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EU Project officer	Carmen LAPLAZA SANTOS (CNECT/H/01)		

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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.
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Contents

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)

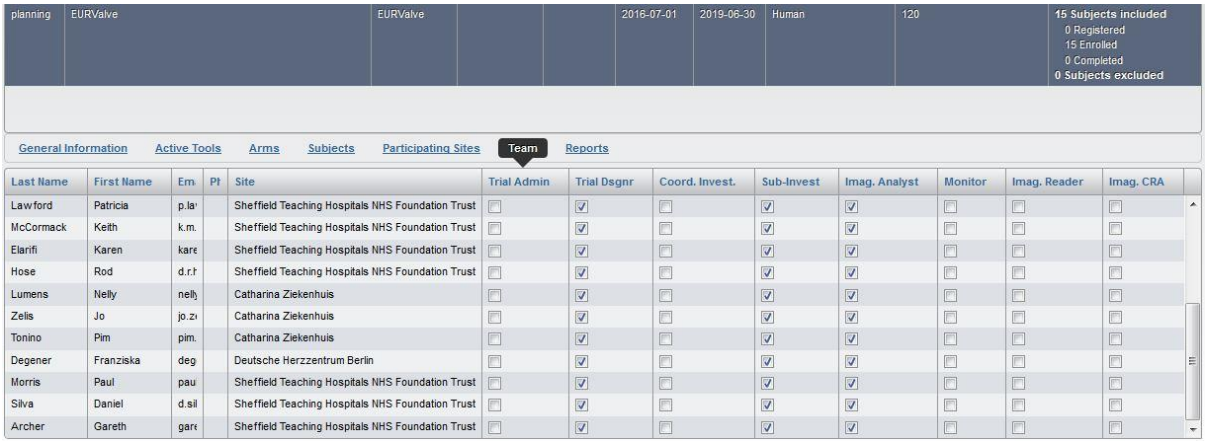

Fig 1 TrialConnect user accounts in EurValve

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)

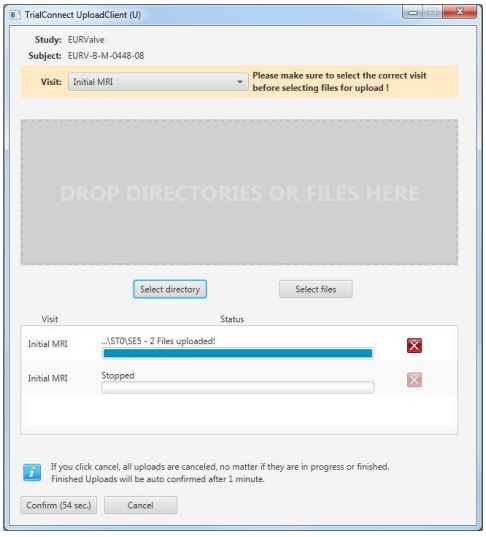

Fig 2 Upload and assignment of study visits

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).

