



European Commission

**Directorate General for Communications Networks, Content and Technology
Sustainable and Secure Society - Health and Well-being**

**H2020 PHC-30-2015 689617
Research and Innovation Action**



Work Package: WP4

**Digital Patient Definition, Data
Collection**

Deliverable: D4.3

Data availability status report

Version: 2v0

Date: 28-Apr-17



DOCUMENT INFORMATION

IST Project Num	H2020 PHC-30-2015 689617	Acronym	EurValve
Full title	Personalised Decision Support for Heart Valve Disease		
Project URL	http://www.eurvalve.eu		
EU Project officer	Carmen LAPLAZA SANTOS (CNECT/H/01)		

Work package	Number	4	Title	
Deliverable	Number	4.3	Title	Data availability status report

Date of delivery	Contractual	30 April 2017	Actual	30 April 2017
Status	Version 2v0		Final <input type="checkbox"/>	
Nature	Prototype <input type="checkbox"/> Report <input checked="" type="checkbox"/> Dissemination <input type="checkbox"/> Other <input type="checkbox"/>			
Dissemination Level	Public (PU) <input type="checkbox"/>		Restricted to other Programme Participants (PP) <input type="checkbox"/>	
	Consortium (CO) <input checked="" type="checkbox"/>		Restricted to specified group (RE) <input type="checkbox"/>	

Authors (Partner)	DHZB		
Responsible Authors	Titus Kühne Marcus Kelm	Email	titus.kuehne@dhzb.de mkelm@dhzb.de
	Partner	DHZB	Phone 0049 30 45932864

Abstract (for dissemination)	In order to establish, train and operate the system, clinical data and imaging data need to be made digitally available to all project partners. Furthermore, functional and geometric measurements based on clinical imaging methods need to be integrated. Using existing database solutions (ArQ) and a telemedicine certified imaging repository (Trialconnect) the clinical part of the data infrastructure has been made available at all three clinical sites and to all technical partners.
Keywords	Data availability, eCRF, Patient-specific data,

The information in this document is provided as is and no guarantee or warranty is given that the information is fit for any particular purpose. The user thereof uses the information at its sole risk and liability. Its owner is not liable for damages resulting from the use of erroneous or incomplete confidential information.

Version Log			
Issue Date	Version	Author	Change
27-04-2017	1.2	MK	Initial version
27-04-201	1.3	SW	Additions
28-04-2017	2v0	PMO, USFD	Final Version



Contents

1	Introduction.....	4
2	Scope of this Document	4
3	Summary	4
4	Imaging data availability.....	5
5	eCRF availability	7
	Definitions.....	9
	Annex 1	11



1 INTRODUCTION

EurValve will develop a clinically – compliant Decision Support System for the management of Valvular Heart Disease. The concept underpinning the project is that of the digital patient, in which we combine all available data on a patient, and interpret it through the operation of computational models. The outputs, novel disease characterisations and ranked intervention alternatives, are provided to the physicians to support their decision.

In order to establish, train and operate the system, clinical data and imaging data need to be made digitally available to all project partners. Furthermore, functional and geometric measurements based on clinical imaging methods need to be integrated.

2 SCOPE OF THIS DOCUMENT

Subsequent tasks will strongly rely on data availability. At the same time sensitive handling of personalized data of three clinical sites is required. This report presents the solutions and mechanisms used in EurValve to overcome these hurdles.

3 SUMMARY

Using existing database solutions (ArQ) and a telemedicine certified imaging repository (TrialConnect) the clinical part of the data infrastructure has been made available at all three clinical sites and to all technical partners. It includes:

- Imaging data in (pseudo-anonymized in DICOM format)
 - Preoperative CT datasets
 - Pre- and post-operative trans-thoracic echocardiography
 - Pre- and post-operative MRI
 - Intra-operative trans-oesophageal echocardiography
- Clinical data (pre-operative)
 - Meta Data
 - Medication
 - Information on pre-existing conditions
- Clinical status data (pre- and post-operative)
 - Symptoms
 - Physiological and Laboratory Measurements
- A common set of Imaging Parameters from CT, MRI, echocardiography
 - Geometric parameters (pre- and postoperatively)
 - Functional parameters (pre- and postoperatively)
 - Flow volumes (pre- and postoperatively)
- Intraoperative data
 - Procedural data
 - Procedural outcome
- Clinical Outcome (post-operative)



