

OPINION-LEADER
EXPERTISE



> 400



LEGAL SPONSOR FRAMEWORK FOR
INVESTIGATOR INITIATED STUDIES



DEVICE AND PHARMA

STRONG
ACADEMIC NETWORK



ISO 14155

GCLP

ISO/ IEC 17025

2011 (GCP) & FDA 21CFR part 11

endorsed by WHO: 2009

for lab testing and quantification: 2008

LANDMARK TRIALS

TARGET AC (The Lancet 2018)	SURTAVI (NEJM 2017)	SYNTAX-II (Eur Heart J 2017)	APPOSITIONHV (Eurointervention 2016)
GLOBAL LEADERS (The Lancet 2018)	RESPOND (Eur Heart J 2017)	EXCEL (NEJM 2016)	TRYTON (ACC 2015)
TALENT (The Lancet 2019)	DESSOLVE III (The Lancet 2017)	ABSORB-II (The Lancet 2016)	ABSORB-STEM TROFHI (Eur Heart J 2015)
SYNTAX III Revolution (EUR HEART J 2018)	PIONEER (Eurointervention 2017)	BIO SOLVE-II (The Lancet 2016)	X-PLORER (Thromb Haemost 2015)

THERAPEUTIC EXPERTISE

DIABETES MELLITUS	HEART FAILURE
ATHEROSCLEROSIS	ELECTROPHYSIOLOGY
HYPERTENSION	RESTENOSIS
ACUTE CORONARY SYNDROME	REMOTE CARDIAC MONITORING
STRUCTURAL HEART	LIPID MODIFYING AGENTS
CORONARY ARTERY DISEASE	STABLE ANGINA PECTORIS

FULL-SERVICE CARDIOVASCULAR RESEARCH ORGANIZATION



CLINICAL EVENT
ADJUDICATION

(E)CRF
DEVELOPMENT

DATA
MANAGEMENT

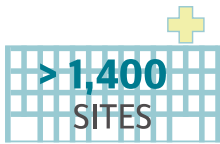
DATA SAFETY
MONITORING BOARD

PROTOCOL
DEVELOPMENT

SAFETY
REPORTING

STATISTICAL
SERVICES

EXPERIENCE IN SITE MONITORING & SITE MANAGEMENT



INDEPENDENT IN-HOUSE CORE LABORATORY SUPERVISED BY CARDIOLOGISTS

ECHOCARDIOGRAPHY

CPA, 2D & 3D, TDI, TEE, TTE, AORTIC, MITRAL, PULMONARY, TRICUSPID, EJECTION FRACTION, LONGITUDINAL STRAIN (GLS)

ELECTROCARDIOGRAPHY

12-LEAD ECG, HOLTER, ECG EVENT MONITORING, IMPLANTABLE LOOP RECORDER

ANGIOGRAPHY

QCA, 3D QCA, BIFURCATION QCA, QVA, SYNTAX SCORE, VIRTUAL FLOW, LV ANALYSIS, TIMI FRAME COUNT, QUANTITATIVE REGURGITATION ANALYSIS

MAGNETIC RESONANCE IMAGING

LEFT VENTRICULAR FUNCTION, RIGHT VENTRICULAR FUNCTION, VIABILITY ANALYSIS, DELAYED ENHANCEMENT

COMPUTED TOMOGRAPHY

PLAQUE CHARACTERIZATION, CT SYNTAX SCORE, VALVE ANALYSIS, CALCIUM QUANTIFICATION, PROCEDURE PLANNING

INTRAVASCULAR IMAGING

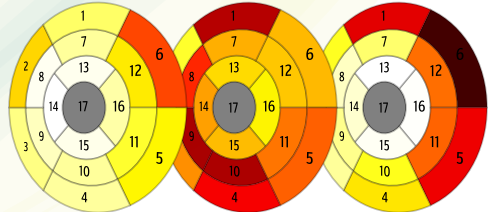
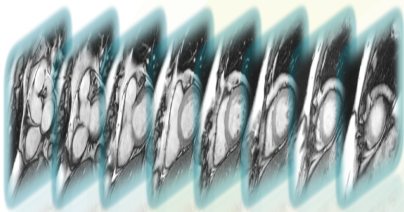
IVUS GRAY SCALE, OPTICAL COHERENCE TOMOGRAPHY, LIGHT PROPERTY ANALYSIS, NEAR-INFRARED SPECTROSCOPY (TVC), VIRTUAL HISTOLOGY



