



September 2019

Date: Tuesday 10th September 2019

Where: British Residence Boston

Time: 8am Start. Access and Full Agenda TBC.

Date: Thursday 12th September 2019

Where: British Consulate General New York

Time: 8am Start. Access and Full Agenda TBC.

The event will focus on innovative early drug development opportunities in London and the south east of the United Kingdom

With support from the British Embassy in Boston and New York, Richmond Pharmacology will be holding an event to showcase how London's unique Life sciences environment can support sustainable and optimised global drug development.

Preliminary Agenda

Description	Speaker
Introductory Remarks	DIT
Supporting innovation in early drug development	Dr Martin O'Kane MHRA
Global Development and Regulatory frameworks	Dr Chris Brünger IDEC
Cardiac Safety & Early Phase Clinical Research	Dr Boaz Mendzelevski Cardiac Safety Consultants
The ingredients for next generation, innovative medicines development and where to find them	Neelam Patel MedCity
Why overseas biopharmaceutical companies come to the UK for early clinical medicines development	Dr Jörg Täubel Richmond Pharmacology
The Use of Radiolabeled compounds in early phase clinical trials	Dr Radivoj Arezina Richmond Pharmacology

First Speakers Confirmed

Dr Martin O'Kane MRPharmS

Medicines and Healthcare products Regulatory Agency (MHRA)

Dr Martin O'Kane is Head of the Clinical Trials Unit at the MHRA. He is a pharmacist by training with a PhD in neuropharmacology and post-doctorate research experience in neuroscience. Following a period in Japan working within the pharmaceutical industry, he joined the MHRA working for the British Pharmacopoeia and was a member of the European Pharmacopoeia Commission's Working Party on Cell Therapy Products. He moved to the Clinical Trials Unit as a Pharmaceutical Assessor in 2007 and has been involved in the assessment of chemical, biological and advanced therapy applications for all phases of study. He became Head of the Unit in 2015 and is currently involved in European Medicine Agency and UK projects to prepare for implementation of the new clinical trials Regulations.

Dr Chris Brünger, MD

President and CEO, Chief Medical Officer

Dr. Brünger has over 20 years of global drug development experience and held senior R&D positions for Schering AG and Pharmacia Corporation in Japan and Germany from 1989 to 2003, before founding IDEC. He is also a licensed physician in Germany and Japan.

Dr. Brünger's unique experience in Japanese clinical practice and medical research, and expertise in international drug development enable him to work with clients to develop effective solutions to integrating Japanese regulatory and marketing requirements into global development programs. He has prepared and managed over 50 PMDA consultations, and pioneered Japanese-Korean clinical co-development and studies in ethnic Japanese outside Japan.

Dr Boaz Mendzelevski MD

President Cardiac Safety Consultants

Dr Boaz Mendzelevski is a consultant cardiologist and President of Cardiac Safety Constants Ltd, a London UK based consulting group that advises the pharmaceutical and biotechnology industry on cardiovascular safety and efficacy issues.

Dr Mendzelevski received his MD degree from the Ben-Gurion University Medical School in Beer-Sheva, Israel. He completed full training in Internal Medicine and in Cardiology - and is a Board Certified Expert in both Internal Medicine and Cardiology. Dr Mendzelevski completed a further sub-speciality training in Interventional Cardiology and Cardiac Electrophysiology at the Royal Brompton Hospital in London, UK.

Neelam Patel Interim Chief Executive Officer

MedCity

MedCity is an enabler, positioning the greater south east of England as a gateway to the UK for life sciences research, development, manufacturing and commercialization. The organisation plays a pivotal role in bridging industry, NHS and academia.

Neelam's significant experience, has included private and public sector and not-for-profit. She has held a number of leadership roles with the pharmaceutical industry and sat on industry research committees at the Association of British Pharmaceutical Industries and has represented industry on a European Innovative Medicines Initiative exploring the linkage of electronic health records for research. Neelam also sits on the steering group for the NICE evaluation pilot of digital health technologies and the Public Health England evaluation advisory group.

Dr Jörg Täubel MD FFPM (CEO)

Richmond Pharmacology

Dr Jorg Taubel is a medical practitioner and CEO of Richmond Pharmacology which he co-founded in 2001. He has worked in clinical pharmacology for over 25 years and during that time he has conducted more than 400 early phase studies in patients and healthy volunteers; usually in the capacity of Principal Investigator since 1995. His experience ranges from first time in man (FTIM) to proof of concept (POC) studies. He has extensive experience in cardiology, neurology, gastroenterology, ethnic bridging studies. His work currently focusses on providing expert advice in cardiac safety assessments and ethnic comparison studies. Dr Taubel is an honorary fellow at St George's University and author of over 50 publications in scientific journals. He is currently

researching the role of hyperglycaemia in relation to sudden cardiac death in Type I diabetic patients. He presented his research at numerous international meetings and workshops in Europe, US and Japan.

Dr Radivoj Arezina MD MSc

Research Director, Richmond Pharmacology

Dr Arezina is a founding director of Richmond Pharmacology and an MHRA-licensed Qualified Person (QP) with the overall responsibility for the IMP aspects of clinical trial conduct at this leading contract research organisation. He qualified in medicine in 1987 at the Medical School of the University of Zagreb, Croatia. Having spent one year in clinical medicine, most of his professional life thereafter has been in clinical research. To date, Dr Arezina has been co-investigator on over 200 clinical trials ranging from bioequivalence to first-into-human and covering different therapeutic areas including cardiovascular, gastrointestinal, CNS, pain, dermatology, endocrinology and urology.

Dr Arezina also teaches modules on investigational medicinal products in clinical trials to undergraduate and postgraduate students at University College London (UCL). He is a member of the Association for Human Pharmacology in the Pharmaceutical Industry (AHPPI, UK) and a fellow of the Royal Society of Medicine.

Venue access, additional speakers and Full agenda to be announced.