



NUI Galway  
OÉ Gaillimh



# CORRIB CORE LAB

RESEARCH CENTRE  
FOR ADVANCED IMAGING  
AND CORE LABORATORY

# CORRIB Research Centre for Advanced Imaging and Core Laboratory

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Current and daily practice of medicine is more and more dictated and regulated by guidelines based on evidence medicine stemming from large randomized trials and registries. The CORRIB Core Lab is playing a key role in assessing the imaging component of these trials and registries.

Imaging provides mechanistic interpretation and maybe a surrogate primary endpoint in the early phase of development of a novel therapeutic principle. To assure the objectivity of the analysis of these trials, the Imaging Core Lab has been developed over the last decades and has become the cornerstone of our objective assessment of trials results in order to guarantee the accuracy, precision, objectivity and reproducibility of these trials.

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The CORRIB Research Centre for Advanced Imaging and Core Laboratory provides unique cutting-edge imaging methods along with decades of expertise in Cardiovascular Imaging.

The CORRIB Core Lab is

- High quality, validated techniques (ISO 14155, GCP,...FDA 21 Part 11)
- Audit ready (USFDA and other regulatory authorities)
- Fast turnaround time (TAT)
- Large Capacity





## Professor Patrick Serruys

Professor Patrick Serruys is a world-renowned expert in interventional cardiology and imaging with more than four decades of experience in clinical trials and innovation in medicine. He has pioneered several interventional procedures and devices such as BMS, DES, BRS and TAVI as well as imaging techniques including quantitative coronary angiography, quantitative IVUS, OCT, near spectroscopy combined with IVUS.

These techniques have been used to assess many pharmacological trials aiming at resolving the issue of restenosis. Professor Serruys has conducted over 90 trials including over 191,000 patients including many interventional trials to assess the clinical benefit of coronary procedures such as POBA, atherectomy, laser ablation, BMS, DES, drug coated balloons.

In parallel he has developed interest for non-invasive imaging of coronary artery disease combining anatomy and functional assessments of CTA. For twenty years he was the chief of department of interventional cardiology at the Thoraxcenter Rotterdam. He has been awarded several gold medals including the ESC and ACC career achievements awards.

He is the author and co-author of more than 4000 peer-reviewed publications and is the author, co-author and editor of more than 42 books including the textbook of the European Society of Cardiology.





## Professor Yoshi Onuma

Dr. Yohinobu Onuma, MD, PhD is a leading expert in the field of noninvasive and invasive coronary imaging and novel coronary devices such as bioresorbable scaffolds. His expertise includes quantitative coronary angiography (2-dimensional, 3-dimensional and bifurcation-dedicated), Syntax Score and multi-slice computed tomography. He holds the position of professor of interventional cardiology at the National university of Ireland Galway. Dr Onuma is also the Medical Director of CORRIB Corelab of Coronary Imaging and Atherosclerosis Research.

Dr. Onuma received his medical degree from Tohoku University School of Medicine in Sendai, Japan. After he fulfilled his cardiology and interventional cardiology fellowship, he joined Erasmus University of Rotterdam and was granted his doctorate in interventional cardiology. Dr. Onuma has published more than 500 manuscripts in peer-reviewed journals and also the author and editor of several books including the textbook of bioresorbable scaffold.







## Professor Osama Soliman

Professor Soliman a cardiologist with more than 2 decades of experience in cardiovascular imaging, clinical trials and innovation in medicine has pioneered several non-invasive imaging techniques and methods. He holds the position of professor of cardiovascular research at the National university of Ireland Galway. Dr Soliman is the Medical Director of CORRIB Corelab for Structural Heart Imaging, Heart Failure and Cardio-oncology.

His corelab methodology and techniques have been used to assess pharmacological and device trials aiming at resolving the issue of non-response to CRT, optimization of device therapy and to provide mechanistic assessments of many first-in-man device trials as well as early phase pharma trials. He is the PI of an ongoing trial aiming at personalised medicine in heart failure.

For the last decade, he has been the chairman of non-invasive imaging core laboratory in Rotterdam 2011-2019.

He is the author and co-author of more than 250 peer-reviewed publications. He is editor /co-editor of several books including the interventional manual of tricuspid valve disease and non-compaction cardiomyopathy.



