CARDIAC SAFETY CONSULTANTS

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WORLD CLASS CONSULTANCY SERVICES DRIVING DRUG DEVELOPMENT

OVERVIEW

Cardiac Safety Consultants Ltd is a European Consulting Group that provides independent consultancy services and expert opinion to Pharmaceutical and Biotechnology companies involved in clinical research and development. Our Consultants bring vast experience and practical knowledge of cardiac safety in drug development.

CONSULTANCY SERVICES

- **TQTc protocol design and development**
- **Global regulatory advice (FDA, EMEA, PMDA)**
- **Independent advisory board support**
- **Biomarker assessment (serum, imaging and electrocardiographic biomarkers)**
- **Expert clinical reports**
- **Drug due diligence (in/out-licensing)**
- **Independent global cardiovascular monitoring**

CONSULTANTS

Boaz Mendzelevski MD

Boaz Mendzelevski, MD, is a Cardiac Safety Consultant based in London, UK with extensive clinical and global regulatory experience. He is a board certified expert in Internal Medicine and Cardiology with further postgraduate training in Interventional Cardiology and Clinical Electrophysiology at the National Heart and Lung and the Royal Brompton Hospital in London. Dr Mendzelevski is a pioneer in establishing the role of safety cardiology in pharmaceutical drug research and has been involved in all stages of drug development clinical trials since 1995.

He was the founder of the Quintiles QECG laboratories in London UK and Mumbai India, and more recently initiated and served as the Lead for the European Cardiac Safety Services division of Covance Inc. Dr Mendzelevski has authored more than 200 expert reports, has attended regulatory cardiac safety meetings in Europe, USA and Japan and has sat on several advisory and data safety boards. Dr Mendzelevski was a member of the Expert Panel for the Step 3 ICH-E14 process. He is a frequent speaker at scientific and industry meetings and serves as the Chairperson of the Annual European DIA Cardiac Safety Conference.

Borje Darpo MD, Ph.D., Associate Professor, F.E.S.C.

Borje Darpo has been a board certified cardiologist since 1989. He specialised in Clinical Electrophysiology and presented his thesis on the Clinical Development of an Antiarrhythmic Drug in 1995. In 1998 he was appointed Fellow of the European Heart Association, in 2000 he became an Associate Professor in Cardiology at the Karolinska Institute in Stockholm. In 1998 he joined Pharmacia and has held positions as Clinical Program Leader in Cardiovascular, Regional Head of EU for Clinical Pharmacology and Senior Director in Pfizer's Clinical Technologies group in Sandwich, UK.

Between April 2004 and March 2006, Dr Darpo held the position as Chief Medical Officer of Daiichi Medical Research in the UK and USA.
In 1997 Dr. Darpo participated as a member of the ad hoc expert committee that had an advisory role in the generation of the CPMP's "Points to Consider" document. He has taken an active role as co-Chair of the ILSI/HESI Cardiovascular Safety Subcommittee. Dr Darpo represented the European Pharmaceutical industry (EFPIA) as Deputy Topic Leader on the ICH E14 Expert Working Group and is currently the Topic Leader for EFPIA on the Implementation Group for the same document. Currently, Dr Darpo works as a Pharmaceutical Consultant, with focus on strategic advice within the Cardiovascular and Metabolic therapeutic area, and cardiovascular safety assessment.

For further information, please email john.sulola@cardiacsafetyconsultants.com or call on +44 (0) 208 788 7744