

Heart Valve Society Mitral Tricuspid Valve Database

Castor EDC Handbook

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1. Introduction



1. Introduction

The following guide contains practical information for participating centers of the Mitral Tricuspid Valve Database. This database is established by the [Heart Valve Society \(HVS\)](#). HVS aims to be a community that promotes research on heart valves in basic research, translational research, and clinical research. Therefore, HVS organizes an annual meeting in which scientists, cardiologists, and cardiac surgeons can meet and exchange ideas. Furthermore, HVS sets up and maintains heart valve research networks (VRNs) to stimulate international collaboration and improvement of heart valve research. These are the [Mitral Tricuspid VRN](#) and [Aortic VRN](#).

The Mitral Tricuspid VRN has established the Mitral Tricuspid Valve Database that collects comprehensive data on patients who undergo an intervention for mitral and/or tricuspid valve stenosis, regurgitation, and prosthesis dysfunction including their characteristics, procedures, and outcomes. The registry is open to centers that perform these interventions. Patients can be included consecutively, or project-based.

1.1 Reading guide

This database guide will address all details needed for participating centers to join the database, the preparations that have to be fulfilled, doing manual data entry, batch uploads, and retrieving follow-up data from other hospitals.

1.2 Quick-Start Checklist

- ▣ **Legal Compliance:** Ensure all legal requirements have been met, including study contracts and obtaining informed consent from patients.
- ▣ **Database Account Setup:** Confirm that the database account information form includes all necessary email addresses for data entry.
- ▣ **Batch Upload Capability:** Explore the possibility of batch uploads. If applicable, contact the database manager to import study data.
- ▣ **Pseudonymization:** Create a key file derived from the participating patient group to pseudonymize both patients and surgeons on a local server.
- ▣ **Data Entry Training:** Verify that proper training has been conducted for all personnel involved in data entry.
- ▣ **Follow-Up Data Retrieval:** Develop a plan to contact local hospitals for the retrieval of follow-up data.

1.3 Contact information

For any questions regarding this handbook or inquiries about the database, please contact the database manager at mitralvalvedatabase@heartvalvesociety.org.

2. Preperation



2. Preparation

Before entering data into the HVS Mitral Tricuspid Valve Database, several preparations must be completed. These include gathering the necessary documents, creating a key file for linking patient and surgeon codes, and ensuring that all personnel responsible for data entry receive proper training. These steps are essential for ensuring data accuracy, compliance with legal requirements, and smooth operation of the database.

2.1 Necessary documents

All the necessary documents for the study are provided in this section. It is crucial that all legal requirements are met, and that anyone responsible for data entry is familiar with the study protocol, as well as knows where to access the Data Dictionary and Case Report Form (CRF).

Legal requirements include signing the Clinical Study Site Agreement (CSSA) and obtaining informed consent from patients unless a waiver has been granted. The informed consent template is available on the website, but it must be adapted to comply with your country's specific regulations. For assistance with legal authorization, please contact the database manager.

The Data Dictionary, an Excel file containing all variables and their definitions, is available for download on the website. Additionally, the Case Report Form (CRF), a PDF document listing all database variables that can be manually filled in, is also accessible online. These resources are essential for ensuring accurate and standardized data entry.

2.2 Key document on your server

For privacy reasons, it is not permitted to upload local patient identifier numbers into Castor EDC. As outlined in the study protocol, a key file must be maintained to link Castor participant IDs with both local patient codes and surgeon codes. This key file should be securely stored at your local hospital and can be organized in an Excel file with two tabs. The first tab should contain two columns: one for the local patient identifier number and the other for the corresponding Castor EDC participant ID. The second tab should include the surgeon codes, which can be simple numeric identifiers (e.g., 01, 02, 03) corresponding to each surgeon. This setup ensures that patient and surgeon privacy is protected while maintaining accurate and accessible data for the study.

2.3 Training

The HVS Mitral Tricuspid Valve Database is managed within Castor EDC. To effectively use Castor, it is crucial to undergo proper training, which can be done through Castor Academy.

