Cardialysis clinical endpoint adjudication plans

Plan	A	B	C
Activities by Cardialysis	**Full-service plan**	**Intermediate plan**	**Make your plan**
Triggering[1]	✓	Third party	
Source docs collection[2,3]	✓	Third party	
Site upload: PDFs	Optional	Optional	
Site upload: DICOM (incl. anonymization)	Optional	Optional	
Translation services	Optional	Optional	
WebCEC platform	✓	✓	
Adjudication forms development	✓	✓	
Upload: PDFs	✓	✓	
Upload: DICOM	✓	✓	
Upload: eCRF	✓	✓	
Narrative writting[4]	✓	✓	
Adjudication meetings[5]	✓	✓	
Periodic status report[6]	✓	✓	
Output generation (SAS)[7]	✓	✓	
Statistical reporting[8]	Optional	Optional	
Core Lab[9]	Optional	Optional	
Safety[10]	Optional	Optional	
DSMB[11]	Optional	Optional	

1 Possible if the eCRF is developed and managed by Cardialysis
2 Source docs collection directly from the sites by Cardialysis includes quality checks on blinding and labelling, and dossier preparation translation coordination
3 When a third party collects source docs, complete adjudication dossiers are delivered to Cardialysis (translation may be added)
4 Narratives can be generated by Cardialysis
5 Meetings can be face-to-face or by teleconference/webex
6 Status report refer to the status of operations (e.g. number of adjudicated events, pending events)
7 SAS output is generated (including combination with the Core Lab database if applicable) and data is transferred to the Sponsor on pre-specified time points (defined in the contract)
8 Statistical reporting of clinical events in SAS
9 Core Lab activities may involve angiography, electrocardiography, echocardiography, and computed tomography
10 Safety reporting can be done by Cardialysis, CEC data is generated reconciliation purposes
11 Data and safety Monitoring Board can be organised by Cardialysis

CARDIALYSIS
Clinical Trial Management - Core Laboratories

More information about Cardialysis

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CARDIALYSIS
Clinical Trial Management - Core Laboratories

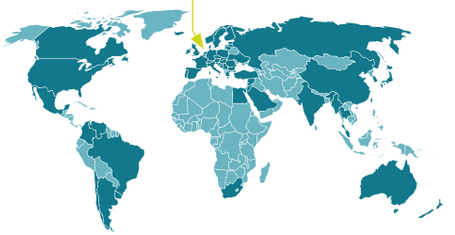
An Academic Research Organisation

Focus on Cardiovascular Research

Clinical Network
> 1,400 SITES

Clinical Trials
> 400

Based in The Netherlands
GLOBAL REACH



- Core laboratory
- Endpoint adjudication
- Data monitoring boards
- Safety reporting
- Trial design
- Protocol development
- Data management
- Biostatistics
- Project management
- Site management
- Site monitoring
- Regulatory submissions