4 IMAGING DATA AVAILABILITY

TrialConnect has been previously used in EU projects. The platform has been customized to match the requirements of EurValve and includes (pseudo-) anonymisation of DICOM image data. Accounts were created for all partners who will access the repository (Fig 1)

planning

EURValve

EURValve

2016-07-01

2019-06-30

Human

120

15 Subjects included
0 Registered
15 Enrolled
0 Completed
0 Subjects excluded

General Information

Active Tools

Arms

Subjects

Participating Sites

Team

Reports

Last Name	First Name	Em	PI	Site	Trial Admin	Trial Dsgnr	Coord. Invest.	Sub-Invest	Imag. Analyst	Monitor	Imag. Reader	Imag. CRA
Lawford	Patricia	p.la		Sheffield Teaching Hospitals NHS Foundation Trust	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
McCormack	Keith	k.m.		Sheffield Teaching Hospitals NHS Foundation Trust	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Elarifi	Karen	kare		Sheffield Teaching Hospitals NHS Foundation Trust	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hose	Rod	d.r.r		Sheffield Teaching Hospitals NHS Foundation Trust	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lumens	Nelly	nelly		Catharina Ziekenhuis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Zelis	Jo	jo.z		Catharina Ziekenhuis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tonino	Pim	pim		Catharina Ziekenhuis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Degener	Franziska	deg		Deutsche Herzzentrum Berlin	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Morris	Paul	pau		Sheffield Teaching Hospitals NHS Foundation Trust	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Silva	Daniel	d.sil		Sheffield Teaching Hospitals NHS Foundation Trust	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Archer	Gareth	gar		Sheffield Teaching Hospitals NHS Foundation Trust	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Fig 1 TrialConnect user accounts in EurValve

The platform allows the upload of image datasets. These are anonymised during the upload process and assigned to pre-defined study-specific imaging time points. (Fig 2)

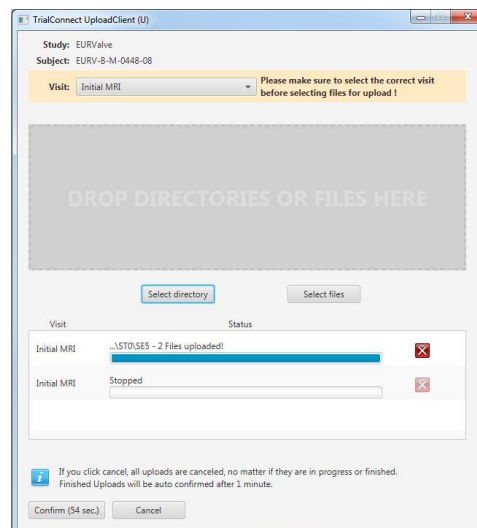


Fig 2 Upload and assignment of study visits



Imaging data of (1) all imaging modalities (CT, MRI, TEE, TTE) from (2) all clinical sites has been successfully uploaded to the TrialConnect platform (Fig 3).

The screenshot displays the TrialConnect platform interface for the EURValve study. The interface is divided into several sections:

- Header:** Includes the logo of DEUTSCHES HERZZENTRUM BERLIN and navigation tabs for Welcome and Trial Connect.
- Left Sidebar:** Contains icons for various functions like patient search, data management, and reporting.
- Table 1 (Patient List):** A table with columns: Status, PID, Arm, and Gender. It lists 18 enrolled subjects with their respective IDs and genders.
- Table 2 (Visit Log):** A table with columns: Visit, Rel. Time, Attached Documents, Completed/Total CRFs, and Status. It shows visits such as Initial Echo, Initial MRI, Initial CT, Intraoperative Echo pre/post, and 6-month follow-up Echo/MRI.
- Table 3 (Imaging Modalities):** A grid of 18 boxes, each representing a specific imaging modality. Each box includes a thumbnail image, the modality name (e.g., WP 3D Whole Heart LV+Aorta, DeRec - 4D QF-SAG-ap), and a status indicator (new, in progress, etc.).
- Right Sidebar:** Contains icons for Subject, Data, and other study-related functions.

