# BIOMARKERS

## UK IN-PERSON 2022

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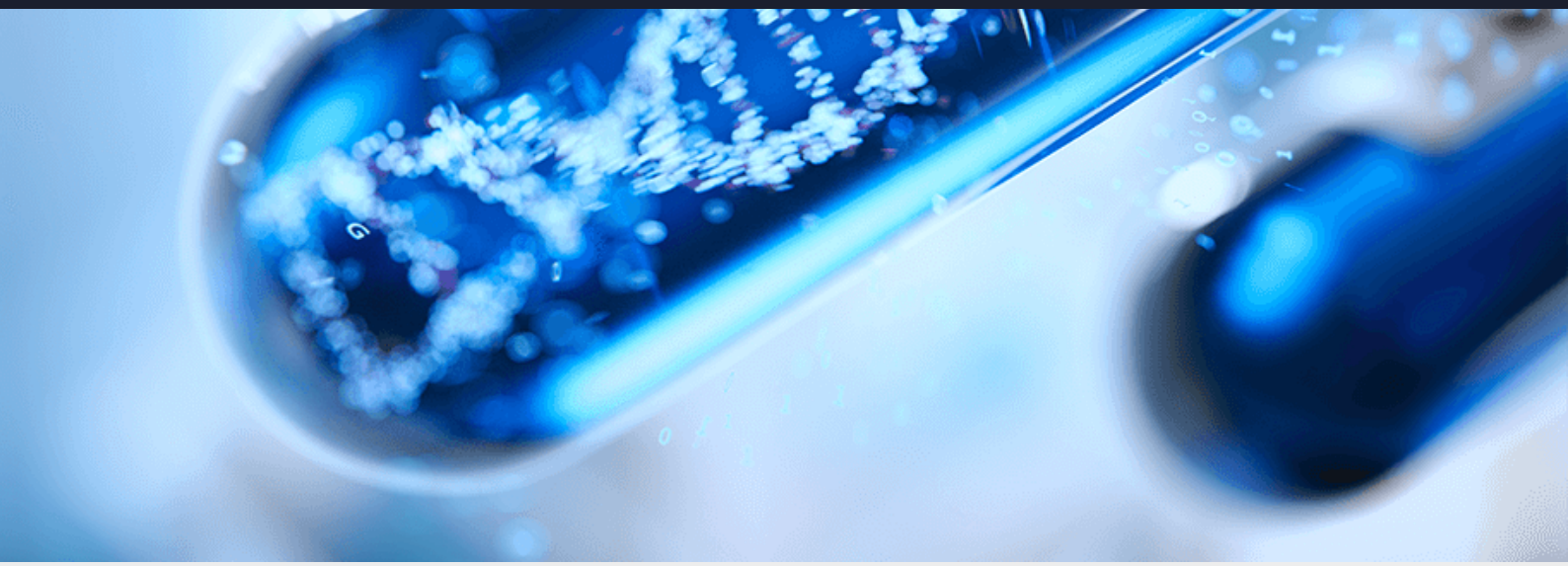

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**I am very excited to reveal what we have in store for you during our interactive and engaging hybrid conference. The Biomarkers UK Congress brings together industry experts from global pharmaceutical and biotech companies, internationally renowned academic & research institutions.** In line with current industry trends, we are pleased to welcome you to this year's event curated to cover cutting-edge research & technological advancements shaping the biomarker industry. This unique event will enable you to gain a forward-looking perspective on the latest technologies and strategies impacting biomarker research across multiple applications and therapeutic areas. This jam-packed conference will provide cutting-edge content through presentations, panel discussions, and speaker Q&As. We are hugely thankful to our speakers, who have given their time to provide interesting, thought-provoking presentations, and to our sponsoring companies, who have worked closely with us to provide you with unique opportunities to access the latest information on solutions and services that can directly impact and improve your research and results. Without their support this event would not be possible, so please do take some time to visit them on-site, but also their featured sponsor pages on the accompanying digital platform and engage with the content and resources that they have made available. A significant proportion of these exciting talks will take place on-site but will be made available on our accompanying digital platform, where you will be able to watch content Live and create a tailored agenda for your needs and interests. The on-demand section of the platform is available for those with a full conference pass. Networking & knowledge-sharing is at the heart of what we do. Apart from the innovative programme, your event experience will be linked to the event app, where you can engage in a variety of event features including AI-based suggestions to make connections, chat through text or video and the ability to schedule meetings with anyone of interest. The event platform is linked to the on-site conference application and will allow you to exchange contact details, files and links to build a wealth of information for your use, post-event. To

# WELCOME

maximise your access to available resources at the event we have created the Digital Gallery , on the digital platform where you can find a host of product information or informative content most relevant to you and your research interests. If you have any questions, please contact a member of the team on-site or if you are accessing the content online, then please do visit us at our Help & Information Desk. In both instances a member of the Oxford Global team will be available to assist and ensure you get the best experience you can from the event. We do hope you will enjoy Biomarkers UK 2022 and look forward to welcoming you to the conference. See you then!

