



genae<sup>®</sup> associates nv

care for clinical research

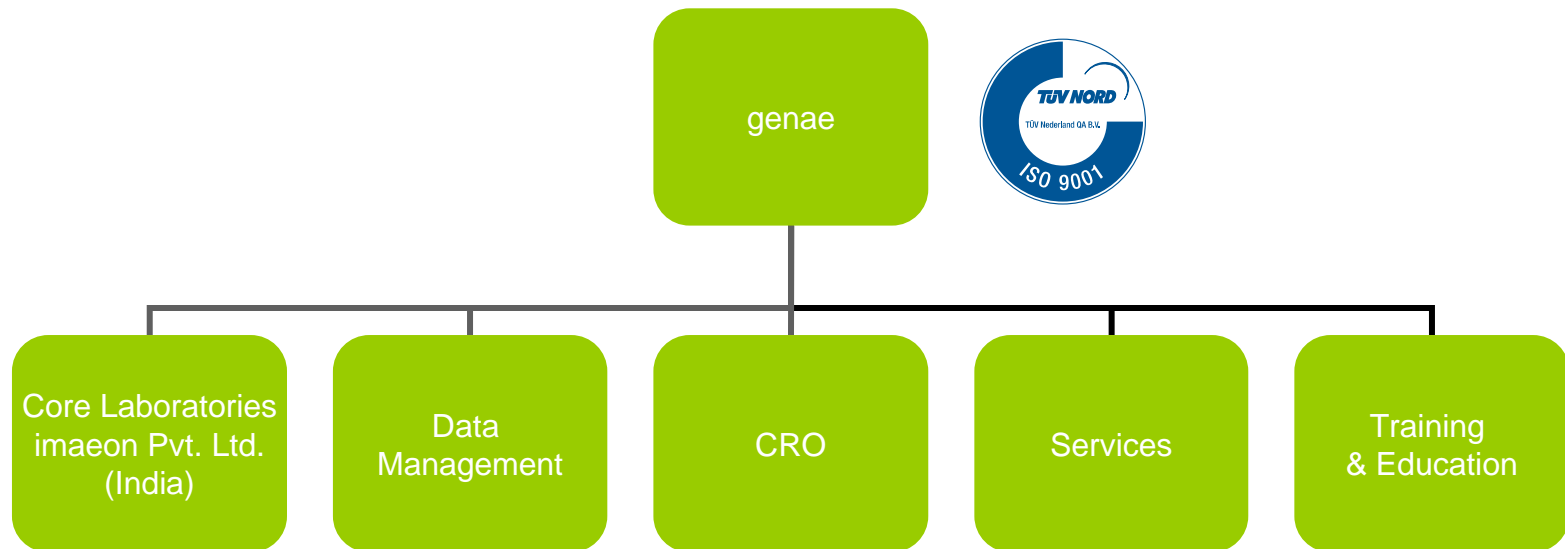
JUNE 2010



- To care about, and to take care of clinical research.
- By channeling its expertise and know-how in the most appropriate format, genae aims at helping to improve healthcare worldwide by providing a broad range of professional services, information and partnering solutions to the medical device, biotechnology, pharmaceutical and healthcare industries.



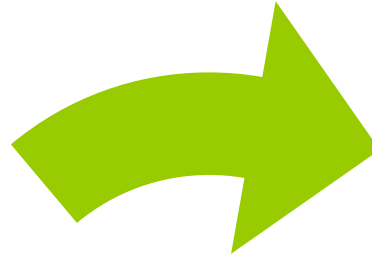
- privately held “Naamloze Vennootschap” (N.V.) under Belgian Law.
- NEN-EN-ISO 9001:2008 certified for:  
Clinical Trial Management, Data Management, Core Laboratories and Services Provider for the Medical Industries.



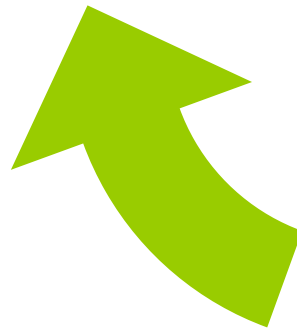
# group approach



genae



e-novex



imaeon



# Medical Advisory Board



The genae Medical Advisory Board (MAB) is an interdisciplinary team of prominent practitioners and researchers. These professionals believe in genae's mission, provide support to genae and serve as an advisory council to the organisation.

