WCP2023 Satellite Meeting

# PATIENT CENTRIC SAMPLING –

## What it is and how it can transform decentralised clinical trials


Sunday 2nd July 2023

Islands Suite, Crowne Plaza,
Glasgow, UK

PCSIG

*Brought to you by the Patient Centric Sampling Interest Group**

*A UK registered Community Interest Company

## WELCOME

On behalf of our organising team and our sponsors, it is very much our pleasure to welcome you to this Patient Centric Sampling Interest Group (PCSIG) satellite event at WCP2023 in Glasgow, *"Patient centric sampling – What it is and how it can transform clinical trials".* This is an exciting opportunity to share experiences, learn about the benefits and challenges of this approach and together look to the future as to how we might facilitate the more routine approach of these technologies where they provide benefit.

This event is only made possible by the support of our sponsors. We hope you engage with them through their delegates at this event and through the links to their websites.

We very much hope you enjoy the event and come away feeling educated and empowered to explore these technologies and workflows to help put the patient first in our clinical trials.

Sincerely

Neil Spooner
Founder and Director, PCSIG

James Rudge
Trajan Scientific & Medical

David Sciberras
FBPhS

## ABOUT THE PCSIG

"ENABLING PATIENTS TO TAKE CONTROL OF SAMPLING"

The Patient Centric Sampling Interest Group (PCSIG) is a not-for-profit organization* that brings together a variety of interested parties and individuals who have a shared interest in promoting patient centric sampling approaches. They are unified by their interest in facilitating the development and implementation of novel sample collection technologies so that they can be integrated into standard of care. The group is focused on fostering a broader understanding and future widespread implementation of these technologies and serves as a clearing-house for information that helps support this cause. Further, the group's aim is to become the industry catalyst for innovation, technology transfer and the sharing of best practice between members, leading to better outcomes for these organizations and the end consumers of the technologies developed. This is accomplished as a collaborative association of passionate individuals.

To ensure that these technologies are what is required by the broader population, the interest group aims to actively engage with stakeholders, including healthcare providers, consumers, patients, regulators, fellow scientists and the media to understand and address their concerns surrounding patient centric blood sampling and analysis.

If you wish to find out more, please email us at info@pcsig.org and / or join our group on LinkedIn. Simply search for PCSIG on LinkedIn and you will get 2 results, a company (please follow) and a group (please join).

PCSIG

*The Patient Centric Sampling Interest Group is registered in the UK as a Community Interest Company (Company Number 14711621)

## PROGRAMME

09:00 - REFRESHMENTS

09:30 – WELCOME – *Neil Spooner (PCSIG)*

09:40 – 1ST SESSION – *Chair David Sciberras, FBPhS*

09:40 Introduction to Patient Centric Sampling - Benefits and Technologies Available
*Ariane Kahnt (Janssen Research & Development, Belgium)*

10:00 Putting the Patient at the Centre
*Jenny Royle (MediPaCe, UK)*

10:20 Bioanalytical and Regulatory Considerations
*Chiara Rospo (UCB, Belgium)*

10:40 – REFRESHMENTS & TRADE STANDS

11:00 Use of Patient Centric Sampling in Clinical Trials & Public Health
*James Rudge (Trajan Scientific & Medical, UK)*

11:20 - QUICK FIRE PRESENTATIONS FROM EACH TRADE STAND (5 min each)

- Routine Adoption of Patient Centric Samples in the Analytical Laboratory
  *Iain Love (Charles River Laboratories, UK)*
- Operational Considerations for Patient Centric Self-Collection
  *John Corcoran ($Q^2$ Solutions, USA)*
- Patient-Centric Sample Collection Enables Denser and More Resilient Data Collection in Clinical Trials
  *Erwin Berthier (Tasso, USA)*
- Utilizing microsampling to improve data, recruitment and diversity in clinical trials
  *Minna Salonen (Trajan Scientific & Medical, Finland)*
- Increasing participant engagement and completion with TAP blood collection technology
  *Patricia Holman (YourBio Health, UK)*

12:30 – LUNCH & TRADE STANDS

13:15 - 2ND SESSION – *Chair James Rudge (Trajan Scientific & Medical, UK)*

13:15 Improving the Multiple Myeloma Patient Pathway: Microsampling for Remote Monitoring of Free Light Chains
*Nithya Paranthaman (The Royal Marsden Hospital, UK)*

13:35 The Use of Volumetric Patient Centric Blood Sampling in Paediatric and Adult Drug Development Programmes
*Hugues Chanteux (UCB, Belgium)*

