Heart Valve Society Valve Research Networks

Castor EDC Handbook

6st of December 2024
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1. Introduction

1. Introduction

The following guide contains practical information for participating centers of the HVS Aortic Valve (AV) Database and the HVS Mitral Tricuspid Valve (MTV) Database. The databases were initiated by several centers and were developed in collaboration with the Heart Valve Society (HVS).

The HVS fosters a collaborative community dedicated to advancing heart valve research across basic, translational and clinical disciplines. To support this mission, HVS hosts an annual meeting where scientists, cardiologists and cardiac surgeons gather to exchange ideas and insights. Additionally, HVS has established Heart Valve Research Networks (VRNs) to stimulate international collaboration and further heart valve research, the Mitral and Tricuspid VRN and the Aortic VRN, which have respectively led to the development of the HVS Mitral Tricuspid Valve (MTV) Database and the HVS Aortic Valve (AV) Database. More information about HVS and the databases can be found on the website (HVS - The Heart Valve Society).

Participating centers will enter data into Castor Electronic Data Capture (from now on referred to as 'Castor'). Castor is an electronic database capture system for securely maintaining research data in an online case report form (CRF). The database complies with all applicable laws and regulations.

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 active data entry;
- ☐ **Batch Upload Capability**: explore the possibility of batch uploads. If applicable, contact the database manager how to import study data;
- ☐ **Pseudonymization**: create a key file derived from the participating patients 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 databases, please contact the database managers at:

HVS MTV Database: mitralvalvedatabase@heartvalvesociety.org

HVS AV Database: aorticvalvedatabase@heartvalvesociety.org

2. Preparation

2. Preparation

Before entering data into the HVS Databases, 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. The Quick-Start-Checklist in section 1.2 might help you to get started.

2.1 Necessary documents

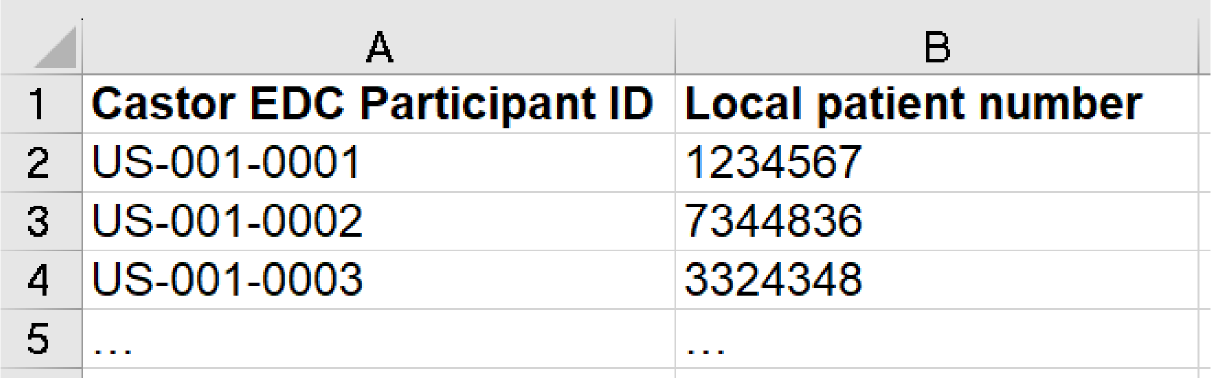
It is crucial that all legal requirements are met and that anyone responsible for data entry is familiar with the study protocol. They should also know where to access the Data Dictionary and CRF.

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

The Data Dictionary, an Excel file containing all variables and their definitions, is available for download on the website. Similarly, the CRF, a PDF document listing all database variables for manual entry, is also available online. These resources are essential for ensuring accurate and standardized data entry.