**Hayley Watson,**

Portfolio and Client Engagement Director

## CONTENTS



**Speaker Biographies & Session Information**

# Biomarkers UK: In-Person

## Exhibition Floorplan - Champagne Suite

| | | | |
|---|---|---|---|
| 1. | Proteome Sciences | 2. | BioLizard |
| 3. | Olink | 4. | 10x Genomics |
| 5. | Oxford Global | 6. | Bio-techne |
| 7. | Precision For Medicine | 8. | CellCarta |
| 9. | Leica Biosystems | 10. | Cellecta, Inc |
| 11. | Rules Based Medicine | 12. | Cell Signaling Technology |
| 13. | Owlstone Medical | 14. | LGC |
| 15. | Personalis, Inc. | 16. | ACROBiosystems |
| 17. | Novai | 18. | Luminex |
| 19. | Quanterix | 20. | Almac Group |
| 21. | Poster Presentations | 22. | Propath |
| 23. | NanoString Technologies | 24. | BioView Ltd. |
| 25. | Somalogic | 26. | NeoGenomics |
| 27. | Indica Labs | 28. | Radiomics |
| 29. | Sino Biological | 30. | TATAA |
| 31. | Lunaphore Technologies S.A. | 32. | The Science Behind |
| 33. | DermTech | 34. | Biognosys |
| 35. | Indivumed | 36. | Merck |

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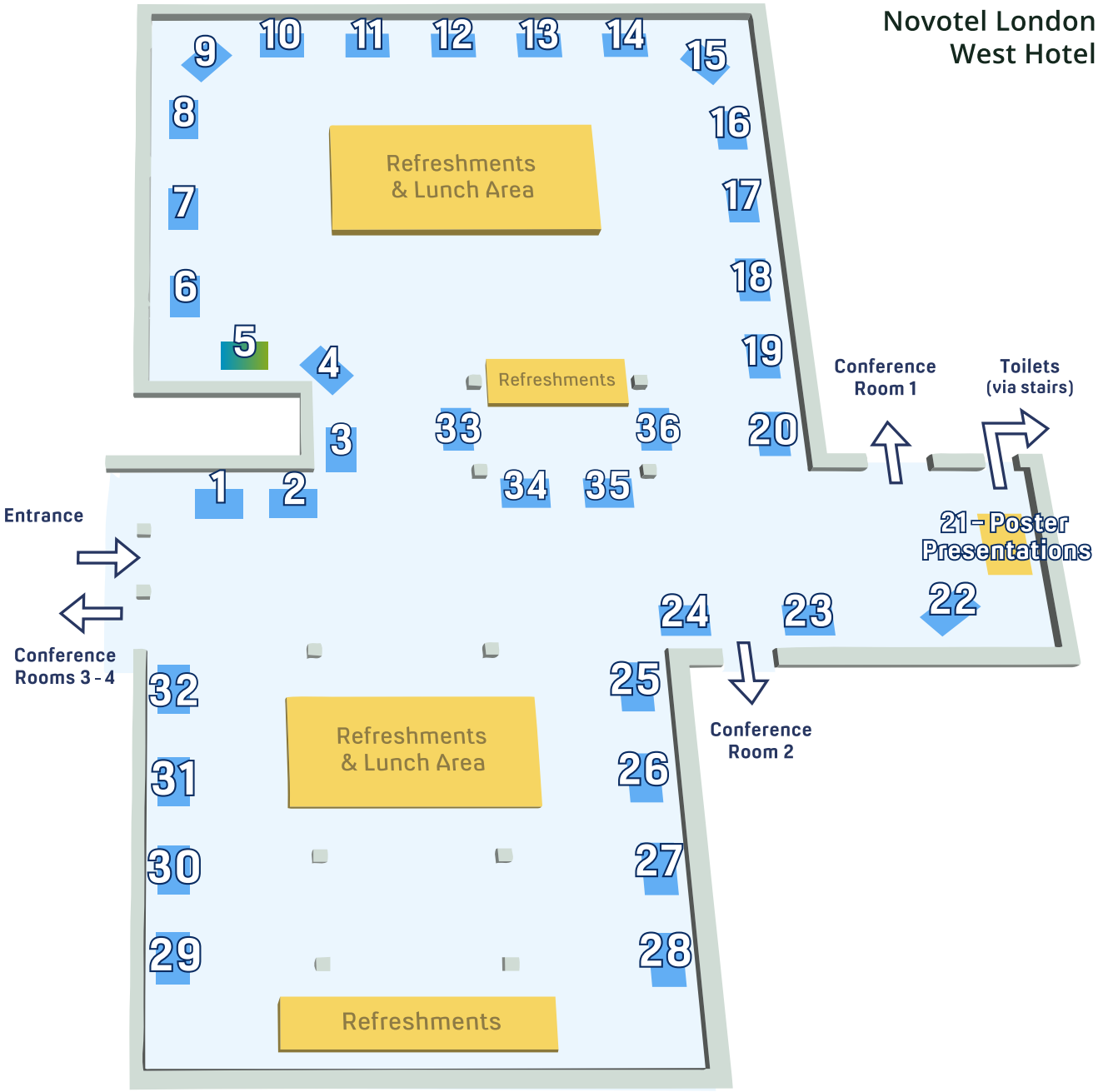