# CORRIB CORE LABS AND ADVANCED IMAGING SCHOLARSHIP

The Core Lab team is a combination of imaging analysts and senior interventional cardiologists originating from three continents Asia, Europe and the North and South Americas with understanding of the specific and local needs in these three continents.

Over the last number of years the team have developed electronic medium to satisfy the telemedicine needs and guidance request by physicians performing complex procedures.

Thanks to the highly educated team, some of the core lab activities unaffordable in a strictly commercial context, can be performed in an academic research basis.

The core lab is not only analysing the procedures of the practitioners, but also guiding the decision-making and finally helping them in editing and reporting their results.







A man with curly hair and glasses is shown in profile, looking towards the right. He is wearing a light blue button-down shirt and is seated at a desk, typing on a laptop. The background is a bright, modern office with large windows and other people working in the distance. The overall atmosphere is professional and focused.

# YOUR VISION



# BNR

By joining NUI Galway, Professor Soliman, Onuma, and Serruys intend to develop a world class centre for innovation, research, collaboration and education.

## Innovation

- In close collaboration with various institutes at NUI Galway, the Cardiovascular team is working to create novel ideas, solutions in diagnostic and therapeutic arenas to improve patients' care.

## Research

- Centre for advanced imaging and core laboratory to support MedTech industry and pharma trials.
- Conduct clinical trials at the front line of innovation
- Foster the relationship with industry and EU regulatory body

## Education

- Attract young physicians who want to be trained in novel imaging techniques, design and conduction of clinical trials,
- Provide young generation of physicians with the know how in assessing the results of trials, think-tank unmet needs in medicine and how to resolve them by innovative concepts and approach

## Collaboration

- Create a multidisciplinary approach, atmosphere uniting experts in different disciplines in the cardiovascular space

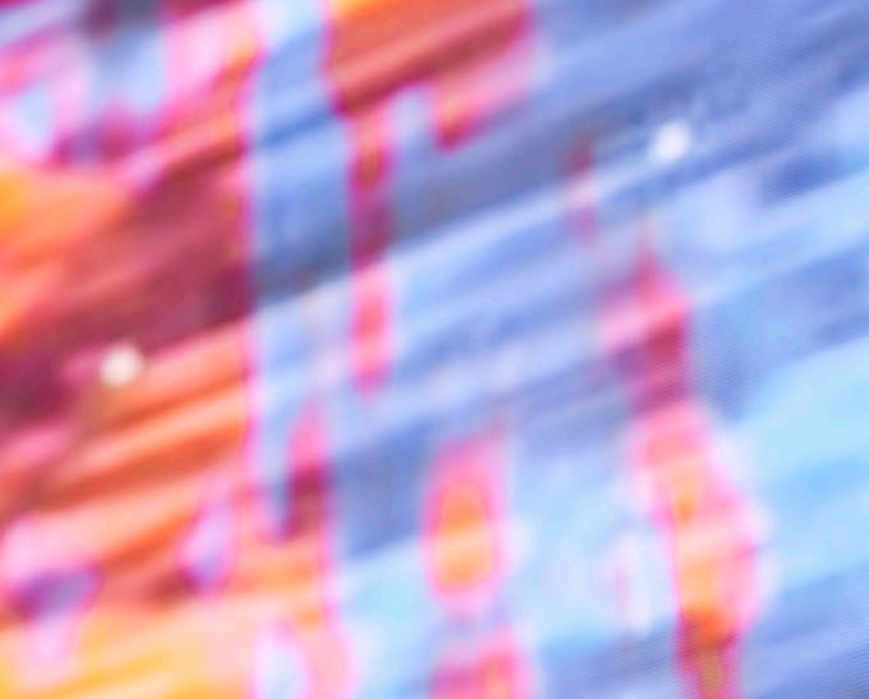
The ultimate goal of this team is to improve the patient care in the context of a cost-effective approach to health care.





CORE  
LAB  
EXPERTISE





Over more than 4 decades,  
our experts have developed  
and perfected over  
60 activities, techniques  
and methods of image  
analysis in the  
cardiovascular arena.