Visit our website:

CARDIAC MRI CORE LAB

Cardiac Magnetic Resonance Imaging (CMRI) is a highly accurate and versatile non-invasive imaging technique. Cardialysis utilizes powerful analysis software for quantification of many parameters and CMRI techniques. CMRI is considered the gold standard for assessment of cardiac volumes, function and tissue characterization (e.g. infarct) making it a key diagnostic tool.



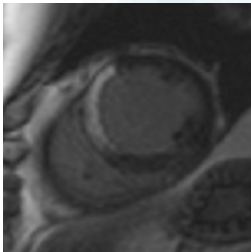
Wall thickening

Wall thickness

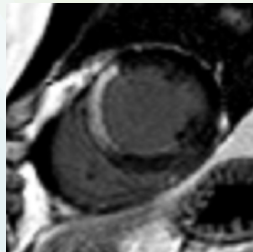
Wall motion

Core Lab Capabilities

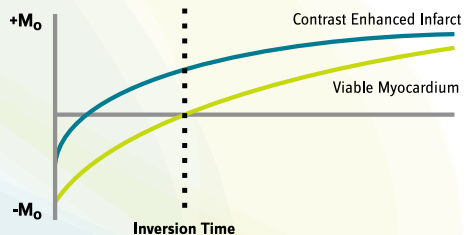
- ✓ **Functional Analysis**
 - Left Ventricle and Right Ventricle
 - End Diastolic and End Systolic Volumes
 - Ejection Fraction
 - Myocardial Mass
 - Wall Motion, Wall Thickness and Wall Thickening
- ✓ **Viability**
 - Infarct Volume and Transmurality
 - Salvageable Area Index
 - Edema
- ✓ **First-Pass Perfusion**
 - Time-Intensity Curve Parameters
 - Myocardial Perfusion Reserve Index (MPRI)
- ✓ **Tissue Mapping**
 - T1, T2, T2* Relaxation Values
 - Parametric Color Maps



MAG



PSIR





QUALITY AND EXPERTISE

Offering a platform for the design and conduct of clinical trials, Cardialysis Core Lab is the perfect partner. Leading experts in the field of cardiovascular imaging supervise Cardialysis' Core Lab activities. CMRI measurements are performed by experienced Core Lab analysts and a second read performed by the Core Lab supervisor.



► Therapeutic Areas

- ✓ Myocardial Ischemia
- ✓ Viability
- ✓ Cardiomyopathies
- ✓ Myocarditis
- ✓ Iron Overload
- ✓ Vascular Diseases
- ✓ Congenital Heart Disease

► Guaranteed Quality

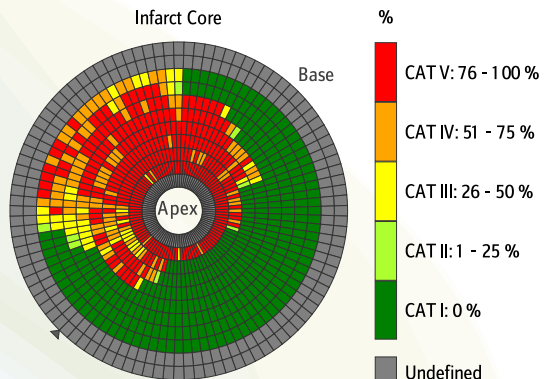
Cardialysis provides site training and certification, including Acquisition Guidelines, WebEx training, and quality monitoring feedback to the investigational sites.