## Medical Advisory Board Members:

- **Pierfrancesco Agostoni, MD**

Chairman

Department of Cardiology

University Medical Center Utrecht

Utrecht, The Netherlands

- **Giuseppe Biondi Zoccai, MD**

Assistant Professor in Cardiology

Interventional Cardiology, University of Turin

S. Giovanni Battista "Molinette" Hospital

Turin, Italy

- **Johannes Bruno Dahm, MD**

Professor of Medicine

Department of Cardiology-Angiology

Heart- & Vascular Center, Clinic Neu-Bethlehem

Göttingen, Germany



## **Aly Talen, RN, Co-Founder & Director Business Development**

Aly has a degree in general and psychiatric nursing with extensive nursing experience in a catheterization laboratory (Hamburg, Germany). She worked as a Clinical Research Associate and Project Manager for Omnicare Clinical Research, a Clinical Research Organization. She founded the CRO 'Talen Clinical Trial Management in 2001', which led to genae associates in 2005.

Aly lived in different countries which facilitates in the contact with different cultures. Her experience and network in the clinical field make her a competent and reliable partner in discussions with key opinion leaders and the industry. She is a talented communicator with a strong clinical research background. Aly believes in providing clear and full support to customers which results in long-lasting relationships and repeat business opportunities.

## **Bart Segers, Co-Founder & Managing Director**

Bart has an engineering background in telecommunications. Previously, he was the General Manager of the European Sales & Marketing organization of Spectranetics International BV, a US based medical device company. Extensive international travel contributed to his affinity with a diversity of cultures and business practices. He has built a strong working relationship with key physicians in minimally invasive therapies and with major medical manufacturers and distribution partners. Bart is a strong communicator and combines people management with product knowledge. He is destined to leading a business that creates both shareholder and social value while delivering maximum support to the customers.

# senior management (cont'd)



## **Johannes B. Dahm MD, MBA, Director Core Laboratories**

Prof. Dahm followed his Internship at Paracelsus Clinic Hemer, Germany (1988-1992) after he studied medicine in Groningen, the Netherlands (1981-1988). He followed his fellowship in Cardiology & Angiology in the Heart Center Bad Oeynhausen (1992-1996), one of the largest cardiovascular centers in Europe. From 1996 - 2006 he held the position of Deputy Director and Head of interventional Cardiology/Angiology at the EMA-University in Greifswald, Germany. Through his research work in basic and clinical Cardiology & Angiology he became Assistant Professor of Medicine in 2002. His work has been published in numerous international journals (i.e. Circulation, CircResearch, JACC, AJC, JEVT, Atherosclerosis, Cath Cardiovasc Interv).

In 2006, he was elected as Director of the Dept. of Cardiology & Angiology at the Heart & Vascular Center Neu-Bethlehem in Göttingen, Germany.

## **Bert Segers, RN, Director Clinical Research**

Bert holds a paramedical nursing degree from the St. Elisabeth Institute in Leuven, Belgium. He started his professional career in the cathlab of Gasthuisberg, the University Hospital of Leuven; where he was exposed to interventional cardiology techniques and the basics of clinical research. After 10 years of cathlab experience, he joined Spectranetics International, a US-based medical device company. As an excimer laser application specialist, he worked in different fields of interventional cardiology, interventional endovascular treatment and cardiac/thoracic surgery in Europe, the Middle East and Russia. He later became the International Manager Clinical Affairs and Training. He was involved in, and responsible for the setup and execution of numerous clinical trials. Bert has a proven track record with key physicians and industry professionals around the globe.

# senior management (cont'd)



## **Dimitri Buytaert, PT, Manager Clinical Research**

Dimitri holds a physiotherapist degree from the Coloma institute in Mechelen, Belgium.

He worked for eight years in a rehab center, specialized in neurological and cardiac treatments and operated his private practice with specialization in manual therapy.

At Wicab, Inc., a US based medical device start-up company, he took responsibility for the European clinical trial development and the clinical device training. Dimitri possesses strong communication and organizational skills and continues to expand his network in the medical device field.