At the bottom of the interface, there are links for "About this Website" and "Powered By Telekom Healthcare Solutions".

Fig 3 Uploaded cases of all three clinical sites

All set-up processes have been finished. By April 30 2017 the platform has been set to “productive mode”. According to good clinical practice, all information will remain in the database and an audit trail will be kept beyond the scope of the project.



5 ECRF AVAILABILITY

During several personal and remote meetings the modelling concept has been discussed and clinically relevant outcome parameters of the 0-dimensional model have been discussed.

The underlying clinical information will be recorded in the ArQ platform, hosted at Sheffield University. Based on D4.1 and in close alignment of all three clinical sites (Eindhoven, Sheffield, Berlin) have jointly prepared a list of parameters that will be available for all patients. Models and further processing pipelines can be built around these data and can be improved as more patients are enrolled.

Furthermore, the data model can be easily used in a second database instance on any retrospective data available. Once available tools provided within the ArQ software will allow the clinical teams to map extracted data onto this model and make it available to the research teams.

The ArQ software itself was discussed in Deliverable 2.1 in the abstract sense, shown below is a selection of two data entry screens which indicated the structure of the live data collection system.

Medications list

Medication	Total Dose	Units	Frequency	Start Date	Stop Date	Discontinue
Paracetamol+caffeine 450mg/25mg tablet	4	mg	2x / day	11-Jul-2016		Discontinue
Oral aspirin	6	mg	4x / day	11-Jul-2016		Discontinue
Facitaxel	2	drops	daily	13-Jul-2016		Discontinue
Facitaxel	1	mg	daily	13-Jul-2016		Discontinue
Enalapril maleate 5mg tablet	1	mg	3x / day	09-Aug-2016		Discontinue

Patient Visits

Date	Type
05 May 2016	Pre-op
01 Jun 2016	Post-op
09 Aug 2016	Pre-op

Figure 4 Initial patient summary page



H2020 PHC-30-2015 689617
WP4: Digital Patient Definition, Data Collection
D4.3: Data availability status report
Version: 2v0
Date: 28-Apr-17



EurValve Database - ArQ Database

Search Transfers Delete Close New Record

Patient Study ID Date of Birth

Patient Summary Dataset Risk factors

Dataset dashboard Medications Risk factors Diagnosis Physiological Measures Labs Echo CT MRI Catheterisation Operation Parameters

Risk Factors

Use "EuroSCORE website (click here to link)" online calculator to calculate the resulting EuroSCORE.

EuroSCORE II

Patient Related factors

Gender Male

Renal Impairment

Extracardiac arteriopathy

Poor Mobility (Frail)

Previous Cardiac Surgery

Chronic Lung Disease (COPD)

Active Endocarditis

risk_critical

Diabetes On Insulin

Cardiac Related factors

NYHA

CCS Class 4 angina

LV Function

Recent MI

Pulmonary Hypertension

Operation Related factors

Urgency of indication

Weight of Intervention

Surgery on Thoracic Aorta

Total Euroscore II

Additional

Previous MI

s/p Coronary bypass surgery

s/p Aortic valve replacement

s/p Mitral valve surgery

Figure 5 Risk factors collection tab with other data entry screen shown on the left.



DEFINITIONS

List of Key Words/Abbreviations

BMI	Body Mass Index
BSA	Body Surface Area
CABG	Coronary artery bypass grafting
CCS	Canadian Cardiovascular Society grading of Angina
COPD	Chronic obstructive pulmonary disease
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine Standard
dPmax	Max Pressure Drop
dPmean	Mean Pressure Drop
DSS	Decision Support System
eCRF	electronic case report forms
ED	End diastole
EF	Ejection fraction
ES	End systole
FS	Fractional shortening
ICD	International classification of disease
JSON	Javascript object notation
LV	Left ventricle
LVEDD	Left ventricle end diastolic diameter
LVOT	Left ventricular outflow tract
LVPWD	Left ventricle posterior wall diameter
MR(I)	Magnetic Resonance (Imaging)
NYHA	New York Heart Association Heart Failure Classification
RV	Right ventricle
s/p	status post
STL	Stereolithography
STS	Society of Thoracic Surgeons Risk Score
TAVI	Transcatheter aortic valve implantation
WP	Working plan