Quality control is supported by :

- ✓ Inter- and intra-observer variability testing
- ✓ Periodic phantom testing
- ✓ Regular review of the validation of the techniques
- ✓ Regular training of Core Lab staff

Our Core Lab processes are validated to meet compliance with international regulatory and industry standards:

- ✓ ISO 14155: 2011 (GCP)
- ✓ ISO 27001 (information protection)
- ✓ GCLP endorsed by WHO: 2009
- ✓ FDA 21 CFR part 11





Visit our website:

ELECTROCARDIOGRAPHY

► ECG Analysis, Advice and Logistics

Cardialysis provides independent ECG data analysis and interpretation for cardiac arrhythmias, conduction abnormalities, cardiac ischemia and infarction. A semi-automated method is used for ECG measurements, which provides greater consistency and reproducibility.

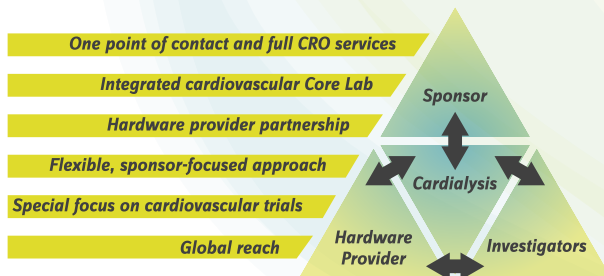
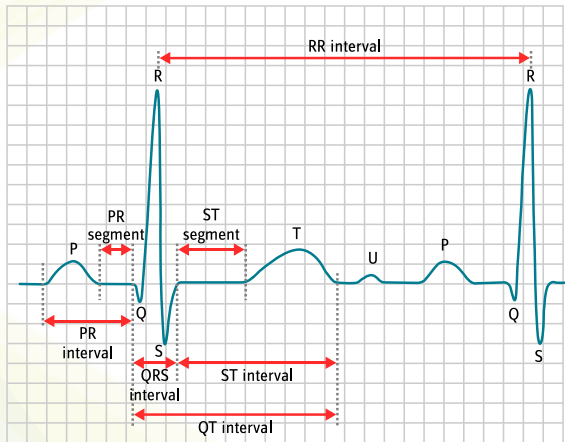
Based on our years of experience in electrocardiography, we can provide you with tailor-made advice for consistent, efficient, and comprehensive ECG data collection and analysis.

► Capabilities

- ✓ 12-lead ECG, including QTc
- ✓ Holter Studies
- ✓ Implantable Loop Recorder electrograms
- ✓ ICD-Analysis
- ✓ Exercise Tolerance Test
- ✓ ECG Analysis, Advice and Logistics

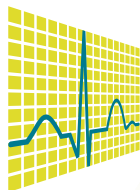
► Expertise

- ✓ Acute and chronic ischemia
- ✓ Over 60 trials conducted
- ✓ Over 250,000 ECGs analyzed



► One stop shop

Cardialysis partners with experienced hardware providers to provide a one-stop-shop for clinical trials utilizing ECG- and Holter Analysis.



▶ ECG

For safety analysis in cardiac and non-cardiac trials.

- ✓ Measurement of PR, QRS and QT/QTc intervals
- ✓ 12-lead ECG
- ✓ Arrhythmia diagnosis
- ✓ Diagnosis of infarction and ischemia
- ✓ ECG analysis is performed semi-automatically

▶ Holter Electrocardiography

Monitoring cardiac arrhythmias over time. Particularly useful for new investigational drugs or devices.

- ✓ 3 to 12 lead systems
- ✓ Cardiac rhythm
- ✓ ST segment analysis
- ✓ QT segment interval
- ✓ Heart rate variability
- ✓ Full-service, including Holter recorders

▶ Implantable Loop Recorder

Continuous ECG monitoring for arrhythmia monitoring can also be facilitated by the use of implantable devices.

- ✓ Analysis of detected arrhythmias
- ✓ Confirmation of AF episodes
- ✓ Determining AF burden
- ✓ Validation of new detection algorithms

▶ ICD

ICD read-outs analysis for all ICD device manufacturers.

