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.

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
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

+31 10 2062828 - info@cardialysis.nl - Westblaak 98, 3012 KM, Rotterdam, The Netherlands - PO Box 2125
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
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
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.
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.

<table>
<thead>
<tr>
<th>Study</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>VALVOSOFT</td>
<td>2019 - To date</td>
</tr>
<tr>
<td>SYNTAX III PCB/CABG</td>
<td>2016 - 2018</td>
</tr>
<tr>
<td>MeRes scaffold</td>
<td>2015 - 2017</td>
</tr>
<tr>
<td>ADVANCE II</td>
<td>Transcatheter aortic valve, 2009 - 2014</td>
</tr>
<tr>
<td>ADVANCE DA</td>
<td>Transcatheter aortic valve, 2012 - 2015</td>
</tr>
<tr>
<td>ABSORB II</td>
<td>Scaffold, 2011 - 2018</td>
</tr>
<tr>
<td>ABSORB EXTEND</td>
<td>Scaffold, 2009 - 2016</td>
</tr>
<tr>
<td>ABSORB</td>
<td>Scaffold, 2006 - 2012</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Modalities</th>
<th>MSCT</th>
<th>ECG</th>
<th>ECHO TTE</th>
<th>ECHO TEE</th>
<th>QCA</th>
<th>IVUS*</th>
<th>IVUS-VH*</th>
<th>OCT*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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