# BIOMARKERS

## NETWORKING DRINKS

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Tuesday 03 May, 5:45pm

in the Exhibition Area

We hope to see you there,

OXFORD
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# DOWNLOAD THE EVENT APP

Scan this QR code to download the event app, Swapcard, which also serves as our digital platform for the event.

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## PLATFORM FEATURES

### BUILD YOUR PROFILE & EVENT TIMETABLE

**Our platform will automatically match you to other attendees with similar interests, the most relevant programme sessions and exhibitors that best fit your requirements.** With pre-event access, you can start to make connections and build your event experience before the live programme begins!

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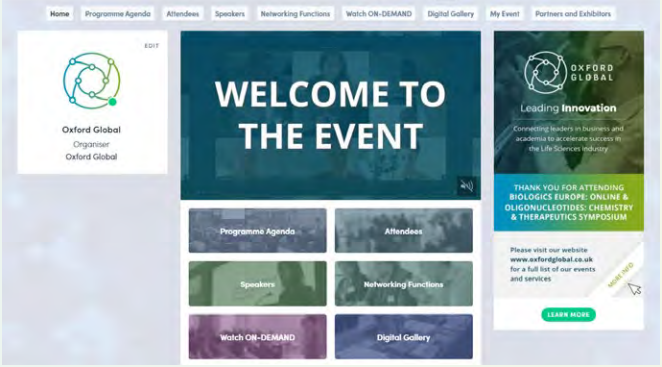
**Connect with our sponsors and exhibitors during the event by searching for specific products, services and solution types.** Connect via arranged meetings / direct chat to discuss your requirements and access a wealth of information from each sponsor's page to review their latest offerings.

### BE PART OF THE COMMUNITY

**With a range of live discussions, Q&A's and serendipitous networking opportunities, getting involved in the event couldn't be easier.** From submitting a question in text during a presentation to taking part in our randomised speed-networking, you choose how and when to meet and connect with others during the event.

### THE PROGRAMME

**Build your own agenda** with our combination of live & recorded sessions, focused panel discussions, roundtable debates and live inter-active workshops. Utilise full-pass benefits to watch any session at any time with full on-demand access.



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Owlstone Medical has developed and commercialized Breath Biopsy® Products and Services for the reliable collection and analysis of volatile organic compound (VOC) biomarkers on breath. We lead the world's largest breath based clinical trials and have established the first high volume breath analysis lab with ISO 9001 certification and a rigorous system of quality checks at every stage of the workflow. Our Breath Biopsy OMNI service for pharmaceutical and academic customers is our complete solution for global VOC biomarker discovery with high-confidence biomarker identification and validation to support drug and diagnostics development programs. We are also experts in miniaturized VOC detection technologies based on Field-Asymmetric Ion Mobility Spectrometry (FAIMS). Once suitable clinical biomarkers have been identified, we have capabilities to devise cost effective, rapid, small footprint devices for point of care, near patient or even home-based testing. Unlike liquid and tissue biopsies, which require blood or tissue samples to be taken, Breath Biopsy provides a completely non-invasive solution that maximizes patient comfort for biomarker measurement.

## Personalis, Inc.

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Personalis, Inc. is a leader in advanced cancer genomics for enabling the next generation of precision cancer therapies and diagnostics. The Personalis NeXT Platform® is designed to adapt to the complex and evolving understanding of cancer, providing its biopharmaceutical customers and clinicians with information on all of the approximately 20,000 human genes, together with the immune system, from a single tissue sample. To enable cancer sequencing, Personalis Clinical Laboratory was built with a focus on clinical accuracy, quality, big data, scale, and efficiency. The laboratory is GxP-aligned as well as Clinical Laboratory Improvement Amendments of 1988-certified and College of American Pathologists-accredited.