This page was intentionally left blank



ANNEX 1

X = data available

Meta Data			Data available Eindhoven	Data available Sheffield	Data available Berlin	pre-interventionally only
Patient State	Character	{pre-op, post-op, modelled, [rest/exercise/characterisation, input/output, measured/inferred]}	X= available	X= available	X= available	
Date of patient record creation	Date	YYYY-MM-DD	x	X	x	automatic
Demographics						
Gender	Character	{Male, Female}	x	X	x	
Year of Birth	Integer	YYYY-MM-DD	x	X	x	
Age	Integer	[Years]	x	X		automatic
Height	Integer	[cm]	x	X	x	
Weight	Integer	[kg]	x	X	x	
BSA	Double	Derived (Mosteller)	x	X	x	automatic
BMI	Double	Derived	x	X	x	automatic
Medication	Medication	Medication	Medication	Medication	Medication	pre- and post
Beta Blocker	Boolean	{TRUE, FALSE}	x	X	x	
ACE-Inhibitors	Boolean	{TRUE, FALSE}	x	X	x	
ARB-Inhibitors	Boolean	{TRUE, FALSE}	x	X	x	
Statins	Boolean	{TRUE, FALSE}	x	X	x	
Loop Diuretics	Boolean	{TRUE, FALSE}	x	X	x	
Diuretics others	Boolean	{TRUE, FALSE}	x	X	x	
Nitrate	Boolean	{TRUE, FALSE}	x	X	x	
Calcium Antagonists	Boolean	{TRUE, FALSE}	x	X	x	
L-Thyroxine	Boolean	{TRUE, FALSE}	x	X	x	
Amiodarone	Boolean	{TRUE, FALSE}	x	X	x	
Cortison	Boolean	{TRUE, FALSE}	x	X	x	
Existing conditions	Risk factors	Risk factors	Risk factors	Risk factors	Risk factors	pre-interventional only
Extracardiac Arteriopathy	Boolean	{TRUE, FALSE}	x	X	x	
Previous cardiac surgery	Boolean	{TRUE, FALSE}	x	X	x	
COPD	Boolean	{TRUE, FALSE}	x	X	x	
Active Endocarditis	Boolean	{TRUE, FALSE}	x	X	x	
Critical preoperative state	Boolean	{TRUE, FALSE}	x	X	x	



Diabetes on Insulin	Boolean	{TRUE, FALSE}	x	X	x	
Recent myocardial infarction	Boolean	{TRUE, FALSE}	x	X	x	
Previous myocardial infarction	Boolean	{TRUE, FALSE}	x	X	x	
Pulmonary Hypertension systolic > 60mmHg	Boolean	{TRUE, FALSE}	x	X	x	
Urgency of Indication	Character	{elective, urgent, emergency, salvage}	x	X	x	
Surgery on Thoracic aorta	Boolean	{TRUE, FALSE}	x	X	x	
Frail	Boolean	{TRUE, FALSE}	x	X	x	
s/p Coronary Bypass Surgery	Boolean	{TRUE, FALSE}	x	X	x	
s/p aortic valve replacement	Boolean	{TRUE, FALSE}	x	X	x	
Stroke	Boolean	{TRUE, FALSE}	x	X		
Arterial hypertension	Boolean	{TRUE, FALSE}	x	X	x	
Heart Failure preserved EF	Boolean	{TRUE, FALSE}	x	X	x	
Heart Failure restricted EF	Boolean	{TRUE, FALSE}	x	X	x	
Diabetes without Insulin	Boolean	{TRUE, FALSE}	x	X	x	
Permanent atrial fibrillation	Boolean	{TRUE, FALSE}	x	X	x	
Intermittent atrial fibrillation	Boolean	{TRUE, FALSE}	x	X	x	
Mitral Valve Disease	Character	none, MS, MI, mixed	x	X	x	
Cause of MVD	Character	ischemic, rheumatic, infective, functional	x	X	x	
Duration of Mitral Valve Disease	Boolean	{TRUE, FALSE}	x	X		
Aortic Valve Disease	Character	none, AS, AI, mixed	x	X	x	
Cause of AVD	Character	calcification, bicuspid valve disease, infective, other	x	X	x	
Duration of Aortic Valve Disease	Boolean	{TRUE, FALSE}	x	X	x	
Bicuspid Aortic Valve	Boolean	{TRUE, FALSE}	x	X	x	
Aortic aneurysm (thoracic)	Boolean	{TRUE, FALSE}	x	X	x	
Aortic aneurysm (abdominal)	Boolean	{TRUE, FALSE}	x	X	x	
Aortic coarctation	Boolean	{TRUE, FALSE}	x	X	x	
Chronic rheumatic disease	Boolean	{TRUE, FALSE}	x	X	x	
Chronic renal impairment	Boolean	{TRUE, FALSE}	x	X	x	
Chronic liver disease	Boolean	{TRUE, FALSE}	x	X	x	
Acute rheumatic disease	Boolean	{TRUE, FALSE}	x	X	x	
Acute renal impairment	Boolean	{TRUE, FALSE}	x	X	x	
Acute liver disease	Boolean	{TRUE, FALSE}	x	X	x	
Malignant disease	Boolean	{TRUE, FALSE}	x	X	x	
Dementia	Boolean	{TRUE, FALSE}	x	X	x	