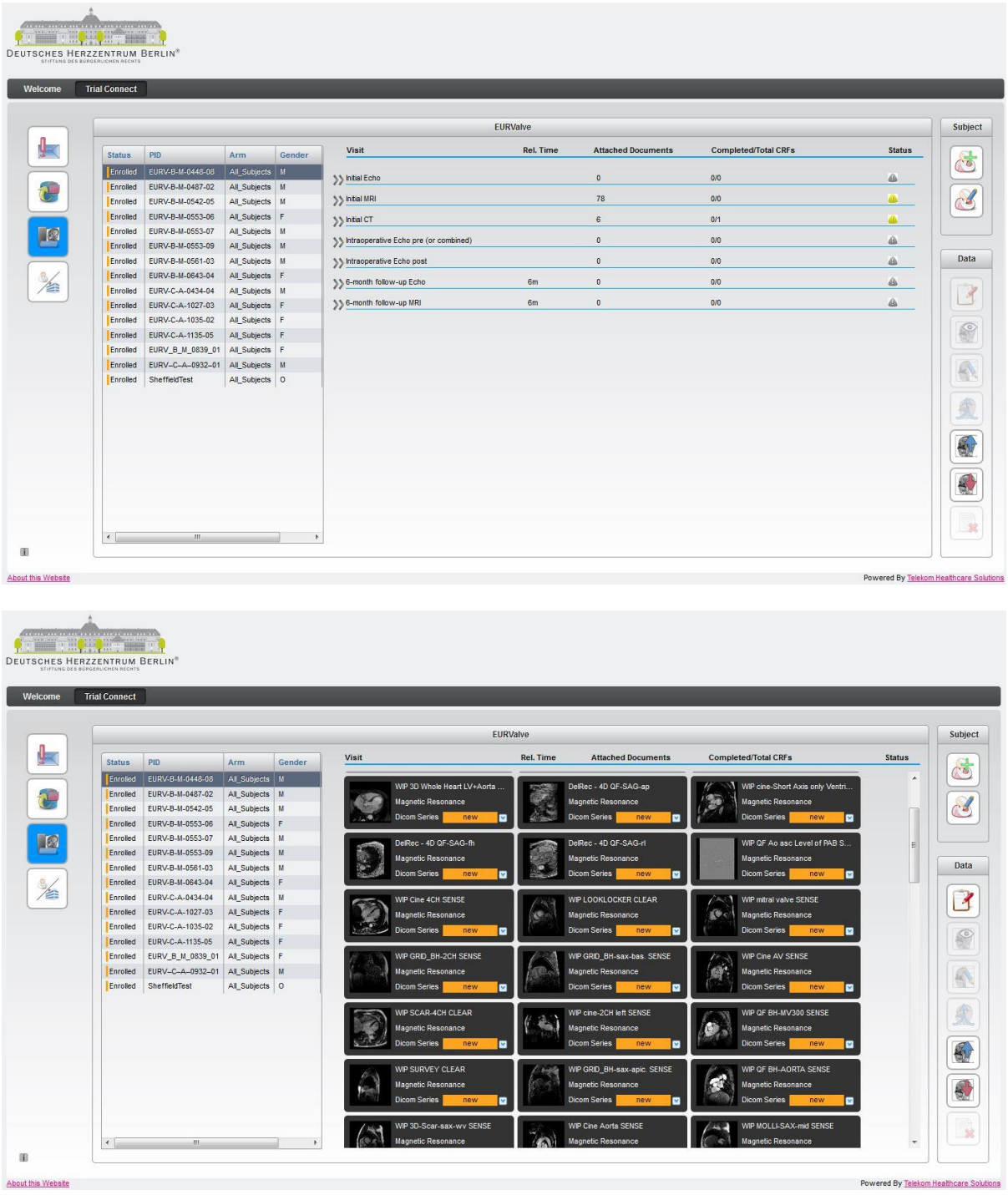

Fig 3 Uploaded cases of all three clinical sites

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.