13:55 Implementation of volumetric absorptive microsampling technology in pediatric and adult clinical development programs
*Micha Levi (Gates MRI, USA)*

14:15 Thinking Patient Centricity: Reflections of a PCS case study
*Silvia Alonso Rodriguez (AstraZeneca, UK)*

14:35 – REFRESHMENTS & TRADE STANDS

14:50 - PANEL DISCUSSION – *Chair Neil Spooner (PCSIG)*

Including all speakers and session chairs

15:30 - END

# OUR SPONSORS

## PLATINUM

Charles River Laboratories are a Contract Research Organization specializing in a variety of preclinical and clinical laboratory, gene therapy and cell therapy services for the Pharmaceutical, Medical device and Biotechnology industries. We offer support in the fields of basic research, drug discovery, safety and efficacy, clinical support, and manufacturing

$Q^2$ Solutions, a wholly owned subsidiary and laboratory division of IQVIA, is a leading global clinical trial laboratory services organization providing comprehensive testing, project management, supply chain, biorepository and specimen management, and clinical trial sample and consent tracking solutions. Through its Decentralized Clinical Trials group, $Q^2$ Solutions is at the forefront of patient-centric sampling, offering a variety of self-collection methodologies and is validating multiple assays using micro-samples that are self-collected by study participants.

Tasso is an emerging healthcare technology company that is transforming the traditional blood collection paradigm with a patient-centric approach. The company's devices enable simple, convenient, and virtually painless blood collection for users.

The Neoteryx range of microsampling products from Trajan Scientific and Medical provide precise, quantitative remote specimen collection. They are easy to use and amenable to automated analysis in the lab, easing workflows and enabling decentralized research and healthcare models in keeping with Trajan's purpose to enrich personal health through scientific tools and solutions.

YourBio Health eliminates barriers to blood collection by allowing a patient blood sample to be collected from any location without the pain of a fingerprick or need for traditional phlebotomy.

## GOLD

Celerion, a global leader in early clinical research services, conducts First-in-Human, clinical Proof-of-Concept and patient dose response studies, cardiovascular safety and clinical pharmacology research supporting product labeling. With purpose-built, co-located clinic and laboratory facilities and highly automated technology, Celerion provides full study services including clinical study conduct, data management and biometrics, PK/PD analysis, medical writing and bioanalytical services.

For over 20 years, Synexa Life Sciences has supported large and emerging biopharma customers across the globe to achieve their clinical milestones through the delivery of cutting-edge biomarker and bioanalytical services. Synexa specialises in the development, validation and delivery of a wide range of complex and custom-designed assays across five laboratory locations

York Bioanalytical Solutions is a specialist regulatory bioanalytical CRO providing PK, biomarker and immunogenicity analysis. We have supported multiple global clinical programs for the successful implementation of patient centric sampling (method development, validation, bridging studies and sample analysis).

Waters Corporation is the world's leading specialty measurement company focused on improving human health and well-being through the application of high-value analytical technologies and industry leading scientific expertise. Whether it's discovering new pharmaceuticals, assuring the safety of the world's food and water supplies, or ensuring the integrity of a chemical entity in production, we are constantly working with our thousands of customers to leave the world better than we found it

## SILVER

Altasciences is an integrated drug development solution company offering pharmaceutical & biotechnology companies a proven, flexible approach to preclinical & clinical pharmacology studies, including formulation, manufacturing, & analytical services. For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, & more complete early drug development decisions. Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology & proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, & data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.

Alturas Analytics is a GLP-compliant bioanalytical CRO, specializing in MS/MS solutions to support early discovery through late-phase clinical trials. In addition to providing PK support services to pharmaceutical companies worldwide, Alturas maintains an intensive research effort to apply new technologies toward scientific advancement.

At Drawbridge, we've created the OneDraw technology to transform the way blood is sampled and shipped. But that's just the start. Our ultimate goal? To give everyone, everywhere access to the powerful health information within their own bodies.

Rhinostics' mission is to revolutionize laboratory workflows, one purpose-built collection device at a time. We improve sample collection comfort and performance while bringing efficiencies to the laboratory to remove costs and save time compared to traditional sample collection intake.

