

## MEET THE SPEAKERS



### FRANÇOIS HOUYEZ

François Houyez is working at the European Organisation for Rare Diseases EURORDIS where he is Director of Treatment Information and Access, and Policy Advisor. He has always been working as a patient advocate since 1989 90s when he started treatment advocacy in Act-Up Paris. He represents EURORDIS at the Patients' and Consumers' Working Party at the European Medicines Agency (EMA) and in the European Network of Health Technology Assessment Agencies (EUnetHTA). He coordinates Eurordis Community Advisory Board Programme in rare diseases. François is also a patient.



### GUY YEOMAN

Guy Yeoman has been the Head of Patient Centricity at AstraZeneca from 2015-17. In this role he and his team were responsible to enable the delivery of patient driven science across the full lifecycle. He is the lead author of the first ever collaborative definition of Patient Centricity. He has spent the last ten years with AstraZeneca, the initial two as the UK Medical Director before moving to Asia to build an integrated medical affairs capability across Asia Pacific. More recently he established a new global Medical Evidence Centre focused on delivering integrated evidence, external science and publications. Prior to joining AstraZeneca he spent five years at GlaxoSmithKline in clinical development, medical affairs and project management before moving to develop UK medical affairs and market access for a French company. Guy qualified in Medicine and worked in the NHS in the 1990's.



### VIVIENNE VAN DE WALLE

Vivienne van de Walle, MD, PhD, CPI, FAPCR studied medicine at the University of Maastricht in the Netherlands and did part of her medical training at the University of Oxford in the UK. She has always combined clinical research with patient care and has been a full-time investigator at independent clinical research sites since 1999. She co-founded the independent research site PT&R in 2006, taking full ownership in 2013. She works as a physician but also as a consultant for pharma, CRO, sites and vendors within the clinical research & life science business. She is a member of the national BROK/GCP exam commission, the ACRON, APCR, ACRP and the VP of the NVFG (Dutch Federation of Pharmaceutical Physicians) and is a member of Leadership Council of the SCRS (Society of Clinical Research Sites).



### HILDE VANAKEN

Hilde Vanaken is a Director of the R&D Operations Innovation department at Janssen. She has more than 16 years of experience in pharmaceutical companies and Clinical Research Organizations, where she held various leading positions in clinical operations, data management, safety management, professional affairs, quality management, strategic business improvement and clinical trial innovation. Prior to clinical research, Hilde worked as a research scientist for 6 years. Hilde has a passion for complex or so called mission impossible projects and has a track record to transform them into success stories. In her current role, she is leading several transformational projects, such as eMeds/ iSTEP (Integrated Smart Trial and Engagement Program), to modernize Janssen's clinical trials and improve the experience of patients and investigators. Next to her role in Janssen, Hilde also leads the cross-pharma Transcelerate eConsent initiative to facilitate the cross-industry adoption of eConsent in close collaboration with external stakeholders such as patients, sites, IEC/IRBs and Health Authorities. Hilde holds a degree in Engineering in Chemical and Agricultural Sciences, a Master in Environmental Sciences and a PhD in Medical Sciences, all from the Catholic University of Leuven in Belgium



### SERGE BODART

Serge Bodart is currently the Subject Matter Expert for eCOA Services at Biomedical Systems, a privately held, global provider of centralized diagnostic services and scientific expertise for clinical trials based in St Louis, Missouri. He is Biomedical Systems representative in the ePRO Consortium. He has been immersed in the ePRO industry for the past 17 years. With his associate, Dr. Pernel, Serge founded SYMFO, a European based ePRO provider. As the Co-founder and Chief Executive Officer of Symfo, Serge has been involved in all aspects of the eCOA life cycle from concept to commercialization. Prior to his ePRO career, he served as Major and helicopter pilot for over 20 years in the Belgian Army Aviation.

Serge is currently based in Montreal, Canada and holds a master's degree of Science in Telecommunications from the Polytechnic Division of the Royal Military Academy in Brussels, Belgium.



### BERT HARTOG

Bert Hartog is currently Innovation Leader at Janssen Pharmaceutica, where he leads transformational innovation projects that have the goal to shape the future of clinical trial execution and position Janssen as a role model in patient-centered clinical research.