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The path from research discovery to effective immune cell therapies requires innovative approaches to match the challenges we face. Examining the full richness of biological complexity—moving from incremental snapshots to a complete systems view—can uncover molecular insights into therapeutic efficacy and toxicity and accelerate the development of novel treatments.

Access the resolution you need to explore complex tumour heterogeneity, suppressive tumour microenvironments, poor trafficking, and intrinsic T-cell dysfunction with single cell and spatial multiomics. Identify novel cell types and biomarkers, track clonal behaviour, and monitor the behaviour of cells over time. Join us to learn how Chromium Single Cell and Visium Spatial solutions from 10x Genomics can transform the way you approach cancer biology and tackle immune cell therapies from a bold new vantage point.

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Abzu® was born from the desire to challenge the fundamental assumptions of contemporary, black-box AI. Abzu's pioneering technology, the QLattice®, is a research engine that accelerates exploration, enabling scientists to bring drugs to market faster.

The QLattice introduces a new standard of interpretability and explainability to life science data sets. Through simple models and straightforward mathematical expressions, Abzu's QLattice achieves a level of transparency and performance in machine learning that is disrupting domains previously dominated by opaque and cumbersome models.

Founded in January 2018, Abzu is a deep tech start-up with offices in Copenhagen, Denmark and Barcelona, Spain. Abzu derives its name from Ancient Sumerian, meaning "the source of the waters of wisdom".

Abzu has raised a total of €8,1M, and last closed a seed round in April 2021 for €4.9M.

## Almac Group

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Almac Diagnostic Services. Always a move ahead in precision medicine. Your global partner for biomarker discovery, development & commercialisation. Our global CLIA and CAP accredited laboratories cover UK, Europe, USA and APAC regions. Our cores services include:

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## Lunaphore Technologies S.A.

Email: contact@lunaphore.com
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Lunaphore Technologies S.A. is a Swiss company born in 2014 with the vision of enabling spatial biology in every laboratory. Lunaphore has developed a game-changing chip technology which can extract spatial proteomic and genomic data from tumours and transform any simple assay into multiplex spatial biology without complexity. Lunaphore empowers researchers to push the boundaries of research to ultimately develop the next generation personalized therapies. For further information on Lunaphore and its products, please visit www.lunaphore.com.

## Merck

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Merck Life Sciences is a leader in biomarker immunoassays, including 200+ MILLIPLEX® multiplex kits with over 1,200 different analytes, for use with Luminex® instrumentation, an ultra-high sensitivity platform for Single Molecule Counting (SMC™), including instrumentation and assays, and a broad portfolio of ELISA kits, all with best-in-class validation. Merck offers the broadest available selection of unique analytes, as well as custom immunoassay development services, allowing you to pick your platform, degree of customization, and validation levels and types to meet investigational or translational research needs. Merck continues to update their portfolio in areas such as oncology, immunology and neuroscience. Merck's latest application area combines high sensitivity anti-drug antibody (ADA) detection using SMC™ technology, combined with MILLIPLEX® multiplex detection of immunoglobulin subtypes and complement pathways. For the first time you can detect ADA and subclass the immunoglobins and then study the effect on the complement pathway all in one portfolio. For all our biomarker kits, we set the performance criteria during assay development and uphold it for subsequent lots to ensure reproducible results you can trust. In addition, Merck continues to provide advancements in stable isotope reagents for solid state,

metabolomics, and MR imaging. Our precision chemistry expertise combined with robust quality systems and global supply chain can support your biomarker detection and analysis.

## NeoGenomics

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NeoGenomics, Inc. specializes in cancer genetics testing and information services, providing one of the most comprehensive oncology-focused testing menus in the world for physicians to help them diagnose and treat cancer. We enable advanced oncology patient care leveraging the most extensive diagnostic solid tumour and hematological test menus, sub-specialty pathology, and expertise in biomarker development. The Pharma Services Division partners with pharmaceutical and research clients in clinical trials and drug development to meet program objectives and delivery from biomarker discovery through CDx validation and commercialization. Our global cross-functional teams are based across a CAP/CLIA global laboratory network in US, Switzerland, Singapore and China.