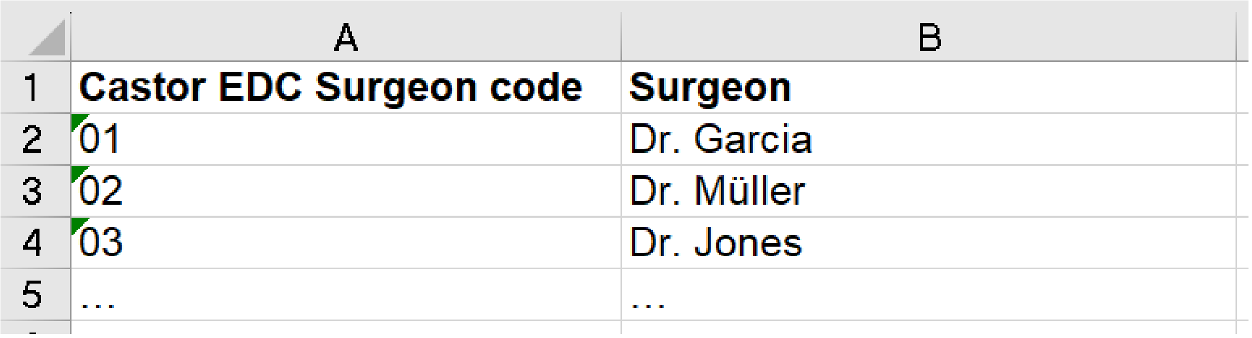
2.2 Key document on your server

To protect patient privacy, local patient identifier numbers cannot be uploaded into Castor. As outlined in the study protocol, a key file must be maintained to link Castor Participant IDs with local patient identifier numbers. This key file should be securely stored at your hospital and can be organized in an Excel file with two columns: one for the Castor Participant ID and another for the corresponding local patient identifier number. An example is shown below.



Castor EDC Participant ID	Local patient number
US-001-0001	1234567
US-001-0002	7344836
US-001-0003	3324348
…	…

In both databases, each surgeon can also be assigned a unique code. If needed, a second tab in the key file can list surgeons along with their corresponding codes, using simple numeric identifiers (e.g., 01, 02, 03). An example is shown below.



Castor EDC Surgeon code	Surgeon
01	Dr. Garcia
02	Dr. Müller
03	Dr. Jones
…	…

This system safeguards the privacy of both patients and surgeons while ensuring the data remains clear and easy to use for research. It enables data to be accurate and standardized without revealing personal information.

2.3 Training

The HVS Databases are managed within Castor. To effectively use Castor, it is crucial to complete proper training through Castor Academy – an e-learning platform designed to help users master the system.

Castor Academy offers tailored trainings for various roles, including data entry, managing surveys, exporting forms and monitoring. The platform features step-by-step tutorials, practical assignments and quizzes to provide hands-on experience with Castor's tools. These courses are key to ensuring data is entered in a structured and validated way, reducing errors and improving data quality.

For those involved in data entry and study administration, 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)

For more information or to begin training, visit Castor Academy.