- ✓ Classification of arrhythmia events stored in ICD
- ✓ Cardiologist supervision





Visit our website:

ELECTROCARDIOGRAPHY

► ECG Analysis, Advice and Logistics

Cardialysis provides independent ECG data analysis and interpretation for cardiac arrhythmias, conduction abnormalities, cardiac ischemia and infarction. A semi-automated method is used for ECG measurements, which provides greater consistency and reproducibility.

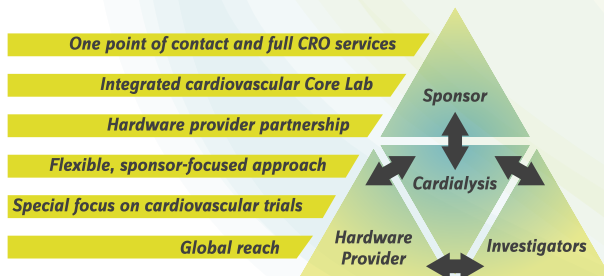
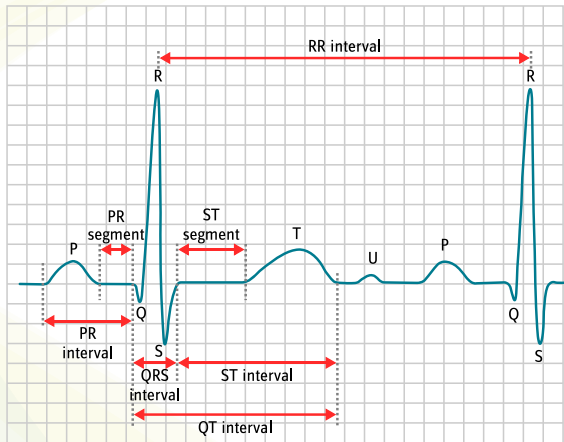
Based on our years of experience in electrocardiography, we can provide you with tailor-made advice for consistent, efficient, and comprehensive ECG data collection and analysis.

► Capabilities

- ✓ 12-lead ECG, including QTc
- ✓ Holter Studies
- ✓ Implantable Loop Recorder electrograms
- ✓ ICD-Analysis
- ✓ Exercise Tolerance Test
- ✓ ECG Analysis, Advice and Logistics

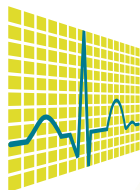
► Expertise

- ✓ Acute and chronic ischemia
- ✓ Over 60 trials conducted
- ✓ Over 250,000 ECGs analyzed



► One stop shop

Cardialysis partners with experienced hardware providers to provide a one-stop-shop for clinical trials utilizing ECG- and Holter Analysis.



▶ **ECG**

For safety analysis in cardiac and non-cardiac trials.

- ✓ Measurement of PR, QRS and QT/QTc intervals
- ✓ 12-lead ECG
- ✓ Arrhythmia diagnosis
- ✓ Diagnosis of infarction and ischemia
- ✓ ECG analysis is performed semi-automatically

▶ **Holter Electrocardiography**

Monitoring cardiac arrhythmias over time. Particularly useful for new investigational drugs or devices.

- ✓ 3 to 12 lead systems
- ✓ Cardiac rhythm
- ✓ ST segment analysis
- ✓ QT segment interval
- ✓ Heart rate variability
- ✓ Full-service, including Holter recorders

▶ **Implantable Loop Recorder**

Continuous ECG monitoring for arrhythmia monitoring can also be facilitated by the use of implantable devices.

- ✓ Analysis of detected arrhythmias
- ✓ Confirmation of AF episodes
- ✓ Determining AF burden
- ✓ Validation of new detection algorithms

▶ **ICD**

ICD read-outs analysis for all ICD device manufacturers.

- ✓ Classification of arrhythmia events stored in ICD
- ✓ Cardiologist supervision





Visit our website:

ECHOCARDIOGRAPHY

Echocardiography is the first-line cardiac imaging modality to assess morphology and function. Characteristically, it is safe, portable and offers high temporal and spatial resolution. Echo has an essential role in the diagnosis and follow-up of cardiac conditions. It enables guidance and monitoring of transcatheter procedures in structural heart diseases.

