Derived DOB	NA	DerivedDOB
Preoperative Factor Known	616	PreopFactorKnown
Preop Factor: Mechanical circulatory support	220 (harvest code)	PreopFactorMulti 220
Preop Factor: Shock, persistent at time of surgery	230 (harvest code)	PreopFactorMulti 230
Preop Factor: Shock, resolved at time of surgery	240 (harvest code)	PreopFactorMulti 240
Preop Factor: Hepatic dysfunction	310 (harvest code)	PreopFactorMulti 310
Preop Factor: Necrotizing entero-colitis, Treated medically	320 (harvest code)	PreopFactorMulti 320
Preop Factor: Necrotizing entero-colitis, Treated surgically	330 (harvest code)	PreopFactorMulti 330
Preop Factor: Coagulation disorder, Hypocoagulable state secondary to medication	360 (harvest code)	PreopFactorMulti 360

Preop Factor: Sepsis	380 (harvest code)	PreopFactorMulti 380
Preop Factor: Preoperative neurological deficit	400 (harvest code)	PreopFactorMulti 400
Preop Factor: Stroke within 48hrs	440 (harvest code)	PreopFactorMulti 440
Preop Factor: Renal dysfunction	450 (harvest code)	PreopFactorMulti 450
Preop Factor: Renal failure requiring dialysis	460 (harvest code)	PreopFactorMulti 460
Preop Factor: Mechanical ventilation to treat cardiorespiratory failure	470 (harvest code)	PreopFactorMulti 470
Diagnosis	1065	DiagnosisMulti
Primary Diagnosis	1070	PrimaryDiagnosis
Fundamental Diagnosis	1075	FundDiagnosis
Procedure	1350	ProcedureMulti
Primary Procedure	1355	PrimaryProcedure
Operation Type	1755	OpType
Number of Cardiothoracic operations	2000	PrvCtOpN
Major POSTOP EVENT: Unplanned Cardiac Reoperation	22, (harvest code)	PostopEventsMulti_22
Major POSTOP EVENT: Unplanned Interventional cardiovascular catheterization procedure	24, (harvest code)	PostopEventsMulti_24
Major POSTOP EVENT: Non-cardiac Reoperation	26, (harvest code)	PostopEventsMulti_26
Major POSTOP EVENT: Renal failure	570 (harvest code)	PostopEventsMulti_570
Major POSTOP EVENT: Postoperative/Postprocedural mechanical circulatory support	40 (harvest code)	PostopEventsMulti_40
Major POSTOP EVENT: Arrhythmia necessitating pacemaker, Permanent pacemaker	74 (harvest code)	PostopEventsMulti_74
Major POSTOP EVENT: Paralyzed Diaphragm	300 (harvest code)	PostopEventsMulti_300
Major POSTOP EVENT: Unexpected Cardiac Arrest	30 (harvest code)	PostopEventsMulti_30
Major POSTOP EVENT: Neurological deficit, Neurological deficit persisting at discharge	4802	POENeuroDefPAtDis
Date of Hospital Discharge	4875	HosDischDt
Mortality Status at Hospital Discharge	4880	MtHospDisStat
Discharge Location	4885	DisLoctn

Date of Database Discharge	4935	DBDischDt
Mortality Status at Database Discharge	4940	MtDBDisStat
Mortality-30-day Status	4945	Mt30Stat

*For sites using the "long list" for fundamental diagnosis, diagnoses, and procedures, be aware that the audit is scored based on the STS "short list."

For patients that do not return to your facility, there is no documentation in your EMR, and there is no other source of documentation, it is acceptable to maintain a tracking log. The tracking log can be maintained using outside software or be within the vendor software. The tracking log should contain:

- Date of the contact with the source
- The source (parent, cardiologist, PCP)
- Means of contact (hone, letter, fax)
- Date the source had contact with patient
- Details of the phone call, letter, fax (including any additional complications, readmissions)
- Maintained in a format that is upload-able for auditing purposes

- **Verification of 30-day status documentation is required to be dated prior to the 2025 Spring Harvest deadline date of 4/11/2025**
- **Sites who fail to submit all (100%) verification will be required to undergo a follow-up audit within one to two years.**

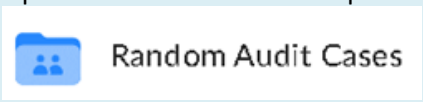
How to Obtain, Bookmark and Label your Random Case Files:

- Below are the specific required bookmarks requested by your auditing surgeon for the random case audit.