Smoking	Boolean	Yes, no, previously smoked	x	X	x	
Smoking (Pack Years)	Integer		x	X	x	
Alcohol consumption	Character	None, mild, rare, regular, alcohol abuse, history of alcohol abuse	x	X	x	
Symptoms						pre- and post
Palpitations	Character	none, at rest, at exercise, always	x	X	x	
Edema	Boolean	{TRUE, FALSE}	x	X	x	
Syncope	Boolean	{TRUE, FALSE}	x	X		
Nycturia	Boolean	{TRUE, FALSE}	x	X	x	
Physical activity	Character	none, sporadically, regular, frequently	x	X	x	
Overall wellbeing (rated by patient)	Character	very good, good, fair, poor, very poor	x	X	x	
NYHA	Integer	{1, 2, 3, 4}	x	X	x	
CCS class 4	Boolean	{TRUE, FALSE}	x	X	x	
Physical fitness (rated by patient)	very good, good, fair, poor, very poor		X	x	x	
Physiological and Laboratory Measurements	Physiological and Laboratory Measurements	Physiological and Laboratory Measurements	Physiological and Laboratory Measurements	Physiological and Laboratory Measurements	Physiological and Laboratory Measurements	pre/post
Heart Rate (pulse)	Integer	beats/min	x	X	x	
Arterial Blood pressure Systolic	Integer	[mmHg]	x	X	x	
Arterial Blood pressure RR Diastolic	Integer	[mmHg]	x	X	x	
Arterial Blood pressure RR Mean	Integer	[mmHg]	x	X	x	
Forced inspiratory Vital Capacity	Integer	[mL]		X		
Forced Expiratory 1 sec volume	Integer	[mL]		X		
Tiffeneau Index	Integer	[%]		X		
Sinus Rhythm	Character	{Sinus, Atrial Fibrillation, Paced}	x	X	x	
Conduction Branch Block	Character	{none, lbbb, rbbb}	x	X	x	
Conduction AV Block	Character	{none, AVBI, AVBIIa, AVBIIb, AVBIII}	x	X	x	
Heart Rate	Integer	[beats/minutes]	x	X	x	
QRS Time	Integer	[msec]	x	X	x	
QT Time	Integer	[msec]	x	X	x	