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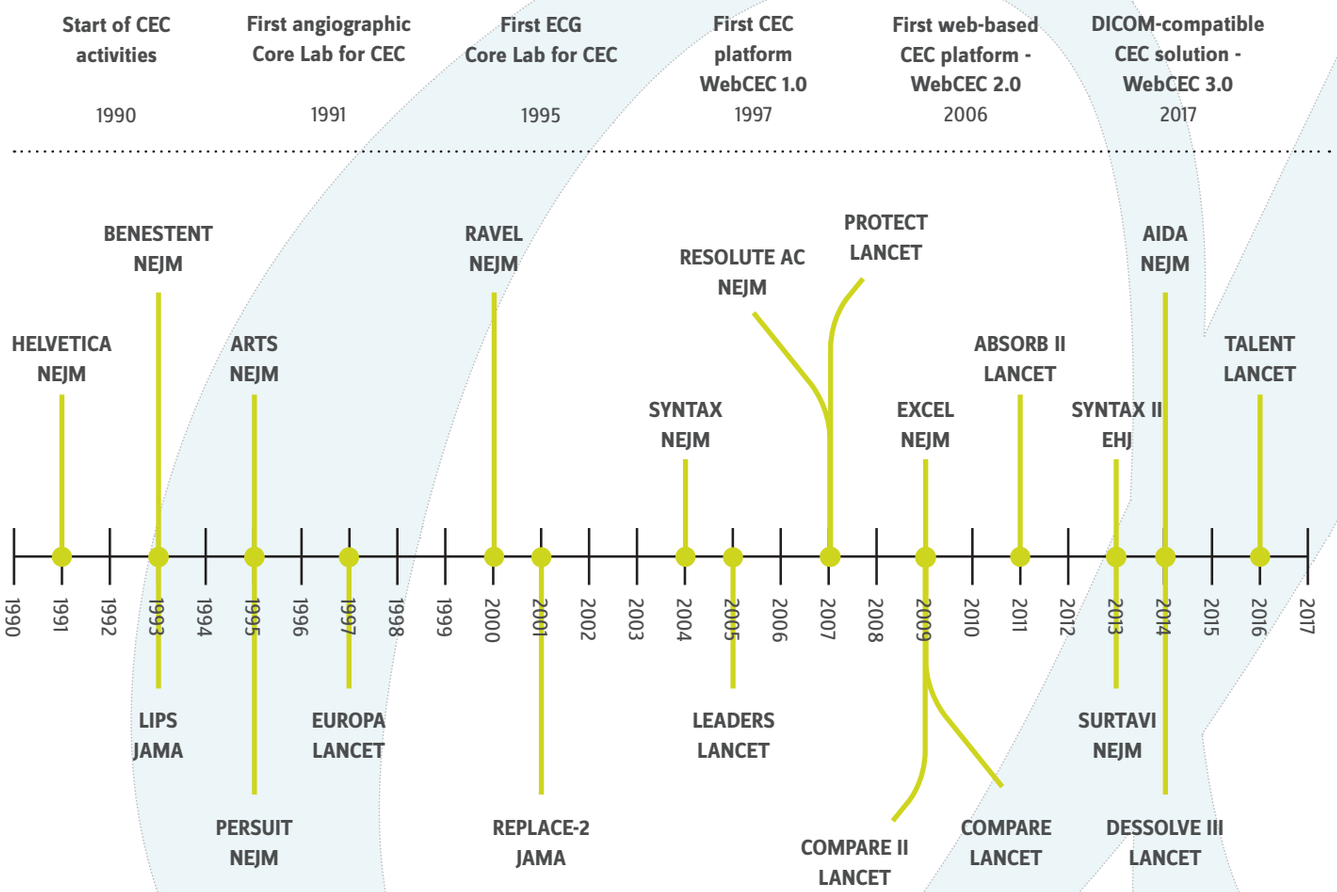
Clinical Endpoint Adjudication Track Record (1990-2019)



YEARS REFER TO THE START OF CEC ACTIVITIES - JOURNALS OF PRIMARY PUBLICATIONS ARE SHOWN

Selected Clinical Trials from 100+ since 1990

29 Years of Experience in Device and Pharma

90,000+ Event Triggers Adjudicated

30+ CEC members 30+ Operations Staff

Why partner with Cardialysis?

- 35+ years of experience in cardiovascular research
- 400+ clinical trials completed
- Full-scope research organization
- Fully-integrated imaging Core Lab
- European focus with Global reach
- Robust academic expertise and network
- Processes supported by cutting-edge technology

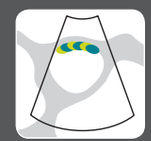
Coronary Stents

Bleeding

Neurological Events

Medication Non-Adherence

Aortic Valve Disease



Para-valvular Regurgitation

Mitral Valve Disease

Peripheral Artery Disease

Cardialysis is a founding member of the **Academic Research Consortium**, an initiative that supports the development of consensus definitions for clinical trials. Fields of cardiovascular research where definitions are available are depicted above.