3. Manual data entry

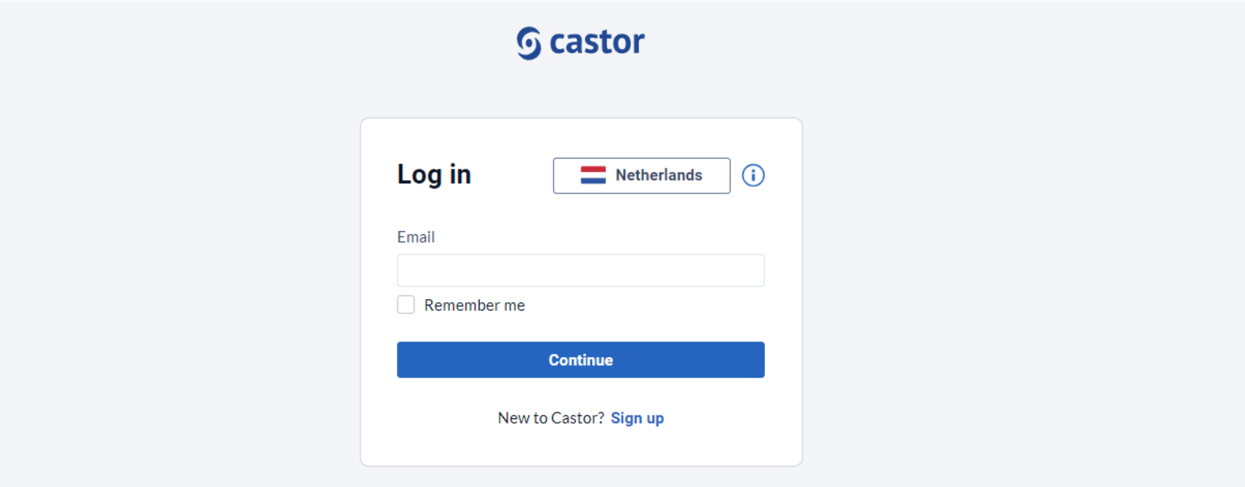
3. Navigation in Castor environment

In this section, navigation in the Castor environment of the HVS Databases is laid out. The applicable sections from the Castor manual, retrieved from the Castor website, are included here.

3.1 Access

To gain access the study, the relevant database manager will add you to the system. You will receive an email invitation with an activation link. Click the link, and you will be redirected to the registration page. Enter your first and last name, set a password and click **Register**. Shortly after registering, you will receive another email to the registered email address with an activation link to verify your account. Click the link to confirm your email address and activate your account.

To log into Castor, go to https://data.castoredc.com, enter your email address and password and click **Login**.



Once you have logged into Castor, the **My Studies** page will display all studies associated with your account. Select either the 'HVS Aortic Valve Database' or the 'HVS Mitral Tricuspid Valve Database' to access the study and start entering data.

If you encounter any issues logging in, please contact the relevant database manager to verify your access permissions.

3.2 Structure of the databases

In Castor, visits and repeated measurements are used to collect data from participants at multiple time points during a study. The databases includes the following visit categories:

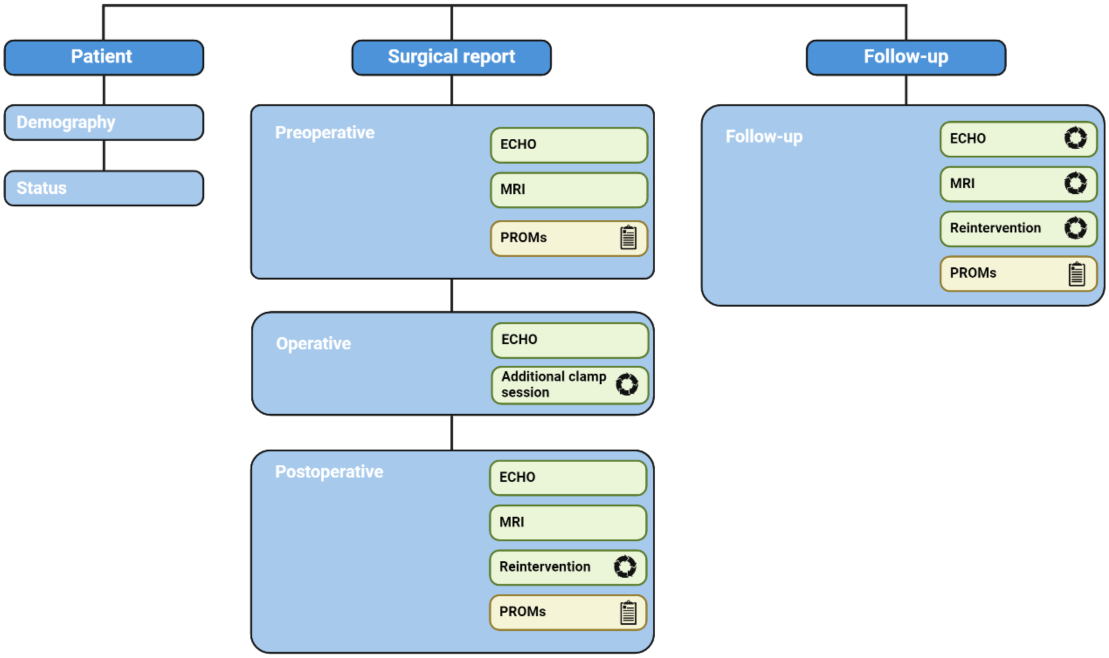
- **Patient**:
    - Demography and status
- **Surgical Report**:
    - Preoperative, operative and postoperative details
    - Details on possible additional clamp sessions
    - Details on possible reinterventions during the hospitalization period
    - Preoperative, intra-operative and discharge echo parameters
- **Follow-up Visits**:
    - Preferably updated annually or whenever an event occurs
- **Health Questionnaires** (only for the HVS MTV database):
    - Applicable only for centers that agreed to administer them