Castor Academy is an e-learning platform designed to help users master the use of Castor's Electronic Data Capture (EDC) system. It offers tailored courses for different roles such as data entry, study building, and monitoring. The platform includes step-by-step tutorials, practical assignments, and quizzes, providing hands-on experience with Castor's tools.

For those involved in data entry, Castor Academy is particularly valuable. It offers specialized training on how to input data accurately and efficiently, navigate forms, manage surveys, and export data. These courses are essential for ensuring that data is entered in a structured, validated manner, thereby reducing errors and improving the quality of clinical or research data collection.

For more information and to begin training, visit [Castor Academy](#). For data entry and study administrator at site, the following trainings are advised:

- Getting started with Castor EDC-CDMS
- Data entry basics
- Data entry in Castor EDC-CDMS
- Exporting and importing data (if applicable)
- Sending individual surveys (if applicable)
- Data validation types (if applicable)
- Data standardization (if applicable)

Castor Academy is an e-learning platform designed to help users effectively learn and utilize Castor's Electronic Data Capture (EDC) system. It offers courses tailored for various roles, including data entry, study building, and monitoring. The platform provides step-by-step tutorials, practical assignments, and quizzes that ensure hands-on experience with Castor's tools.

For data entry, Castor Academy is particularly helpful because it offers specific training on how to input data accurately and efficiently into the system, navigate forms, manage surveys, and export data. These courses are essential for ensuring that data is entered in a structured and validated manner, reducing errors and enhancing the quality of clinical or research data collection.

3. Manual data entry



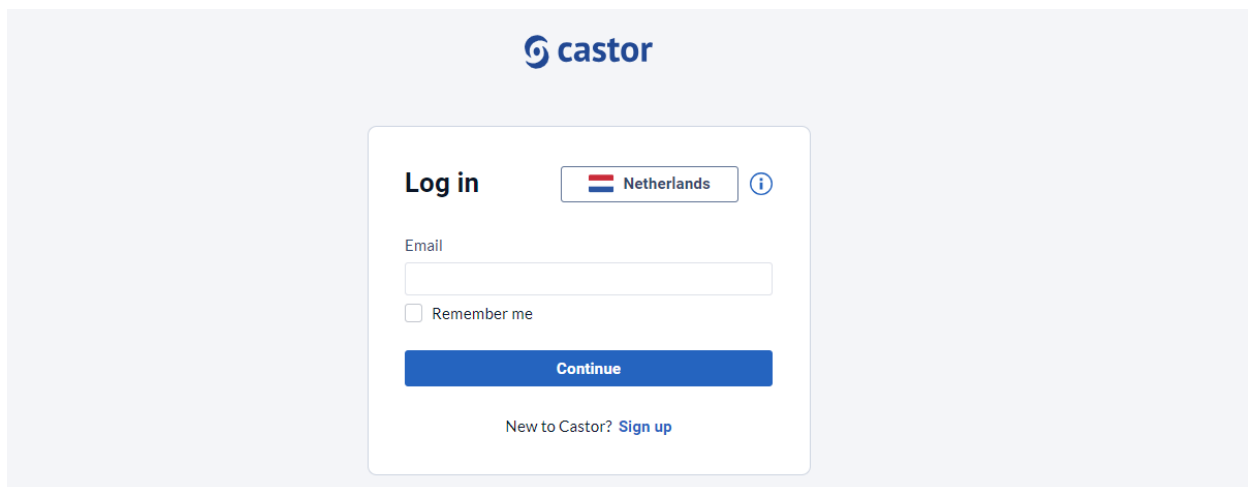
3. Navigation in HVS Mitral Tricuspid Valve Database Castor environment

In this section, navigation into the HVS Mitral Tricuspid Valve Database Castor environment is laid out. The applicable sections from the Castor EDC manual retrieved from the [Castor website](#) are put here, including additional information and applicability on the HVS Mitral Tricuspid Valve Database.