SCIEX helps scientists in pharma discovery, development and manufacturing to transform pipeline capacity and capability through the adoption of CE and LC-MS technologies. You benefit from innovative technology that makes complex workflows easier and more efficient, while delivering the utmost in data quality. Highly reliable instrumentation, with high sensitivity and dynamic range for a variety of analytical applications. Advanced software with automation to make data processing easier

Veloxity Labs, LLC provides rapid and client centric bioanalytical and biomarker services. We offer both non-regulated and GLP analysis of non-clinical and clinical samples.

Winnoz Technology, Inc., an innovator in decentralized healthcare and biosensing technology, specializing in advanced medical devices. Winnoz develops Haiim Vacuum-assisted Blood Collection System, a **portable**, **reusable**, and **lower labor required** blood drawing technology which enables you to conduct onsite blood sampling, **significantly reducing testing cycles**, and **scaling up your testing services** to provide **timely care** to your clients."

## SPEAKERS

### SILVIA ALONSO RODRIGUEZ (ASTRA ZENECA, UK)

*Thinking Patient Centricity: Reflections of a PCS case study*

A focused patient centric approach is key to secure the present and future of clinical trials. Strategies which are faithful to the overall clinical vision of novel therapeutics require new and innovative precision medicine approaches that places the patient at the centre of drug development. Agile approaches to patient enrolment requires an emphasis on flexible sampling, ease of access, and deployable digital technologies allowing care givers and clinical trialists to monitor the well-being and safety of their patients on clinical trials. Partially we have COVID to thanks for the PCS acceleration and change of mindset especially with the use of various home sampling approaches. Home sampling is now a standard practice for many clinical trial sample testing, making some healthcare providers more accessible to patients and in their comfort of their home.

With this presentation, Silvia would like to reflect on the importance and considerations of a patient centricity approach as well as sharing her reflections and experience working in a PCS case study. She will also be looking at the overall considerations, challenges, and successes of a PCS case study.

#### BIO

Silvia is currently working at AstraZeneca as Associate Director-Operations Lead in TSEM (Translational Science & Experimental Medicine) in early R&I and has a particular interest in the areas of Innovation, Patient Centricity and Digital Health. She joined AZ in 2019 as a Biosamples Project Lead within PMB and Silvia's first involvement in a PCS case study triggered her interest in decentralized trials and the patient centricity work.

Prior to Astrazeneca, Silvia worked at the University of Cambridge and before that at various life science, pharma and biotech organizations in Switzerland and Spain, such as such Roche Glycart, ETH Zurich, 4-Antibody AG, Covance CLS (now Labcorp), INIBIC (Instituto de Investigación Biomédica A Coruña)-Hospital Infantil Teresa Herrera and Centro Oncologico de Galicia (COG). Silvia has a scientific background and holds a biomedical clinical laboratory degree obtained in Spain.

### HUGUES CHANTEUX (UCB, BELGIUM)

*The Use of Volumetric Patient Centric Blood Sampling in Paediatric and Adult Drug Development Programmes*

These last years, the use of patient centric sampling approaches has significantly grown in clinical research. Indeed, compared to conventional venous blood sampling, they bring several advantages for both patients and clinical scientists. However, implementation in clinical drug development of such new sampling techniques for pharmacokinetic application requires robust bridging strategy to ensure acceptance of these data (and their subsequent analysis using population PK or other modelling tools) by health authorities at time of new drug application.

The presentation will showcase 3 examples of implementation of a patient centric sampling approach (based on volumetric absorptive microsampling [VAMS]) in clinical drug development. The overall clinical pharmacology strategy for bridging between plasma exposure (obtained from venous blood sampling) and blood exposure (obtained with VAMS) will be shared and key results from the bridging will be presented. Finally, the importance of each program specificities in the development of an adequate bridging strategy will be highlighted.

#### BIO

Hugues Chanteux is currently working at UCB (Belgium) as quantitative clinical pharmacology lead for CNS programs where he was deeply involved in the implementation of VAMS as blood sampling technique in his programs. Before joining UCB, he graduated in pharmacy and obtained a PhD in pharmaceutical sciences in 2003 from Catholic University of Louvain in Belgium. After his

PhD and a post-doc, he joined UCB Pharma in 2005 where he started his career in the preclinical DMPK department where he has been head of in vitro ADME laboratory for more than 10 years. Finally, for more than 5 years, in parallel to his clinical pharmacology role, he is head of clinical PBPK team which supports drug development of new chemical entities.