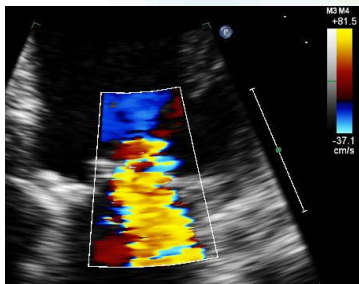
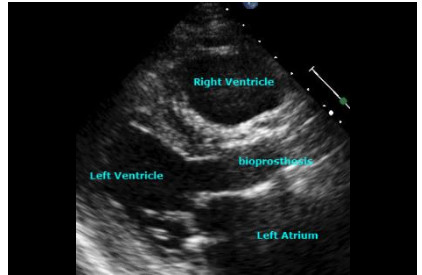
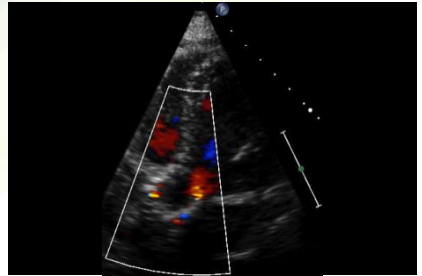
CORE LAB

► Capabilities

- ✓ TTE
- ✓ TEE
- ✓ 2D
- ✓ 3D
- ✓ Doppler & TDI
- ✓ LV & RV Functions
- ✓ Strain
- ✓ Hemodynamics
- ✓ Structural & Congenital Heart Diseases
- ✓ Heart Failure

► Expertise

- ✓ Over 31,000 exams analyzed
- ✓ Over 25 Echo Trials Executed
- ✓ Extensive Transcatheter Therapy Experience



ECHO TEAM

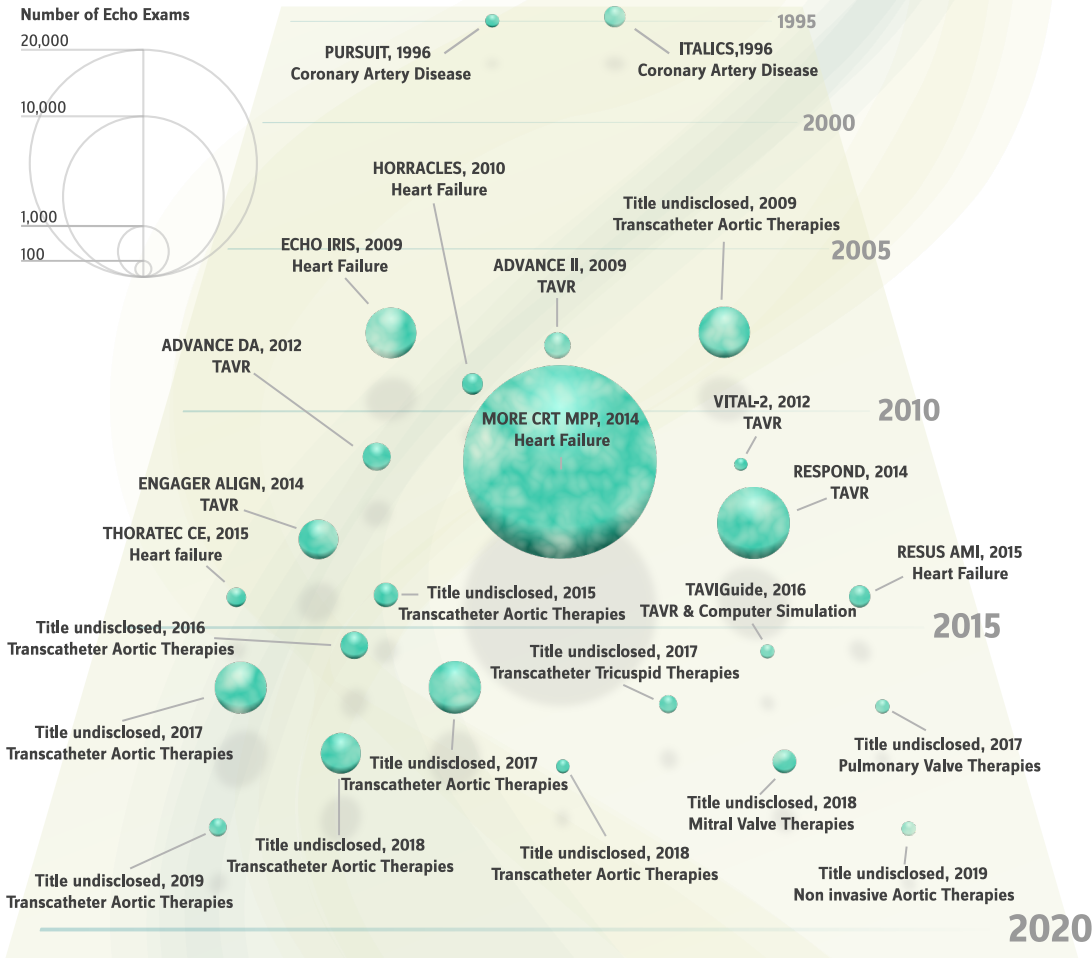
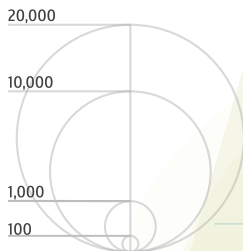
A team of senior analysts and supervisors at Cardialysis provide independent central expert echocardiographic analyses and adjudications. Our Core Lab methodologies are based on state-of-the-art recommendations and guidelines from the American Society of Echocardiography, European Association of Cardiovascular Imaging and Academic Research Consortium.