## offices in Antwerp, Belgium

genae runs two access controlled offices - totalling 850m<sup>2</sup> - which are centrally located in Antwerp.

Two international airports are located within a range of 50 km.

The data center is equipped with an Inergen clean agent fire suppression system and is located in a 24/7 monitored and sealed room with automated backup systems.

Source data is archived in S02 safety vaults consisting of fire resistant insulation according to DIN 4102.



*facade of genae's contemporary CRO offices in Antwerp*



- document creation (clinical investigational plan, patient information, etc.)
- site selection
- study start up activities e.g. regulatory & ethics approval, agreements, essential document collection, etc.
- monitoring
- set-up and communication with safety or clinical event committees
- safety reporting to authorities
- study close-out



- CRF design & creation
- data entry & verification (double data entry)
- Validated, industry standard paper CRF and EDC platforms
- Data Management including query management & data cleaning
- statistical analysis services including power calculations
- clinical investigational reports (interim, final)





## imaeon core laboratories joint venture

- VIBGYOR Scientific Research (Ahmedabad, India)
- genae associates (Antwerp, Belgium)
- Cardiovascular Center Aalst (Aalst, Belgium)
- Prof. J.B. Dahm (Göttingen, Germany)

While meeting or exceeding all quality standards in a timely and cost-effective manner, imaeon offers expert evaluations of medical images from multi-modality environments and quality clinical research services.

Operates from the main facilities and offices in Ahmedabad, India and from the subsidiary in Antwerp, Belgium.

Focus on the pharmaceutical, biomedical and medical device industries.

# core laboratories (cont'd)



imaeon core laboratories joint venture





## image analysis, quantitative & qualitative quantification

- quantitative coronary and peripheral angiography (QCA / QVA)
- intravascular ultrasound (IVUS) and IVUS related techniques
- multiple gated acquisition scan (MUGA)
- duplex ultrasound
- electrocardiogram (ECG)
- echocardiography (ECHO)
  
- optical coherence tomography (OCT) – Q2 2010
- computed tomography (CT) angiography
- magnetic resonance imaging (MRI)
- multi slice computer tomography (MSCT)



## CE marking

The MDD's main purpose is to harmonize national controls to allow free movement of medical devices throughout the European Union and the European Free Trade Associations while ensuring that all devices within the European Union are reasonably safe to use. genae's medical device experts assist you in complying with the Medical Device Directive. On request, we will send you our report on obtaining the CE mark and on how we determine your device classification, check all relevant essential requirements, prepare the relevant technical documentation and on how we communicate with the Competent Authorities and Notified Bodies on your behalf.



## Reimbursement

Services include:

- Verification and assessment of the existing clinical data.
- Collection of technical and clinical data from the original Technical File.
- Formulation of dossier rationale.
- Preparation, production and submission of the reimbursement dossier.
- Follow-up and tracing.



## Clinical Research with Medical Devices (EU & US)

- genae's introduction about clinical research with medical devices is designed for anyone involved in pre- and post-market studies within the medical device industry. Developing medical devices and therapies is a complex and costly matter and can take many years to complete. This course covers all aspects of clinical research activities that are performed during pre- and post-market studies.



## areas

- coronary artery treatment
  - multi- and single vessel
  - small vessel
  - bifurcation lesions
  - CTO
- other artery treatment
  - thoracic aneurysms
  - renal artery stenosis
  - carotid artery stenosis
  - SFA & BTK lesions
  - CLI
- heart failure
- mitral valve regurgitation:
  - percutaneous
  - surgical
- percutaneous aortic valve replacement
- neuro-stimulation
- cartilage repair



## treatments & devices

### treatments

- cell therapies
- gene therapies
- surgical or percutaneous repair

### devices

- stents:
  - bare metal
  - drug eluting / coated
  - bioactive
  - biodegradable
- atherectomy devices
- thrombectomy devices
- drug eluting balloons
- cerebral protection
- novel devices
- cartilage implants



## study specifications

	<b># subjects</b>	<b># sites</b>	<b>follow-up</b>
first-in-man	up to 100	1 to 10	30 days to 5 years
pivotal	50 to 360	5 to 30	30 days to 5 years
regulatory / post-marketing	90 to 3.000	6 to 45	1 to 5 years

additional information



[www.genae.com](http://www.genae.com)