### ARIANE KAHNT (JANSSEN, BELGIUM)

*Introduction to Patient Centric Sampling - Benefits and Technologies Available*

Technologies that enable patient centric sampling (PCS), or the practice of sample self-collection by patients, have the potential to improve certain processes in clinical studies. PCS devices allow sample collection remotely from clinical facilities for example in a home sampling setting or in remote geographical locations. They can offer benefits regarding clinical trial recruitment and can improve logistical hurdles. Especially with regards to collecting small and precise blood volumes, those devices can reduce patient burden and can also provide opportunities for additional sampling time points or regarding the participation of a more divers patient population (e.g., for geriatric, and paediatric patients). Examples of successful applications in diagnostic testing have been described, and their application for pharmacokinetic (PK) and biomarker analysis is increasing. Many PCS devices provide a dried blood sample whereas traditional PK samples are collected from venous blood, which is further processed to liquid plasma. Depending on the compound's properties, the PCS sample require less cumbersome handling, storage and shipment processes and might bring novel drugs faster to the market and reduce costs.

This presentation will summarize the technologies available and will provide a general overview with a focus on PK sampling applications. The value of PCS and potential considerations for an implementation in clinical drug development will be discussed to further promote and enable decentralized clinical trials in the future.

#### BIO

Ariane Kahnt is a pharmacist by training and obtained a Ph.D. in Natural Sciences (Chemistry) from the University of Leipzig, in Germany in 2012. After her postdoctoral research on the structural identification of unknowns in atmospheric aerosols (University of Antwerp, Belgium) and metabolomic and proteomic research for potential Biomarkers (University of Auckland, New Zealand) she joined the Bioanalytical Department at Janssen Research and Development in Belgium in mid-2016. Ariane monitors and provides bioanalytical support on different projects in pre-clinical and clinical development, including method development and validations of PK assays using LC-MS technologies. Since 2018 she leads a small team of lab technician, and is as a Senior Scientist responsible for the implementation of bioanalytical strategies, scientific oversight, and contributes to bringing molecules to medicine to patients.

### NITHYA PARANTHAMAN (THE ROYAL MARSDEN HOSPITAL, UK)

*Improving the Multiple Myeloma Patient Pathway: Microsampling for Remote Monitoring of Free Light Chains*

Multiple Myeloma (MM) is categorised as a relapsing-remitting blood cancer with unpredictable relapse patterns. Due to an inevitable relapse, blood test monitoring is crucial and requires frequent visits to the phlebotomy clinics. The measurement of serum free light chains (FLC) can provide a rapid indication of MM disease progression and therapeutic response. Volumetric absorptive microsampling (VAMS) introduces a self-administered, capillary blood sampling technique that has potential to be a promising tool for remote MM monitoring. Among MM patients who frequent the Royal Marsden Hospital (RMH) phlebotomy clinic, 72 patients had paired serum and VAMS samples collected. A total of 97% of study participants were satisfied with their first experience with VAMS for the quantification of FLC. There was no significant difference in perception of pain between phlebotomy and VAMS (P=0.5502); however, 63% of patients preferred VAMS; 4% preferred phlebotomy; and 32% had no preference. On average, participants travelled 27 miles from their home to the RMH, ranging from 2-146 miles. The majority (63%) attended the clinic that day for phlebotomy services only. More than a third of patients (34%, n=24) had routine blood tests postponed/deferred by their treating team due to the Covid-19 pandemic. If given the choice between phlebotomy or VAMS, 86% (n=61) would've preferred the use of VAMS at home to avoid traveling to the hospital during the pandemic. The

results from this trial indicated that MM patients are both satisfied with and prefer microsampling as an alternative for venepuncture in the routine monitoring of FLC.

BIO

Nithya Paranthaman is currently a Senior Scientific Officer at The Royal Marsden Hospital (RMH; Sutton, UK). Nithya's research focuses on developing remote patient monitoring schemes in cancer pathways. Her PhD dissertation involved method development and optimization of microsampling tools to monitor disease status in multiple myeloma patients. Prior to joining the RMH, she worked at Sanofi Genzyme (MA, USA) and Novartis (NJ, USA). Her research interests lie at the intersection of medicine and science.

## CHIARA ROSPO (UCB, BELGIUM)

*Bioanalytical and Regulatory Considerations*

Bioanalytical validations of methods to quantify analytes using patient centric sampling technologies need to include all the conventional assay validation assessments and several additional technical considerations that must be evaluated with proper planning ahead of clinical studies to ensure methods are fit for purpose. These additional assessments are part of the ICH guideline M10 on bioanalytical method validation and study sample analysis guidance. In this talk real case studies will be presented with focus on validation challenges and analysis of clinical samples.