BOOKMARKS

- Admission H&P
- Operative Notes
- Anesthesia Record
- Postop ICU Admit Note
- ICU Cardiology Consult Note
- Cardiac testing (pre and postop)
  - Includes: One preop ECHO/TEE Report
    One postop ECHO/TEE Report
- Discharge Summary
- 30 Day Proof of Alive/Dead Status
- Genetic Testing Lab Results
- Gestational Age Documentation + Birth History

- Rename your files using the file naming system – OpIDVxxxxxx. If you have more
- than one file related to that case, name it – OpIDVxxxxx_B.
- Upload the **20** random audit pdf files to the *BOX* folder labeled "Random Audit Cases".



  - In the event the auditor notes a case ineligible for audit, another "oversampling" case will be used. Do not include oversampling cases in the upload. You may wish to prepare and save the first two cases on the oversampling list at your site.
  - To learn more about the audit process, visit the STS audit website for this year's CHSD audit webinar.
- Additional File Upload hints:
  - Do not upload the same named file twice.
  - If records packaged by HIM, ask them not to send meds, labs, and flowsheets.
  - Documentation of the abnormal chromosomal sequence, and not the associated syndrome name.
  - Inotropic drip/pH and Lactate documentation to support your coding of preop shock.
  - Sepsis criteria (temp instability, pressor support, WCB) to support your coding of preop sepsis.
  - Neurological postop assessments (PT/OT/Neurology notes) to support not using the complication "neuro deficit" (temporary or present at discharge) when notes support the potential for a neuro deficit as in the case of a postop cardiac arrest, IVH, stroke, or watershed ischemic injury.

Once your organization's medical records are obtained, the initial review of medical records will begin. During this time, you may be contacted by email regarding questions (including missing information) to allow a thorough and accurate audit.

You will receive a reminder email of your upcoming audit three weeks prior and an email seven days prior to the date. It is possible that on the day prior to audit, the auditing surgeon could be called into the OR at their site. In the event this occurs, the auditing surgeon contacts CRS, and CRS will email you immediately regarding the cancellation and rescheduling. We understand that your site surgeon may be called into the OR last minute also. If you need to cancel and reschedule, please email us as soon as you know, even if it is over the weekend.

Step 7: Day of Audit

On the day of your audit, the following agenda will be followed:

TBD but around 8:00 am - 9am (Site Time)

- Introductions to auditing surgeon (optional), data manager, and CRS audit team
- Site data manager presents site's data abstraction process to STS audit team.
- STS audit team reviews site OR Case Log results.

9am - TBD

- Auditing Surgeon and CRS work virtually auditing random and mortality cases
- If the auditing team is unable to locate a needed piece of information, CRS contacts the site data manager by email or text.
- When complete, CRS sends draft audit results to the site data manager by email.

TBD but between 2pm and 5pm (Site Time) Summary Conference

- The site surgeon, site data manager, auditing surgeon, and CRS meet by webinar.
- The start time of the Summary Conference will be provided after your audit date is selected. The start time is based upon your time zone and the time zone of the auditing surgeon.
- The site may also invite other members of their team to the Summary Conference.
- The audit team will again review the purpose of the audit.
- The audit team will summarize:
    - 20 case audit results
    - major complications audit results
    - mortality case reviews results
    - recommendations

At the conclusion of the summary conference, your site has five working days to adjudicate any discrepancies noted in the draft audit report. Please provide explanations or documentation to *angelae@cardiacregistrysupport.com and/or beths@cardiacregistrysupport.com and/or dianeh@cardiacregistrysupport.com*. If your site offers no feedback by the end of the fifth working day, results will be emailed to STS. Afterward, STS will then provide your site with the final audit results.

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