- Non-invasive imaging core lab provides 30 Core Lab validated, vendor neutral imaging techniques and analysis methods from 5 imaging modalities (Echo, MSCT, MRI, ECG and Aortography)
- Coronary imaging Core lab provides 30 Core Lab validated, vendor neutral imaging techniques and analysis methods from 5 imaging modalities (QCA, Angiography, IVUS, OCT, MSCT)





# WHY PARTNER WITH US





The three new professors at NUI Galway have been collaborating for more than a decade and have developed a comprehensive and innovative diagnostic and therapeutic approach of coronary and structural heart diseases that contributed to improved patients care.

This iconic backlight screenshot reflects their scientific complicity developed over more than a decade that have resulted in many scientific and innovative medical advances integrating the lessons learned from a holistic approach of the cardiovascular field.

Being in Galway, we are in the very heart of the so called "European Silicon Valley" that concentrated all the innovative concepts generated by our industry partners in collaboration with the numerous academic institutions of the NUI Galway such as CURAM, REMIDI, Bioinnovate., Lambe's institute.

This team provides more than four decades of expertise in clinical trials, education and innovation to industry and academic partners.

Connected with strong regulatory background of experts in device, diagnostic and therapeutic device.





A photograph of a modern, multi-story building with a large glass facade. The building is set in a courtyard with several trees and a field of tall, dry reeds in the foreground. The sky is a clear, pale blue. A large, white, stylized word 'EXCELLENCE' is overlaid on the right side of the image, with a teal diagonal line cutting through it from the bottom right towards the top right.

# EXCELLENCE





SCIENCE

From conventional imaging, computer simulation and machine learning, our imaging Centre and Core Lab provides cutting-edge techniques to shed light into mechanistic performance of novel device or drug or diagnostic strategy.

The most accurate, reproducible and cost-effective image analysis and image approach. Highly trained staff, strict regulatory measures to ensure the highest image performance standards in clinical trials.



# TRIAL SERVICES







CORRIB Core Lab technical services are championed by leading cardiovascular imaging experts who excel in providing independent, accurate, high-quality image analysis to a range of clients. High-quality, compliant image analysis plays a critical role in enabling Industry to achieve stringent regulatory and clinical strategy objectives in the development of diagnostic and therapeutic solutions for a range of Structural Heart and Coronary Cardiovascular conditions.

**CORRIB Core Lab provides both non-invasive and coronary imaging techniques and analysis methods using 9 principal imaging modalities:**