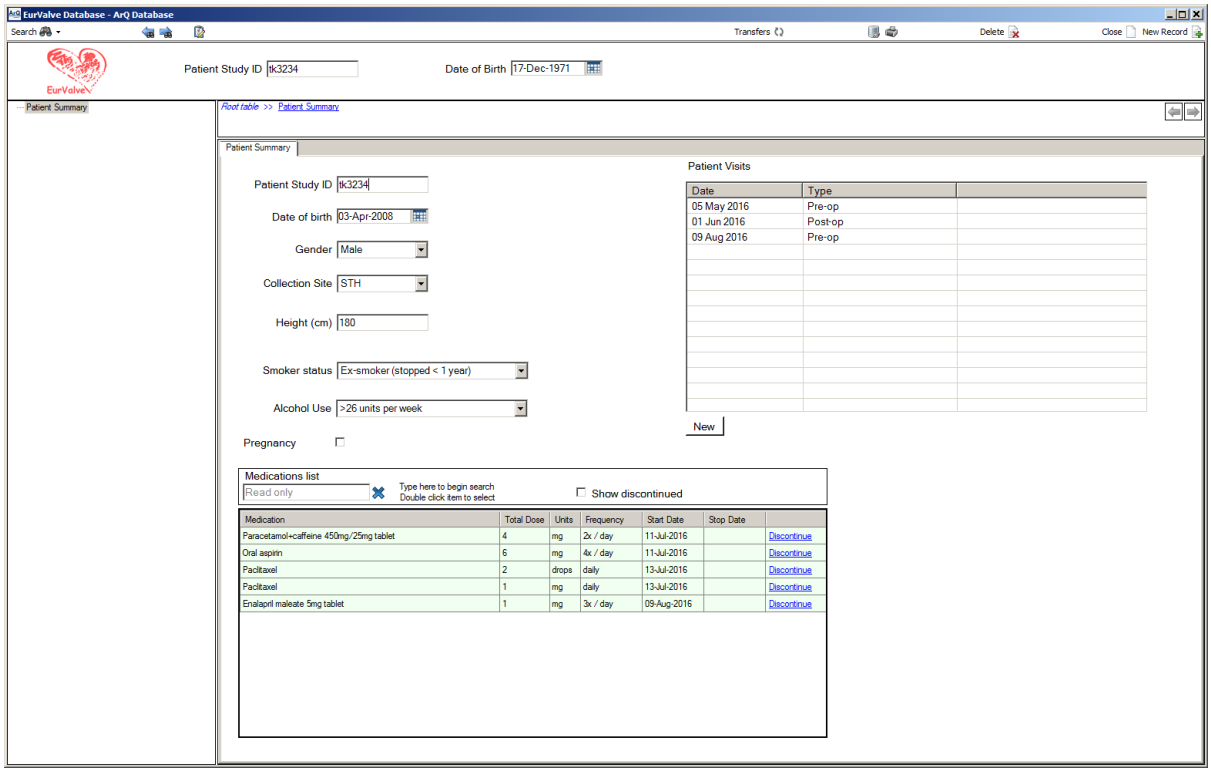

Figure 4 Initial patient summary page

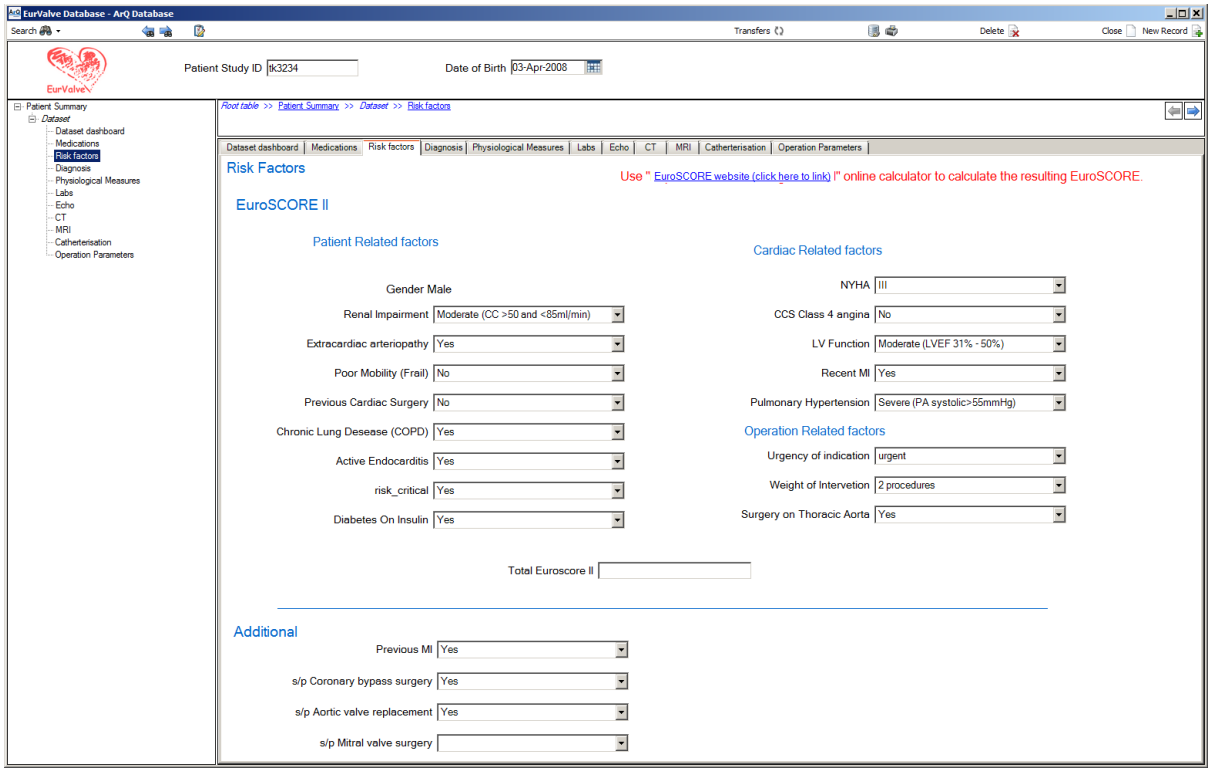

Figure 5 Risk factors collection tab with other data entry screen shown on the left.

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

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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 MitralValve 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 Lenght 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 Lenght 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-sysolic	Integer	[mm]	x	X	x	
Ascending Aorta Diameter_end diastolic	Integer	[mm]	x	X	x	
Descending Aorta Diameter_end-sysolic	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 anulus diameter	Integer	mm	x	X	x	
Aortic Valve Area	Double	[cm²]	x	X	x	
Mitral Valve Effective Regurgitant Orifice Area	Integer	[mm²]	x	X	x	
Mitral valve open area	Double	[cm²]			x	
Mitral valve annulus circumference	Integer	[mm]			x	
Left Atrial Area	Double	[cm²]	x	X	x	
Right Atrial Area	Double	[cm²]	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-operativly
Surgery	Character	{SAVR, TAVR,MVRepair, MVReplace}	x	X	x	
Access	Character	{Sternotomy, Hemisternotomy, Right anterior Thoracotomy, transapical, transfermoral, 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	
Reperfusions Time	Integer	[min]	x	X	x	
Clinical Outcome (at follow up)						only post-operativly
Procedural Sucess	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 after30days after procedure	Boolean	{TRUE, FALSE}	x	X	x	
Post-procedureal 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-operativly
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	