QTc Time	Integer	[msec]	x	X	x	
Lab Values			x			
Haemoglobin	integer		x	X	x	When? pre op/post op
Hematokrit	integer		x		x	
CK	integer		x		x	
CK-MB	integer		x		x	
NT-ProBNP	integer		x	X	x	
hsTroponin	integer		x		x	
hsCRP	integer		x		x	
TSH	integer		x		x	
Creatinine	integer		x	X	x	
AST	integer		x		x	
ALT	integer		x		x	
6-Minute-Walk distance	integer	meters	x	x*	x	
6-Minute-Walk SpO2	integer	%	x	x*	x	
6-Minute-Walk-Perceived Exertion (Borg scale)	integer	0 Nothing at all - 10 Maximal	x	x*	x	
Health watch data						
Average resting heart rate	integer	beats/minute	x	x	x	
Average normal activity heart rate	integer	beats/minute	x	x	x	
Difference btw. resting and activity heart rate	integer	beats/minute	x	x	x	
Average Sum of steps/day	integer	steps/day	x	x	x	
Average Sum of activity/day	integer	activity/day	x	x	x	
Activity/Heart rate index	integer		x	x	x	
Time after activity to reach normal heart rate	integer	minutes	x	x	x	
Average Duration of Sleep	integer	minutes	x	x	x	
Interruption of Sleep (where steps are visible)	integer	minutes	x	x	x	
Tachycardia (w/o incr. activity)	boolean	true/false	x	x	x	
Tachycardia induced during		Rest/Sleep, Exercise, both	x	x	x	
Average Length of Tachycardia	integer	minutes	x	x	x	
Bradycardia	boolean	true/false	x	x	x	
Bradycardia induced during		Rest/Sleep, Exercise, both	x	x	x	
Average Length of relevant Bradycardia < 50/min	integer	minutes	x	x	x	



Essential Imaging Parameters (CT>MRI>Echo)						pre/post
Imaging modality used for geometric information	String	CT, MRI, 3D echo	x	x	x	
LVEDV	Double	ml	x	X	x	
LVESV	Double	ml	x	X	x	
LVEF	Integer	%	x	X	x	automatic
Global Strain longitudinal	Integer	%	x	X	x	
Global Strain circumferential	Integer	%		?	x	
Global Radial strain	Integer	%		?	x	
Muscle mass	Integer	g		X	x	
LV-length	Integer	mm	x	x	x	
RVEDV	Double	ml	x	X	x	
RVESV	Double	ml	x	x	x	
RVEF	Integer	%		X	x	
Ascending Aorta Diameter_end-systolic	Integer	[mm]	x	X	x	
Ascending Aorta Diameter_end diastolic	Integer	[mm]	x	X	x	
Descending Aorta Diameter_end-systolic	Integer	[mm]	x	X	x	
Descending Aorta Diameter_end diastolic	Integer	[mm]	x	X	x	
Diameter Bulbus	Integer	[mm]	x	X	x	
Sinutubular junction diameter	Integer	[mm]	x	X	x	
Aortic valve annulus diameter	Integer	mm	x	X	x	
Aortic Valve Area	Double	[cm ²]	x	X	x	
Mitral Valve Effective Regurgitant Orifice Area	Integer	[mm ²]	x	X	x	
Mitral valve open area	Double	[cm ²]			x	
Mitral valve annulus circumference	Integer	[mm]			x	
Left Atrial Area	Double	[cm ²]	x	X	x	
Right Atrial Area	Double	[cm ²]	x	X	x	
Imaging modality used for flow volumes		CT, MRI, echo	Echo	MR/echo	MR/echo	
Aortic valve Regurgitation Fraction	Integer	%		x	x	includes perivalvular leakage
Effective Stroke Volume	Double	ml	x echo	x	x	
Cardiac output	Double	ml	x echo	x	x	
LV Contraction time	Integer	ms	x echo	x	x	
Mitral Valve Regurgitation Fraction	Integer	%	x echo	x	x	
Mitral Valve Regurgitation Volume	Double	[mL/beat]	x	X		