Follow us on
LinkedIn

ECHO TRACK RECORD

Number of Echo Exams



Device, Postmarketing 11 Studies | Device, Feasibility 5 Studies | Device, IDE 3 Studies | Drug, Phase II 2 Studies | Drug, Phase III 2 Studies | Device, Pivotal 1 Studies | Pre-Clinical 1 Studies



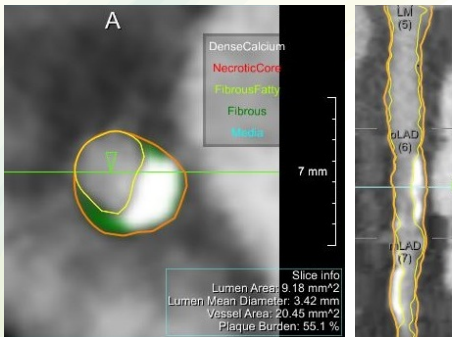
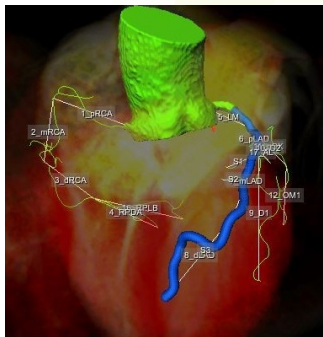
Visit our website:

CARDIAC CT CORE LAB

Cardiac CT (Computed Tomography) is routinely performed to visualize cardiac and coronary anatomy in 3D. The detection and quantification of coronary artery disease is commonly referred to as Coronary Computed Tomography Angiography (CCTA), which is also used to assess atherosclerotic plaque progression or regression. In addition, cardiac CT is used to diagnose structural heart diseases and plan interventions.

