



Dr. Albers' services are available through
Clinical Device Group

Overview

There is always a next step. After working in the medical device industry for more than 20 years I founded Albers Clinical Evidence Consultancy. This company offers services to the medical industry, including strategic clinical evidence planning, design, preparation conduct of clinical studies and analysis of study data. In addition, services are provided with respect to employing the evidence to obtain market clearance and reimbursement coverage and publication of the evidence in scientific journals. Further detailed information about these consultancy services can be found on my company's website: www.alberscec.com.

Throughout my study and my career I was always intrigued by the combination of technology and medical science. I studied Applied Physics with a special focus on biomedical engineering and biophysics. That focus was maintained during my PhD study on a biophysical, electrophysiological topic.

Subsequently, I joined the medical device industry. Here I was involved in virtually all aspects of the clinical evaluation of new products, including early prototype testing, regulatory clinical trials and physician sponsored studies. My involvement ranged from study design and preparation, monitoring and data management to analysis, reporting and publication. More recently, I was involved in strategic business processes related to the collection of clinical evidence. Throughout my career I was a frequent discussion partner with regulatory agencies in various geographies (Europe, USA and Japan). I am also familiar with the regulations in these geographies with respect to clinical trials and product registration. During the preparation of several presentations and scientific publications I developed extensive writing and presentation skills.

In my clinical assignments I have always been looking for the optimal combination of a scientific approach and business sense. Moreover, I pursue a holistic attitude: create solutions with the overall process and objectives in mind.

Employment

- 2009 **Owner/consultant**, Albers Clinical Evidence Consultancy
Consultancy services for the medical industry with respect to strategic planning, collection, presentation and publication of clinical evidence for new and existing products.
- 2006 – 2009 **Principal Scientist**, Medtronic SQDM, Arnhem, The Netherlands
Clinical evidence strategies for the Subcutaneous Diagnostics and Monitoring (SQDM) business unit. Overall publication strategy and preparation of manuscripts.
- 2003 – 2006 **Manager Science Team**, Vitatron Medical, Arnhem, The Netherlands
Managing a group of scientists responsible for a wide range of scientific aspects related to clinical and research studies.
- 2000 – 2003 **Senior Clinical Scientist**, Vitatron Medical, Dieren, The Netherlands
Scientific support for clinical and research studies. Implementation of a support center for outcome study initiatives and physician initiated studies.
- 1996 – 2000 **Manager Clinical Study Center**, Vitatron Medical, Dieren, The Netherlands
Management of the Clinical Study Center (about 20 employees). Overall project and resource management, compliance management (implementation of ICH-GCP).
- 1992 – 1996 **Clinical Evaluation Manager**, Vitatron Medical, Dieren, The Netherlands
Clinical evaluation of cardiac pacing systems, including protocol/CRF development, study monitoring, data management, analysis and reporting.
- 1987 – 1992 **Clinical Research Associate**, Cordis Europa, Roden, The Netherlands
Clinical evaluation of diagnostic and therapeutic catheters for cardiology, radiology and neurology applications, including protocol and CRF development, study monitoring, data management, analysis and reporting.

Education

- 1983 – 1987 **PhD study**, Twente University, Enschede, The Netherlands
Thesis: Microscopic volume conduction of myo-electrical activity.
- 1977 – 1983 **Applied Physics**, Twente University, Enschede, The Netherlands
Master thesis: Raman spectroscopy study of DNA molecular structures.

Publications

- Microscopic volume conduction of myo-electrical activity. A theoretical and experimental approach to the forward problem in electromyography. (PhD thesis) 1987; ISBN 90-71382-16-8
- The electrical conductivity of skeletal muscle tissue. Experimental results of different muscles in vivo. *Clinical Neurology and Neurosurgery* 1984; 86:228
- A model study on the influence of structure and membrane capacitance on volume conduction in skeletal muscle tissue. *IEEE Trans Biomed Eng* 1986; 33:681-689
- Model of electrical conductivity of skeletal muscle based on tissue structure. *Med Biol Eng Comput* 1986; 24:34-40
- Frequency domain modeling of volume conduction of single muscle fiber action potentials. *IEEE Trans Biomed Eng* 1988; 35:328-332
- Microscopic and macroscopic volume conduction in skeletal muscle tissue, applied to simulation of single-fibre action potentials. *Med Biol Eng Comput* 1988; 26:605-610
- Sensitivity of the amplitude of the single muscle fibre action potential to microscopic volume conduction parameters. *Med Biol Eng Comput* 1988; 26:611-616
- Quantitative analysis of single muscle fibre action potentials recorded at known distances. *Electroencephalogr Clin Neurophysiol* 1989; 73:245-253
- Avoiding atrial undersensing by assessment of P wave amplitude histogram data. *Pacing Clin Electrophysiol* 1994; 17:1878-1882
- Efficacy of Preventive Pacing in Patients with Paroxysmal Atrial Fibrillation (PAF). Results of the AFTherapy study. *Swiss Cardiology Association* 2002
- Understanding Capture Detection. *Europace* 2004; 6:561-569
- Reduction of the pace polarization artifact for capture detection applications by a tri-phasic stimulation pulse. *Europace* 2004; 6:570-579
- Form Analysis Using Digital Signal Processing Reliably Discriminates Far-Field R Waves from P Waves. *Pacing Clin Electrophysiol* 2004; 27:1615–1624
- Rejection of atrial sensing artifacts by a pacing lead with a short tip-to-ring spacing. *Europace* 2005; 7:67-72
- Automatic analysis of pacemaker diagnostic data in the identification of atrial tachyarrhythmias in patients with no prior history of them. *Europace* 2005; 7:242-247
- Hybrid Ablation and Preventive Pacing Therapy to Control Persistent Atrial Fibrillation: The HAPPI-AF Trial. *American Heart Association* 2006
- Verification of Alert Messages of an Advisory System in Pacemakers. *Cardiostim* 2006
- Health related quality of life relative to clinical outcomes in patients with atrial fibrillation treated with ventricular rate stabilisation pacing. *Neth Heart J* 2006; 14:81-88
- Individualized selection of pacing algorithms for the prevention of recurrent atrial fibrillation: results from the VIP registry. *Pacing Clin Electrophysiol* 2006; 29:124-134
- Conventional and dedicated atrial overdrive pacing for the prevention of paroxysmal atrial fibrillation: the AFTherapy study. *Europace* 2007; 9:1110-1118
- Atrial Fibrillation Detection by a Subcutaneous Monitoring Device. *Computers in Cardiology* 2008; 35:413–416
- Incidence of Paroxysmal Atrial Fibrillation in patients treated with Cardiac Resynchronization Therapy and continuously monitored by device diagnostics. *Europace* 2010; 12:71-77