BIO

Chiara Rospo is a Bioanalytical Scientific Manager at UCB with more than 20 years of experience in clinical development. She started as bioanalytical scientist working in different pharma companies and biotech (Pharmacia, GlaxoSmithKline, Cell Therapeutics) where she held roles of increasing responsibility. In 2009 she joined UCB Biopharma SRL as Head of Discovery Bioanalysis and in 2015 she was appointed as Bioanalytical Scientific Manager. In addition to her role, she co-leads a cross functional team setting up the strategy and guiding the implementation of patient centric sampling in UCB decentralized clinical trials.

## JENNY ROYLE (MEDIPACE, UK)

*Putting the Patient at the Centre*

How and why should we engage patients in early clinical development? How can we do this and avoid setting unrealistic expectations? How do we balance information from patients with other expertise and requirements? All will be covered in this talk and questions after are welcome. Join with me as we discuss.

BIO

Jenny has many years experience in the pharmaceutical industry, as well as founding a digital patient engagement and research group bridging the NHS, charities, academia and Pharma. She has delivered infrastructure, patient standards and charters, coalition structures and patient co-creation projects, facilitation, and patient research for Pharma, CROs and academia.

## JAMES RUDGE (TRAJAN SCIENTIFIC & MEDICAL, UK)

*Use of Patient Centric Sampling in Clinical Trials & Public Health*

Since the Covid-19 pandemic, there has been a noticeable increase in the interest of using patient centric sampling (PCS) in clinical trials, both in-clinic, but also in remote settings. Much focus has been given to the collection of capillary blood, both wet and dried. Wet blood has the benefit of being converted to plasma and serum, and so can be used for tests such as safety panels. However dried blood conveys much better stability for a large range of analytes, such as drugs and metabolites used in PK/PD studies.

For several years, PCS has proven successful in providing crucial samples from patients in remote settings and for cases where venepuncture is a challenge, such as accessing collapsed veins or sampling children. However, transitioning from traditional clinical and public health trial design towards remote or hybrid trials is not without its challenges. This presentation will highlight benefits and challenges of PCS in clinical and public health trials, and showcase examples where this has been as success as well as discussing what the future may hold.

BIO

James Rudge, PhD, is Technical Director at Neoteryx, the microsampling product brand of Trajan Scientific and Medical. He is a co-inventor of the patented Mitra® device and VAMS® technology. Dr. Rudge has co-published 16 papers on VAMS microsampling with co-authors from around the globe, and he authored a book chapter on VAMS in 2021. Among his recent events and speaking engagements, Dr. Rudge was a vision speaker at the 2021 CPSA (Clinical & Pharmaceutical Solutions through Analysis) USA virtual conference and chaired a session at the Outsourcing Clinical Trials conference UK & Ireland, focused on decentralized clinical trials. He is involved in several international research collaborations, including a large European research consortium addressing unmet needs in inflammatory disease.

## MICHA LEVI (GATES MRI, USA)

*Implementing a Patient-centric sampling strategy in the global clinical development of RSM01 (Anti-RSV mAb)*

The presentation will showcase the successful implementation of a patient-centric sampling strategy in the global clinical development of RSM01, an anti-RSV monoclonal antibody, by utilizing dried blood collected on VAMS (Volumetric Absorptive Micro Sampling) technology. The presentation will provide a real-world example to demonstrate the comparable conclusions from VAMS versus serum, in addition to the numerous benefits of this approach and its value in advancing global clinical drug development. Attendees will gain insights into the development and validation of the patient-centric sampling strategy and how it was utilized to collect high-quality samples for pharmacokinetic analysis. Additionally, the presentation will highlight the potential applications of this approach in other therapeutic areas.

BIO

Dr. Micha Levi is a Clinical Pharmacologist and Pharmacometrician at the Gates Medical Research Institute. He specializes in implementing pharmacometrics strategies and Model-Informed Drug Development (MIDD) approaches to develop therapies for TB, Malaria, RSV, and other infectious diseases in resource-limited settings. Dr. Levi's research involves using quantitative methods to optimize dosing, evaluate drug efficacy, and inform drug development decisions.

## PLATINUM SPONSOR PRESENTATIONS

### IAIN LOVE (CHARLES RIVER LABORATORIES, UK)

*Routine Adoption of Patient Centric Samples in the Analytical Laboratory*

Patient Centric Sampling is well understood to provide choice and benefit to the patient as well as effecting improvements to the speed and efficiency of Clinical trials. As we move towards these unique sample formats, the analytical laboratory is challenged with adapting in order to sustain the provision of high quality data in support of critical decision making. This short presentation will describe the key considerations of the analytical lab in providing support for clinical studies employing patient centric sampling.