Repeated measurements within each visit ensure consistent data collection,, essential for longitudinal data analysis. These measurements include:

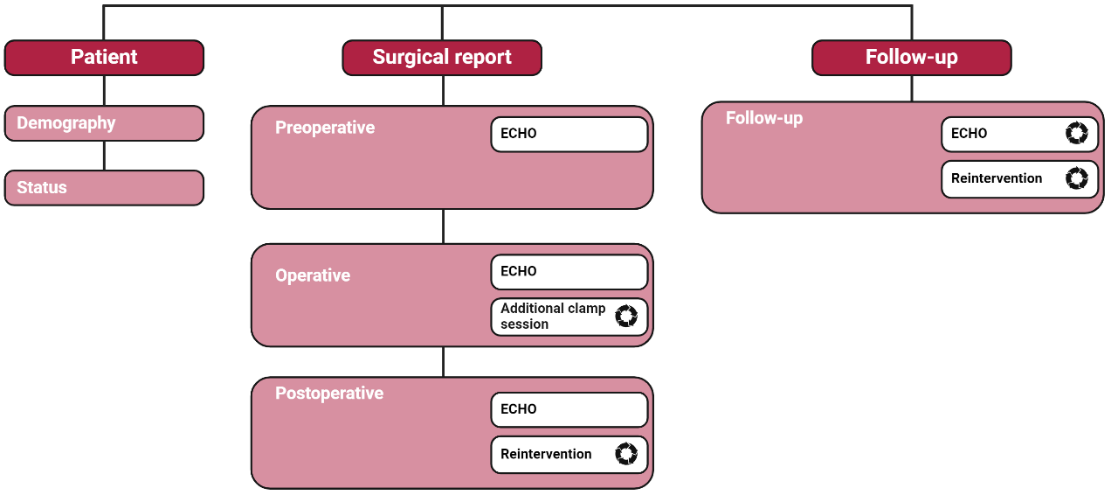
- Echo parameters
- Additional clamp sessions
- Reinterventions (both during the hospitalization of the first intervention as well as during follow-up)
- MRI parameters and Patient Reported Outcome Measures (PROMs) for the HVS MTV Database specifically.

The structure of the databases are figured below.