3.1 Access

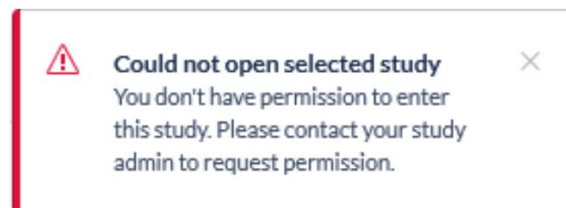
To access the study, you will be added by the database manager. You will receive an invitation by email for the study. Click on the activation link in the email and it will redirect you to the registration page. To register Castor account, fill in your first and last name and choose a password. Click on 'Register'. Shortly after registering a user details, an email with an activation link will be sent to the email address a user has provided. Click on this link to confirm that the supplied email address belongs to a user and verify a user account.

To log into Castor CDMS, go to <https://data.castoredc.com> and enter your email address and password and click on 'Login'.



Once you have logged into Castor EDC, you will see the 'My Studies' overview where all of the user studies (databases) are shown. Choose the HVS Mitral Tricuspid Valve Database to enter the study and start data entry.

If the following warning shows, please check if the study has the button is blank, and the status says 'Not Live'. The study might be in maintenance mode. Please wait and check if a maintenance period was announced.



If you are still unable to log in, please contact the database manager to check if you have the correct management permissions.

3.2 Structure database

In Castor, repeated measurements and visits refer to the process of collecting data from participants at multiple time points throughout a study. In the database, visits include the following categories:

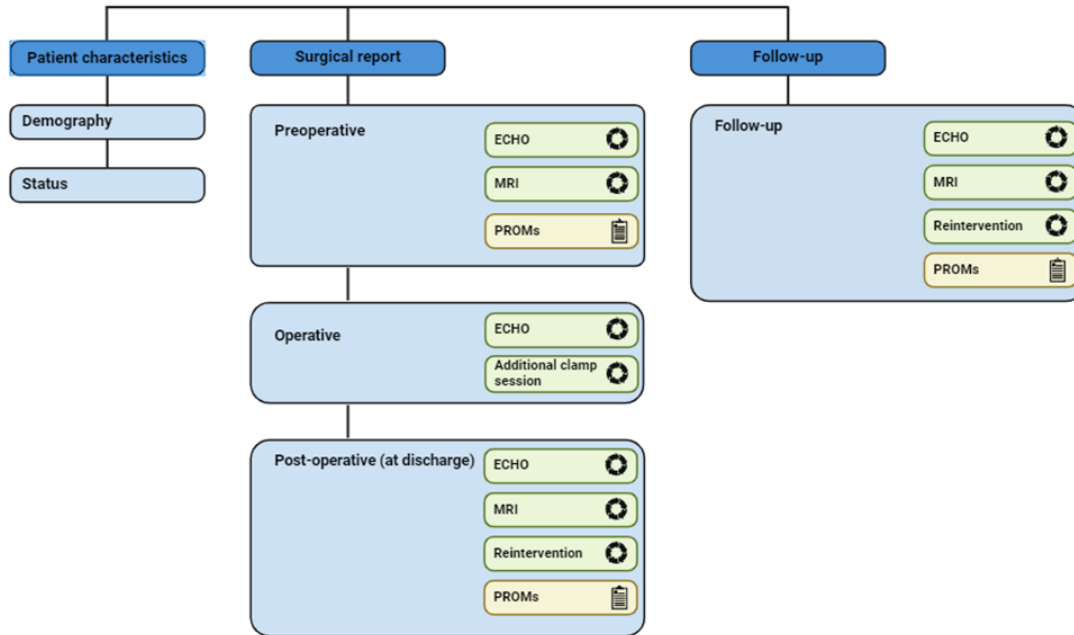
Patient Information: Demographics and status

Surgical Report: Preoperative, operative, and postoperative details

Follow-up Visits: Preferably updated regularly or whenever an event occurs

Health Questionnaires: Applicable only for centers that agreed to administer them

Repeated measurements within each visit facilitate the collection of consistent data points, which are essential for longitudinal analysis. These measurements include ECHO and MRI parameters, additional clamp sessions, reinterventions, and Patient Reported Outcome Measures.