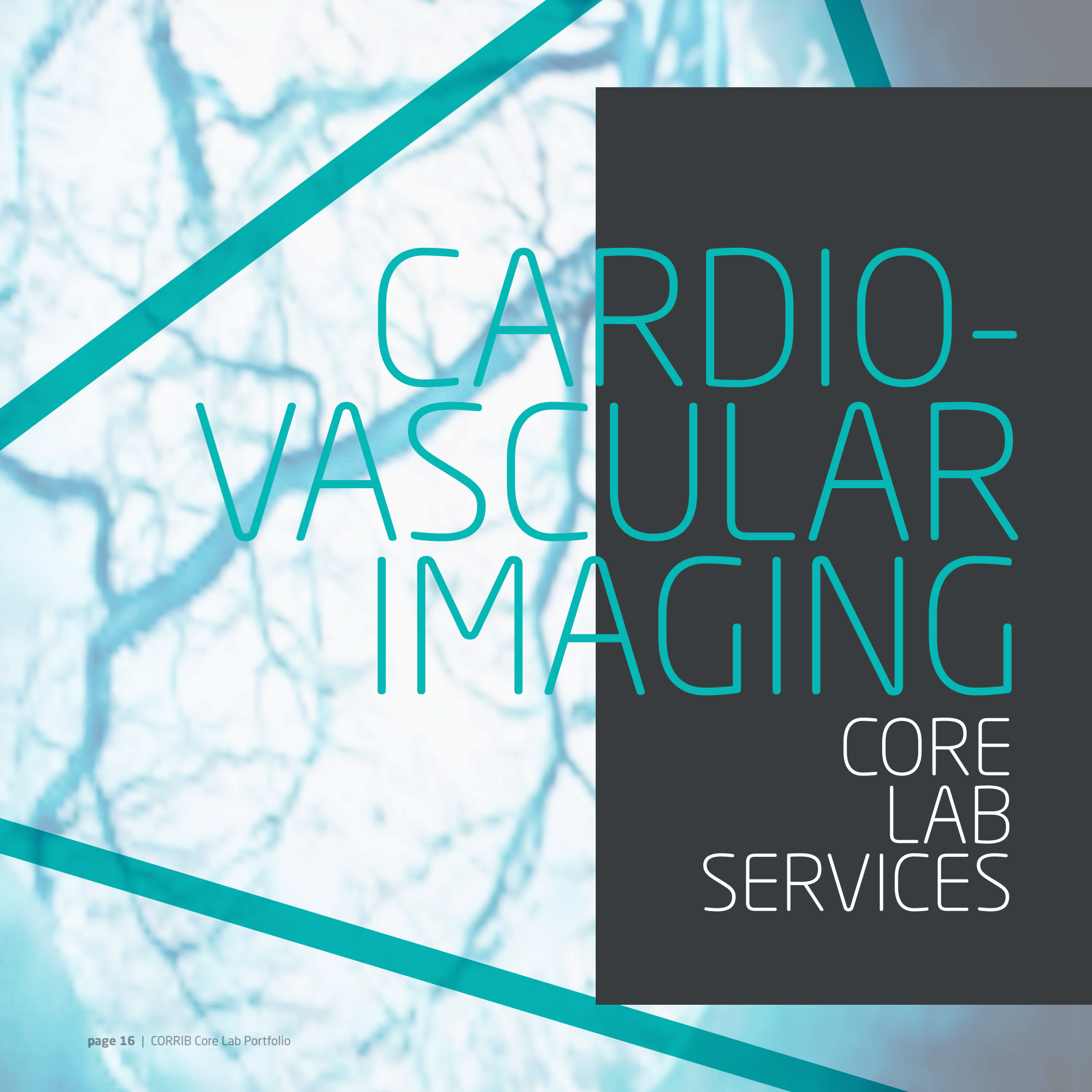
- Angiography
- Aortography
- Echocardiography
- Electrocardiography
- Intravascular Ultrasound
- Multi-Slice Computed Tomography
- Magnetic Resonance Imaging
- Optical Coherence Tomography
- Quantitative Coronary Angiography

CORRIB Core Lab utilises in-house state-of-the-art data processing system that accepts both electronically or physically shipped Core Lab material in standard DICOM format or specific formats. The CORRIB Core Lab also uses validated and vendor-independent software packages that are compatible with virtually all commercially available imaging vendors.

All operational CORRIB Core Lab techniques are validated to meet compliance with the latest international regulatory and industry standards:

ISO 14155: 2011 (GCP)  
GCLP endorsed by WHO: 2009  
FDA 21 CFR part 11.





# CARDIO- VASCULAR IMAGING

CORE  
LAB  
SERVICES



## ANGIOGRAPHY CORE LAB

### A. Angiography core lab (Coronary and Peripheral)

- 2D and 3D QCA measurements
- Bifurcation dedicated QCA
- Curvature and compliance analysis
- Video-densitometry – aortic and mitral regurgitation measurements
- Quantitative Flow Ratio
- Pre-adjudication angiographic analysis of Event Cases (Based on QFR according to ARC-2 definition)
- Assessment of Device Success
- Anatomic Syntax Score, Logistic Syntax Score, Syntax Score II and Syntax Score III
  - MI Syntax Score
  - CABG Syntax Score
  - Residual Syntax Score
  - Functional Syntax Score

### B. Angiography (post structural interventions)

- Quantitative Angiography of PVL (Videodensitometric) analysis of AR (TAVI)
- Depth of Implantation (TAVI)
- Quantitative Aortography mitral (TMVR)

## INTRAVASCULAR IMAGING CORE LAB

### A. Grayscale Intravascular Ultrasound (IVUS)

- Echogenicity analysis

### B. Virtual Histology IVUS (VH-IVUS)

### C. 2D and 3D Optical Coherence Tomography (OCT)

- Light intensity analysis
- Light attenuation analysis
- Light backscattering analysis
- Tissue characterization
- Ultrafast OCT

### D. Photo-acoustic imaging

### E. Near-Infrared Spectroscopy (NIRS)



## CORONARY PHYSIOLOGY CORE LAB

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- Fractional Flow Reserve (FFR) measurements
- Coronary Flow Reserve (CFR) measurements
- Instantaneous Wave Free Ratio (IFR)
- Pressure Velocity Analysis
  - Epicardial conductance
  - Microcirculatory conductance
  - Zero flow pressure
  - Forward wave distal to PCI site
  - Backward Expansion Wave
  - Index of Myocardial Resistance (IMR)