HVS Mitral Tricuspid Valve Database structure



HVS Aortic Valve Database structure

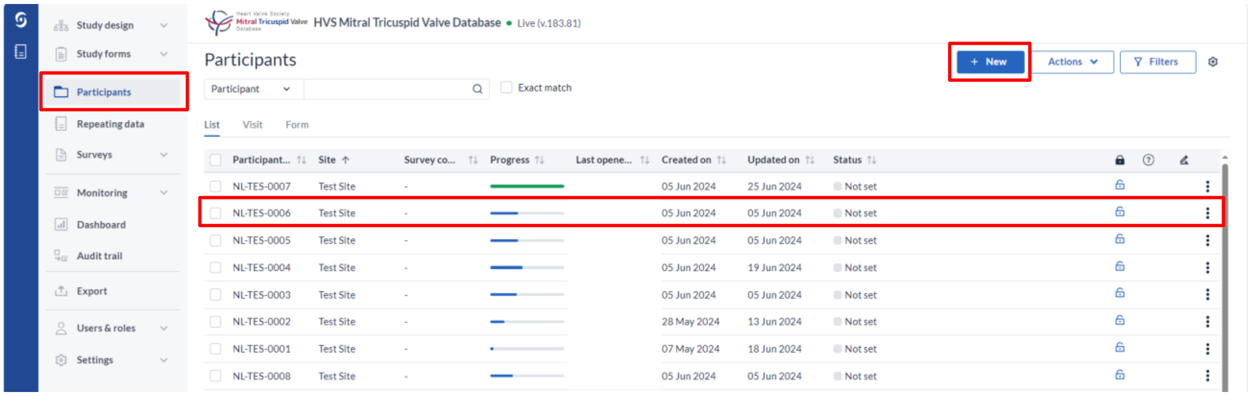


3.3 Adding and opening a participant for data entry

Once you enter the study, you will see a list of all participants based on your access level. To add a new participant to the database, you will need to create a new participant.

Creating new participant participants must be done from the **Participants** tab, and by clicking the **+ New** button. Then, select the site the participant is from and click **Next**. The new participant will be created and opened, allowing you to begin data entry.

To open an existing participant, double-click their row in the participants list.

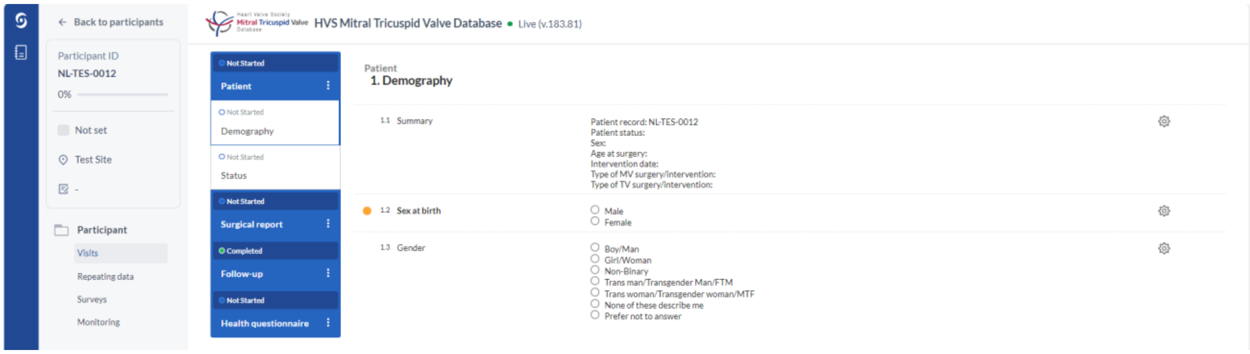


☐	Participant...	Site	Survey co...	Progress	Last opene...	Created on	Updated on	Status
☐	NL-TES-0007	Test Site	-			05 Jun 2024	25 Jun 2024	Not set
☐	NL-TES-0006	Test Site	-			05 Jun 2024	05 Jun 2024	Not set
☐	NL-TES-0005	Test Site	-			05 Jun 2024	05 Jun 2024	Not set
☐	NL-TES-0004	Test Site	-			05 Jun 2024	19 Jun 2024	Not set
☐	NL-TES-0003	Test Site	-			05 Jun 2024	05 Jun 2024	Not set
☐	NL-TES-0002	Test Site	-			28 May 2024	13 Jun 2024	Not set
☐	NL-TES-0001	Test Site	-			07 May 2024	18 Jun 2024	Not set
☐	NL-TES-0008	Test Site	-			05 Jun 2024	05 Jun 2024	Not set

3.4 Data entry

When opening a participant, you will be redirected to the first form, **Patient – 1. Demography**.

Please note that centers in the HVS MTV database applying project-based approaches may have a different interface, as certain forms are hidden and specific project forms are visible. For example, health questionnaires will only be visible for centers that enroll patients prospectively and agreed to conduct health questionnaires.