3.3 Add/Open a participant for data entry

Once you enter the study, you will see a list of all participants (including patients) available based on their access level. To add a new participant to the database, a user will need to create a new participant. Creating new participant participants must be done from the Participant tab, by clicking on the “+ New” button. Then, select a user site and click ‘Next’. The participant will be created and opened so a user can begin data entry.

To open a previously created participant, double-click the row the participant is located on.

Participants

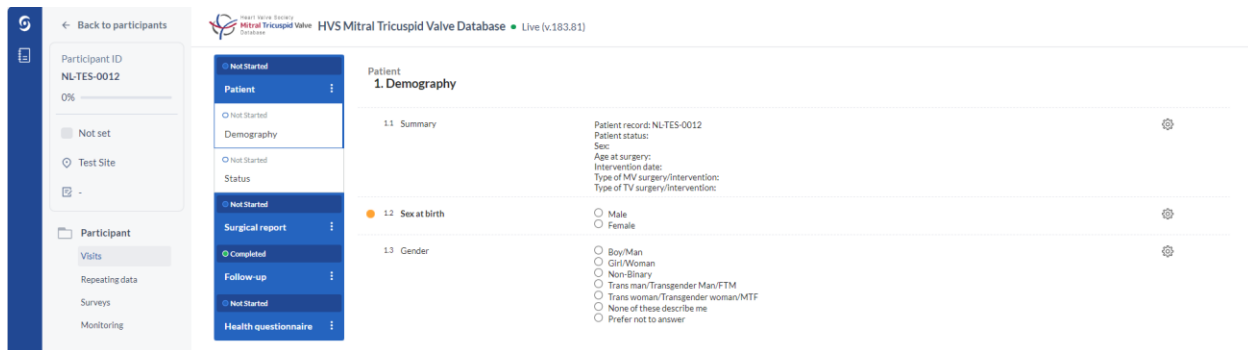
+ New Actions Filters

Participant	Site	Survey co...	Progress	Last opene...	Created on	Updated on	Status
NL-TE5-0007	Test Site	-	<div style="width: 100%;"></div>		05 Jun 2024	25 Jun 2024	Not set
NL-TE5-0006	Test Site	-	<div style="width: 100%;"></div>		05 Jun 2024	05 Jun 2024	Not set
NL-TE5-0005	Test Site	-	<div style="width: 100%;"></div>		05 Jun 2024	05 Jun 2024	Not set
NL-TE5-0004	Test Site	-	<div style="width: 100%;"></div>		05 Jun 2024	19 Jun 2024	Not set
NL-TE5-0003	Test Site	-	<div style="width: 100%;"></div>		05 Jun 2024	05 Jun 2024	Not set
NL-TE5-0002	Test Site	-	<div style="width: 100%;"></div>		28 May 2024	13 Jun 2024	Not set
NL-TE5-0001	Test Site	-	<div style="width: 100%;"></div>		07 May 2024	18 Jun 2024	Not set
NL-TE5-0008	Test Site	-	<div style="width: 100%;"></div>		05 Jun 2024	05 Jun 2024	Not set

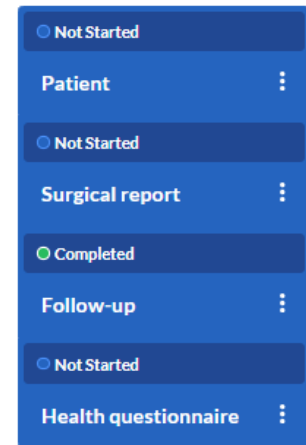
3.4 Doing data entry

When you open a participant, you will be taken to the first form, Patient 1. Demography.

Please note that centers applying project-based could have another interface, as certain forms are shielded or and specific project forms are visible. For example, the health questionnaires will only be visible for centers that enroll patients prospectively and do health questionnaires.



An overview of the study forms (visits and forms of the study). Visits consist of forms and each form contains a set of questions. You can click on the visit of interest in this panel to start entering the required data.