CCTA

- ✓ Plaque Quantification
- ✓ Plaque Characterization
- ✓ Progression/Regression
- ✓ Bioresorbable Scaffold Assessment
- ✓ Stenosis Analysis
- ✓ CT Syntax Score

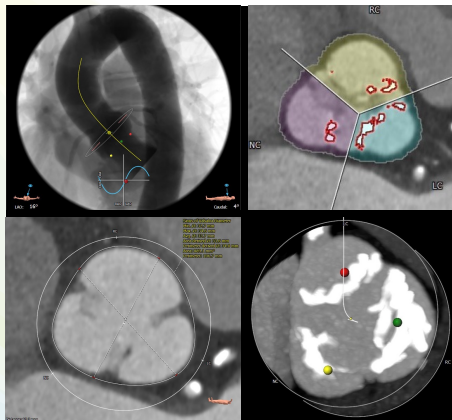


Try out the free SYNTAX Score I and II calculators at: www.syntaxscore.com



Structural Heart

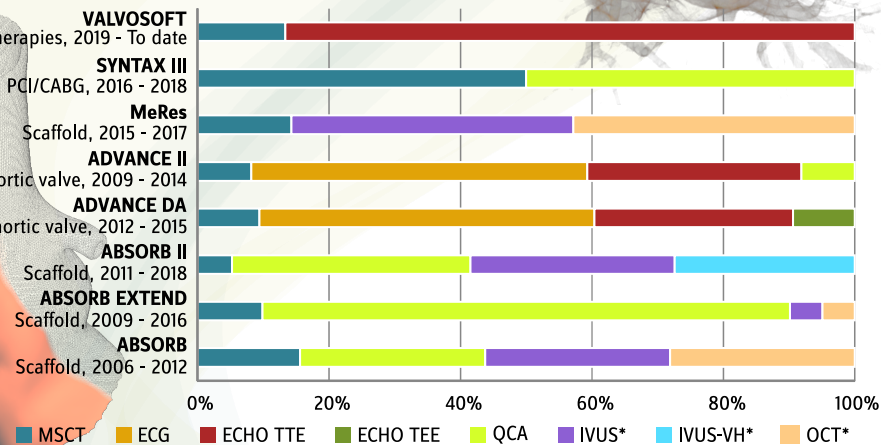
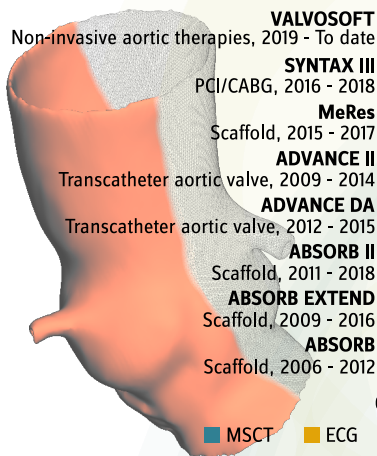
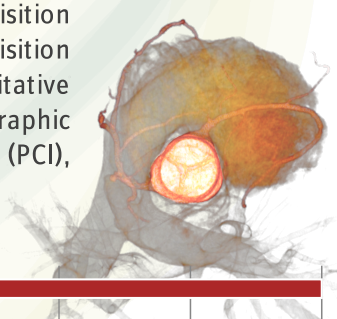
- ✓ TAVR planning
- ✓ Valve Calcium Quantification
- ✓ Left Atrial Appendage
- ✓ Pulmonary & Tricuspid
- ✓ 3D Modelling
- ✓ Leaflet Mobility
- ✓ Mitral Assessment
- ✓ Patient Selection





► Multi-Modality Approach

Our services include study design and CT endpoints, acquisition guidelines, web-based training and certification of CT acquisition sites, CT data handling, independent qualitative and quantitative CT readings. Our track record includes quantitative CT angiographic follow-up after percutaneous coronary interventions (PCI), monitoring of bypass graft patency and pre-TAVI evaluations.



* counted as vessels

► Guaranteed quality

Cardialysis provides site training and certification, including acquisition guidelines, WebEx training, and quality monitoring/ feedback to the investigational sites.

Quality control is supported by:

- ✓ Inter- and intra-observer variability testing
- ✓ Periodic phantom testing
- ✓ Regular review of the validation of the techniques
- ✓ Regular training of core lab staff



Our core lab processes are validated to meet compliance with international regulatory and industry standards:

- ✓ ISO 14155: 2011 (GCP)
- ✓ ISO 27001 (information protection)
- ✓ GCLP endorsed by WHO: 2009
- ✓ FDA 21 CFR part 11