### JOHN CORCORAN ($Q^2$ SOLUTIONS, USA)

*Operational Considerations for Patient Centric Self-Collection*

A brief overview of the operational and logistical consideration around deploying self-collection devices to study participants and the impact on accessioning at $Q^2$ Solutions Central Lab . Including on-line ordering, requisition and kit building, shipping to and from a site or participant, specimen handling and processing, patient and site support and lab accessioning.

### ERWIN BERTHIER (TASSO, USA)

*Patient-Centric Sample Collection Enables Denser and More Resilient Data Collection in Clinical Trials*

Patient-centric sampling solutions are emerging as powerful solutions to reach participants that are underserved or understudied in clinical trials as well as population health and research studies. These technologies require careful design of the implementation protocol, however, in particular regarding logistics and support mechanisms for the participants. Beyond moving visits to the home, patient-centric technologies open new windows into physiological mechanisms by allowing the collection of clinical data at times and frequencies that were not previously available.

### MINNA SALONEN (TRAJAN SCIENTIFIC & MEDICAL, FINLAND)

*Utilizing microsampling to improve data, recruitment and diversity in clinical trials*

- Addressing the FDA guidance on diversity and pediatrics with microsampling.
- Low rejection rates enable remote collection and better data collection.
- Elimination of cold-chain shipping can reduce costs and expand the reach into underserved communities.

### PATRICIA HOLMAN (YOURBIO HEALTH)

*Increasing participant engagement and completion with TAP blood collection technology*

Pat Holman, Clinical Development for YourBio Health will be sharing information about YourBio Health services for blood testing in clinical trials and introduce the TAP blood collection devices which reliably collect a high quality whole blood sample from the upper arm making remote self-collection a viable option. Innovative 'halo' technology enables a user experience that is virtually painless and has been demonstrated to increase participant engagement by 200% in remote clinical trials.

## ORGANISERS / SESSION CHAIRS

### JAMES RUDGE - *Trajan Scientific & Medical, UK*

#### BIO

James Rudge, PhD, is Technical Director at Neoteryx, the microsampling product brand of Trajan Scientific and Medical. He is a co-inventor of the patented Mitra® device and VAMS® technology. Dr. Rudge has co-published 16 papers on VAMS microsampling with co-authors from around the globe, and he authored a book chapter on VAMS in 2021. Among his recent events and speaking engagements, Dr. Rudge was a vision speaker at the 2021 CPSA (Clinical & Pharmaceutical Solutions through Analysis) USA virtual conference and chaired a session at the Outsourcing Clinical Trials conference UK & Ireland focused on decentralized clinical trials. He is involved in several international research collaborations, including a large European research consortium addressing unmet needs in inflammatory disease.

### DAVID SCIBERRAS – *FBPhS*

#### BIO

BSc in Human Biology and MSc in Biopharmacy. PhD in Clinical Pharmacology (University of London, Royal Free Hospital). 30 years experience at Merck, GE Healthcare, Amgen and most recently UCB leading early phase drug development projects in a wide variety of therapeutic areas. Responsibilities included first in human, proof of concept and providing clinical pharmacology input and advice to late stage development programmes. Initiated and led the implementation of microsampling (VAMS) in 2 global UCB early development programmes. Fellow of the British Pharmacological Society (served as clinical section committee member) and previous Chair of Association for Human Pharmacology in the Pharmaceutical Industry (AHPPI). Previous Chair of ABPI Experimental Medicines Group.

### NEIL SPOONER - *Chair and Founder of PCSIG*

#### BIO

Neil Spooner (Ph.D., C.Chem., F.R.S.C.) is the Founder of Spooner Bioanalytical Solutions and the Patient Centric Sampling Interest Group. Neil is a Senior Visiting Research Fellow at the University of Hertfordshire, Editor in Chief of Bioanalysis Journal, and Co-Chair of the Reid Bioanalytical Forum. He has published over 60 peer reviewed manuscripts and made more than 40 podium presentations at international conferences. Neil has extensive experience in the quantitative bioanalysis of drugs, metabolites and biomarkers in the pharmaceutical industry. His current focus is on working with partners to progress microsampling and patient centric sampling technologies for the generation of high quality quantitative bioanalytical data.

## NOTES