Bert has 25 years' industry experience in Global Clinical Operations and related functions. He received his MSc in Biomedicine and PhD in Medicine from Utrecht University in the 1990's, and started his career as CRA with Eli Lilly in the Netherlands. After spending time in QA and IT he joined JNJ in 2005 in a Global Project Management role before he returned to clinical operations in 2008. His main focus today is to develop capabilities for digital health in clinical trials, including digital outcome measures and technologies for remote patient monitoring.



### DENIS LACOMBE

Denis Lacombe graduated with his MD from the University of Marseilles (France) in 1988 and obtained a Master Post Doctoral Fellowship at The Roswell Park Cancer Institute (Buffalo, NY USA) for research in pharmacology and pharmacokinetics from 1989 to 1991. From 1991 to 1993, he worked as a Clinical Research Advisor in charge of the development of a new drug in oncology in the pharmaceutical industry.

Dr Lacombe joined the EORTC in 1993 as a research fellow and quickly became a very active and productive Clinical Research Physician involved in the conduct of clinical research from protocol development through publication for a number of oncology indications from phase I to phase III. Dr Lacombe contributed to the strategic evolution of the EORTC pan-European clinical and translational research infrastructure by setting up various supportive assets such as regulatory and pharmacovigilance expertise as well as partnership models with the pharmaceutical industry.



### GREET MUSCH

Greet Musch obtained a PhD in Pharmaceutical and Biomedical Sciences at the Free University of Brussels .

She joined the Pharmaceutical Industry ( Research oriented ) for 8 years where she was responsible for all the chemical and pharmaceutical analytical activities related to the development of new innovative drugs .

She moved to the Federal Public Health services as a senior quality assessor and assisted in several projects related to EMA/CHMP as well as to Generics .

Since August 2004 she was in charge of the R&D department within the Federal Agency of Medicines and Health Products in Belgium .

From February 2009 she has been designed as Director-general for the DG Pre-authorisation She is involved in different working groups related to unmet medical need , early acces and clinical research in a broad sense



## ANNABELLE BRUYNDONCKX

Annabelle Bruyndonckx joined Simmons & Simmons in 2013, after more than 14 years at another international law firm, where she headed the Pharmaceuticals & Healthcare group.

Annabelle read law at the Catholic University of Louvain and spent half a year on an exchange program at the Rijksuniversiteit of Leiden. She was admitted to the Brussels bar in 1998 and was a part-time lecturer at the Catholic University of Louvain from 1997 to 2003.

Today, Annabelle is the head of the Belgian Regulatory Affairs Society's (BRAS) Educational Group, where she organizes training sessions on various pharma and medical devices related topics. Annabelle is also a member of the European Food Law Association (EFLA) and the Brussels Pharma Law Group.

She is frequently invited to speak at international conferences on various topics and has published numerous articles in legal and trade journals relating to various regulatory and compliance matters specific to the Health & Life Sciences sectors. Since 2010, she is a regular lecturer of the European Healthcare Compliance Ethics & Regulation program organized by Sciences Po (France) and Seton Hall Law (United States).

Annabelle's publications include numerous chapters on pharma compliance and procurement in the Second Edition of the Treatise of Pharmaceutical Law – Marketing of medicinal products for human use: Belgian and European law, 2016 (volume 1) – 2017 (volume 2), as well as notably "Promoting Medical Devices in Belgium" in Promoting Medical Devices Globally, bilingual edition, May 2009, and "Promoting Medical Products in Europe & North America", second edition, June 2007. Annabelle is also a frequent legal writer in the bilingual newspaper Le Specialiste – addressed to 35,000 healthcare professionals and institutions – where she addresses the legal aspects of various new health topics.



## KATIE GALLAGHER

As Policy Adviser at The European Patients' Forum (EPF), Katie is responsible for EPF's strategy on access to healthcare, developing and implementing activities within the 'Access' thematic area, including the coordination of the EPF internal Working Group on Access, and developing EPF's policy and advocacy work on non-discrimination and inclusion of vulnerable groups, medical devices, eHealth and data protection.

Katie holds a Bachelor of Science with Honours (BSc Hons) in Biological Sciences (Medical Biology) degree from The University of Edinburgh.

Prior to joining EPF, Katie was responsible for the coordination and development of sports and activities programmes at The British School of Brussels (BSB), worked as Policy Officer for the International Diabetes Federation European Region (IDF Europe) and worked for the Health Threats Unit, of the European Commission.

To be continued.