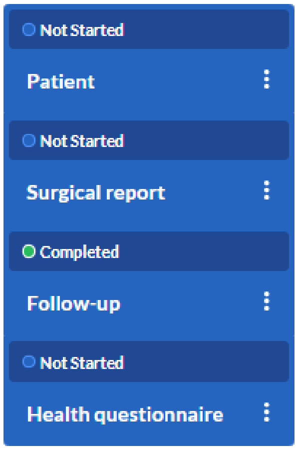
Participant ID
NL-TES-0012
0%
Not set
Test Site
-

Patient
1. Demography

1.1 Summary
Patient record: NL-TES-0012
Patient status:
Sex:
Age at surgery:
Intervention date:
Type of MV surgery/intervention:
Type of TV surgery/intervention:

1.2 Sex at birth
○ Male
○ Female

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


○ Not Started
Patient ⋮
○ Not Started
Surgical report ⋮
○ Completed
Follow-up ⋮
○ Not Started
Health questionnaire ⋮

On the right, you see an overview of the study forms. A study form can consist of Visits, Repeating data or Surveys, and each study form contains a set of questions. You can click on the study form of interest in this panel to start entering the required data.

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

Elements of each question

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

Bold data fields are mandatory, such as weight or height.

On the lefthand side of the data fields, you will see a status icon:

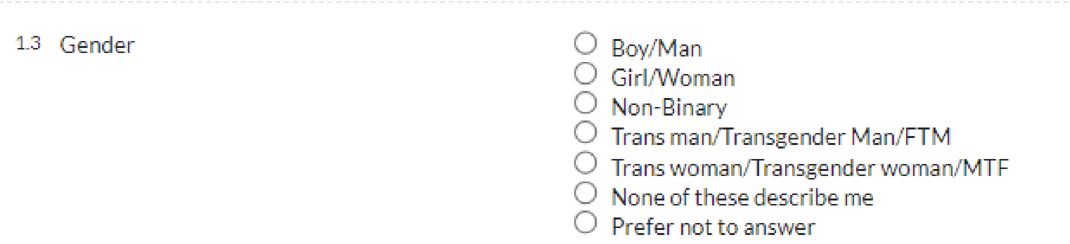
- a green circle indicates a completed field.


● 1.2 **Sex at birth**
○ Male
● Female

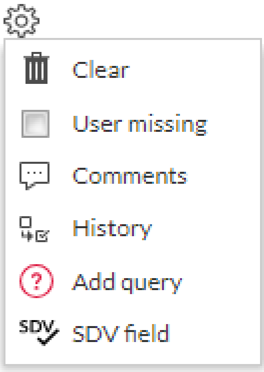
- An orange circle means data entry is required


● 1.2 **Sex at birth**
○ Male
○ Female

- No circle means data entry is not required or the field shows the value based on an automatic calculation.


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 on the righthand side, containing several options for each question:



1. Clear: if the data that has been entered into a field has to be cleared.
2. User missing: if data is not available for a data field, the field should be marked as missing. A window will open, which asks 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 checked. This option should be followed when data is not available for a mandatory data field.
3. Comments: comments can also be added to clarify any field.

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.

4. Batch uploads

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4.1 Batch uploads

Manually entering patient data can be time-consuming. To streamline this process, it is important to consider batch uploads to save time and resources. If your center has existing data from prior studies or registries, such as national or international databases or registries related to valve interventions, or if your center has a local database and you are interested in automating data entry through batch uploads, please contact the relevant database manager to collaborate on data mapping and perform imports tailored to your specific needs.

4.2 Available data mapping

Data mapping has already been completed for the following registries:

- 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 and Transcatheter Hartklepinterventies (THI)

If you have relevant data from these sources or if you have your own database or registry and are interested in utilizing it, please contact the relevant database manager for further assistance.

5. Follow-up data

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After a valve intervention, regular follow-ups are essential to track recovery and long-term outcomes. These assessments may include echo scans to evaluate heart and valve function, details of complications, reinterventions, or other 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 follow-up care often occurs at local hospitals and not at the hospital where the procedure was performed, participating centers should actively reach out to these local hospitals and healthcare providers to gather follow-up data. Establishing these connections early in the study process is vital to ensure a smooth flow of information, and so we strongly encourage participating centers to prioritize building these relationships from the beginning of the study onwards.

We are committed to offer support and guidance where necessary to facilitate these collaborations, ensuring that critical follow-up data is not lost.