Once you have completed the first form, you can navigate to the next form by clicking on 'Next'. To navigate to the previous form, click on the 'Previous' button. If the user is on the first or the last form, the buttons 'Previous' and 'Next' will be grayed out.

3.4.1 Elements in each question

Data is entered into questions or data fields. Once you answer a question in the form, a user will see a small wheel turning to the left of the field and this means the data is being saved.

When the question is bold (such as sex at birth), the question is mandatory. On the right of questions, you will see a status icon. This icon indicates if

- a question has been answered (green circle)



- or data entry is required and no input has been entered yet (orange circle)

● 1.2 Sex at birth

- Male
- Female

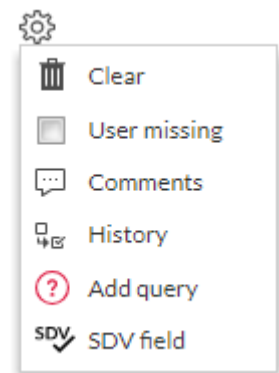
- or data entry is not required - field shows the value based on calculation (no icon).

1.3 Gender

- Boy/Man
- Girl/Woman
- Non-Binary
- Trans man/Transgender Man/FTM
- Trans woman/Transgender woman/MTF
- None of these describe me
- Prefer not to answer

Each field is accompanied by a cogwheel, containing several options for each question.

1. Clear: If data that has been entered for a field, has to be cleared
2. User missing: If data is not available for a question, the field should be marked as missing value. A window will open to ask to provide the reason why the data is missing. Select the appropriate option and if necessary, add a comment. Click 'Mark as missing' to store the option and return to the question list. The field marked as 'User Missing' will be grayed out in the list and marked as 'Completed'. This option should be followed when data is not available for a mandatory question.
3. Comments: If you want to add a comment to a field. Add a user text.



3.5 Further information Castor

For further information on Castor, please choose the most recent guide and data entry (or monitor) based on your role, which you can find on the [Castor website](https://heartvalvesociety-vrn.org/)

4. Batch uploads



4. Batch Uploads

4.1 Batch uploads

Manually entering patient data can be time-consuming, and duplicating efforts is inefficient. To streamline this process, it is important to consider batch uploads, which can save significant time and resources. If studies have already been conducted or if data from national or international registries related to mitral and/or tricuspid valve interventions is available, it could be valuable for your center. Additionally, if your center has a local database and you are interested in automating data entry through batch uploads, please reach out. We can collaborate on data mapping and perform imports tailored to your specific needs. For further support and guidance, please contact the data manager.

4.2 Available data mapping

Data mapping has been completed for the following databases. If you have data available and are interested in utilizing it, please contact the data manager for further assistance.

- International Consortium for Health Outcomes Measurement (ICHOM)- [Set of Patient-Centered Outcome Measures for Heart Valve Disease](#)
- European System for Cardiac Operative Risk Evaluation (EuroSCORE) II - [EuroSCORE II](#)
- Nederlandse Hart Registratie (NHR)- [Cardiochirurgie](#), [Transcatheter Hartklepinterventies \(THI\)](#)

5. Follow-up data



5. Follow-up data

After a mitral and/or tricuspid valve intervention, patients require regular follow-up care to monitor their recovery and long-term outcomes. This follow-up may include various assessments such as ECHO scans to evaluate heart function, as well as detailed information regarding any complications, reinterventions, or other significant developments in the patient's health. Ensuring that this data is consistently included in the database is crucial for maintaining comprehensive and reliable records, which are essential for tracking patient outcomes, identifying trends, and evaluating the success of interventions over time.

Since the hospital where the procedure was performed is not always the one providing follow-up care, patients often receive these services at local hospitals closer to their homes. As a result, it is important for participating centers to actively reach out to these local hospitals and healthcare providers to retrieve follow-up data whenever possible. Establishing these connections early in the study process is vital to ensure a smooth flow of information. We strongly encourage participating centers to prioritize building these relationships from the outset, and we are committed to offering support and guidance where necessary to facilitate these collaborations, ensuring that critical follow-up data is not lost.