CT data						
Calcification of Aorta	Integer	{none, few, significant}	x	X	x	
Calcification of Valve	Integer	{none, few, significant}	x	X	x	
Echo data						
Aortic Valve dPmean	Double	[mmHg]	x	X	x	
Aortic Valve dPmax	Double	[mmHg]	x	X	x	
Aortic Valve Regurg.	Integer	{0,1,2,3,4}	x	X	x	
Mitral Valve Regurg.	Integer	{0,1,2,3,4}	x	X	x	
Mitral Valve Regurg. Pathology	Character	{degenerative, functional}	x	X	x	
Mitral Valve Morphology	Character	{normal, prolapse, flail leaflet, ruptured papillary muscle}	x	X	x	
Right Ventricular Systolic Pressure	Double	[mmHg]	x	X	x	
Doppler E-Wave	Double	[cm/sec]	x	X	x	
Doppler A-Wave	Double	[cm/sec]	x	X	x	
Tissue Doppler E-Wave	Double	[cm/sec]	x	X	x	
Tissue Doppler A-Wave	Double	[cm/sec]	x	X	x	
Tricuspid Valve Regurg.	Integer	{0,1,2,3,4}	x	X	x	
Operative Data	Operative Data	Operative Data	Operative Data	Operative Data	Operative Data	only intra-operatively
Surgery	Character	{SAVR, TAVR, MVRepair, MVReplace}	x	X	x	
Access	Character	{Sternotomy, Hemisternotomy, Right anterior Thoracotomy, transapical, transfemoral, transaortic, transsubclavian}	x	X	x	
CABG operation	Boolean	{TRUE, FALSE}	x	X	x	
Valve sparing surgery	Boolean	{TRUE, FALSE}	x	x	x	
Valve type if replacement	Character	mechanical, biological	x	X		



Replacement valve size, mm	Integer	[mm]	x	X	x	
Modell of aortic valve	Character	free text field	x	X	x	
Cardioplegia	Character	{Blood, Crystalloid}	x	X	x	
Crossclamp Time	Integer	[min]	x	X	x	
Cardio-Pulmonary Bypass Time	Integer	[min]	x	X	x	
Reperusions Time	Integer	[min]	x	X	x	
Clinical Outcome (at follow up)						only post-operatively
Procedural Success	Boolean	{TRUE, FALSE}	x	X	x	
Procedural Death	Boolean	{TRUE, FALSE}	x	X	x	
Cause of Failure	Character	free text field	x	X	x	
Intraoperative Bleeding complications	Boolean	{TRUE, FALSE}	x	X	x	
Tamponade after surgery	Boolean	{TRUE, FALSE}	x	X	x	
Postoperative pacemaker	Boolean	{TRUE, FALSE}	x	X	x	
TAVI Anulus Rupture	Boolean	{TRUE, FALSE}	x	X	x	
TAVI Coronary Occlusion	Boolean	{TRUE, FALSE}	x	X	x	
Death after surgery	Boolean	{TRUE, FALSE}	x	X	x	
Time until death	Integer	days	x	X	x	
Stroke w/i 30days after procedure	Boolean	{TRUE, FALSE}	x	X	x	
Stroke after 30days after procedure	Boolean	{TRUE, FALSE}	x	X	x	
Post-procedural bleeding	Boolean	{TRUE, FALSE}	x	X	x	
Revision surgery	Boolean	{TRUE, FALSE}	x	X	x	
Hospital re-admission	Boolean	{TRUE, FALSE}	x	X	x	
Heart failure	Boolean	{TRUE, FALSE}	x	X	x	
Prolonged ventilation	Boolean	{TRUE, FALSE}	x	X	x	
Prolonged delirium	Boolean	{TRUE, FALSE}	x	X	x	
Newly developed frailty	Boolean	{TRUE, FALSE}	x	X	x	
Neurologic impairment	Boolean	{TRUE, FALSE}	x	X	x	automatically
early mortality	Boolean	{TRUE, FALSE}	x	X	x	automatically
late mortality (>30days)	Boolean	{TRUE, FALSE}	x	X	x	Automatically
Quality of Life (WHOQOL-BREF)						Pre- and post-operatively
Item 1 to 30 (includes Summary scores of Domains)	WHOQOL-BREF_item..	integer	x	X	x	
Domain 1 (physical) score = Q3 + Q4 + Q10 + Q15 + Q16 + Q17 + Q18		integer	x	X	x	Automatically
Domain 2 (psychological) score = Q5 + Q6 + Q7 + Q11 + Q19 + Q25		integer	x	X	x	Automatically



Domain 3 (social) score = Q20 + Q21		integer	x	X	x	
Domain 4 (environmental) score = Q8 + Q9 + Q12 + Q13 + Q14 + Q22 + Q23 + Q24		integer	X	X	X	