## COMPREHENSIVE COMBINED MULTI-MODALITY IMAGING AND SIMULATION

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- Shear stress analysis
- 4D Wall Stress analysis
- Von Mises stress analysis
- Fusion Imaging of MSCT plus NIRS, OCT plus VH-IVUS, OCT plus IVUS-Echogenicity



## COMPREHENSIVE STATISTICAL REPORTING SPECIFICALLY ADAPTED FOR IMAGING DATA

- Mixed model
- Clustering
- Bayesian approach
- Linear regression
- Bland-Altman

## HIGH BLEEDING RISK CORE LAB

- DAPT Score
- PRECISE DAPT Score
- ACUITY Score
- CRUSADE Score
- PARIS Score



## ECHOCARDIOGRAPHY CORE LAB

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Our Echo Core lab provides accurate and reproducible qualitative and quantitative assessments of various cardiovascular Echocardiographic measurements in clinical trials. With more than two decades of experience and expertise, our Echo core lab services include:

### **Cardio-oncology core lab and cardiac Safety measurements**

- Serial Echocardiographic chamber quantification analysis:
- LV Tri-plane Global Longitudinal Strain (GLS), LV size and ejection fraction
- RV Global Longitudinal Strain (GLS)

### **Conventional Echocardiography core lab**

- Two-dimensional and Doppler Echocardiography measurements
- Valvular hemodynamic analysis – device success
- Dedicated Valvular Regurgitation analysis (combination of Echocardiographic and Quantitative Angiographic analysis of AR)
- Stress Echocardiography and Regional Wall Motion Analysis
- 2D Contrast Echocardiography Analysis
- Tissue Doppler imaging Analysis

### **4D echocardiography measurements of ventricular size and ejection fraction**

- 4D LV chamber quantification
- 4D RV chamber quantification
- 4D Structural Heart Analysis (pre-planning)

### **Echocardiographic for Mitral Pre-procedural Planning**

- Speckle tracking echocardiography measurements
- 2D Cardiac Performance Analysis (CPA) of Left Ventricular Strain, Rotation and Twist measurements
- 2D CPA of right ventricular strain measurements
- 2D CPA of left atrium strain measurements



## ECG CORE LAB

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- 12-Leads ECG conventional measurements
- Drug safety and cardiotoxicity assessments (QTc...new Q-wave...QRS duration)
- Holter analysis
- Remote monitoring analysis and reporting

## MRI CORE LAB

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- MI size quantification
- LV size and function measurements
- RV size and function measurements
- CMR Volumetric imaging
- CMR Tissue Characterisation (Oedema, perfusion, scar size)
- CMR 4D Flow

## CORONARY MSCT CORE LAB

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- Lumen analysis
- Plaque quantification and characterization analysis
- FFR-CT (in collaboration with HeartFlow)
- MSCT Syntax Score
- Micro-CT analysis (Fracture, discontinuity assessment in preclinical model)

## STRUCTURAL - MSCT

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### A. preplanning and screening committee

- TAVI pre- and post-procedural MSCT analysis
- Mitral pre- and post-procedural MSCT analysis
- Tricuspid pre- and post-procedural MSCT analysis
- Pulmonary and RVOT pre- and post-procedural MSCT analysis
- LAA pre- and post-procedural MSCT analysis





Ionscópacht / Mionghnáthamh  
Endoscopy / Minor Procedure





# CORE LAB EXPERTISE AND EXPERIENCE

We support you through all phases of clinical trials

- Providing advice on the choice of imaging modality in clinical trials
- Design of the imaging component of the clinical trial
- Imaging sites selection, training and approval
- Setup of the imaging acquisition at participating sites
- Support all secure image transfer
- Site performance index via central quality control and quality assurance of imaging
- Central reading of images by trained staff
- 100% over read by world experts (Cardiologists and Radiologists)
- Fast turnaround time (5 business days) of image read
- Imaging data interpretation by our expert leadership to support data submission and mechanistic understanding of therapy or treatment











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**CORRIB**  
**CORE LAB:**