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Olink offers an unmatched high-multiplex technique to identify actionable biomarkers, with a strong focus on the human plasma proteome. Using minimal sample volume, we provide quantifiable results with high-throughput, exceptional sensitivity and specificity, with coverage across a broad dynamic range. Our mission is to accelerate proteomics together with the scientific community across multiple disease areas to enable new discoveries and better understand complex real-time human biology. We are committed to develop our offering and are continuously expanding our protein coverage for a growing number of biological processes and pathways.

Olink is well-established in Europe (HQ Uppsala, Sweden) and the USA (HQ Boston, MA), with a rapidly developing presence across Asia. We also work with a growing number of core labs around the world offering analysis and support to an expanding global customer base.

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Quanterix is a company that's digitizing biomarker analysis with the goal of advancing the science of precision health. The company's digital health solution, Simoa, has the potential to change the way in which healthcare is provided today by giving researchers the ability to closely examine the continuum from health to disease. Quanterix' technology is designed to enable much earlier disease detection, better prognoses and enhanced treatment methods to improve the quality of life and longevity of the population for generations to come. The technology is currently being used for research applications in several therapeutic areas, including oncology, neurology, cardiology, inflammation and infectious disease.

## Sino Biological

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Sino Biological Europe GmbH sits in Frankfurt, Germany, with a local sales and service team, as well as our protein inventory.

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## Cellecta, Inc

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## TATAA

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ACROBiosystems continue to grow and adapt to bring more value to our clients by providing more technical resources and custom services, promoting training and communication opportunities, initiating collaborations in the bio-industry community, and facilitating transactions in the dynamic global and each niche market.

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www.twitter.com/Biorelate
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It is estimated that over 80% of all biomedical knowledge is still held in unstructured text, making it extremely difficult to access and use in analytical workflows. This huge resource of untapped knowledge is currently unavailable within public or proprietary databases as, even the most up to date manually curated databases do not cover the wealth or breadth of information stored within this text, and there is at least a 6-month lag between publication and curation. Biorelate has developed a fully automated NLP/AI platform to mine cause-and-effect data buried within biomedical literature. Galactic Data includes more than 16M cause-and-effect interactions across proteins, chemicals, cells, phenotypes and more, all within 1.4B+ contextual points for flexible disease modelling, all curated automatically. Biorelate works with pharma companies providing this valuable data through direct access to support data owners and data scientists and an easy-to-use web application for biologists, bioinformaticians, and analysts.

## BioView Ltd

www.bioview.com
www.twitter.com/bio_view
www.linkedin.com/company/bioview2020

BioView Ltd is a worldwide leader in developing and marketing automated scanning platforms for the imaging and analysis of cells.

BioView CTC scanning systems are designed to automatically detect, image and characterize circulating tumour cells from peripheral blood samples, providing:

- Automated 3D imaging compatible with any cell enrichment technique, from standard glass slide to membrane and complex 3D microfluidic chips.
- Automated analysis of any number of protein and genomic markers utilizing advance AI algorithms. Automated analysis takes place in parallel to imaging, making results available as soon as sample automated scan is completed.
- High throughput/High Capacity/One Step Operation.

The BioView CTC scanning systems are provided with a complimentary 2-year manufacturer development kit, which includes tailoring of imaging and analysis algorithms to the specific assay/s processed by the laboratory.

BioView CTC systems introduce high level of automation, standardization and sensitivity, in an all-in-one closed scanner, which is easy to operate and integrate with any circulating tumour assay.

## Cell Signaling Technology

**Tel: 978.867.2388**

Email: support@cellsignal.com

www.cellsignal.com

www.twitter.com/cellsignal

www.linkedin.com/company/cell-signaling-technology

Founded by research scientists in 1999, Cell Signaling Technology (CST) is a private, family-owned company with over 400 employees worldwide. Active in the field of applied systems biology research, particularly as it relates to cancer, CST understands the importance of using antibodies with high levels of specificity and lot-to-lot consistency. That's why we produce all of our antibodies in house and perform painstaking validations for multiple applications. And the same CST scientists who produce our antibodies also provide technical support for customers, helping them design experiments, troubleshoot, and achieve reliable results.

## CellCarta

**Tel: +1 (514) 360-3600**

Email: info@cellcarta.com

www.cellcarta.com

www.twitter.com/CellCarta

www.linkedin.com/company/cellcarta

Leading provider of specialized precision medicine laboratory services with integrated platforms in immunology, histopathology, proteomics, genomics, and related specimen collection and logistics services. CellCarta supports the entire drug development cycle, from discovery to late-stage clinical trials, and operates globally with laboratories in Canada, USA, Belgium, Australia, and China.

## Charles River Laboratories

www.criver.com
www.twitter.com/criverlabs
www.linkedin.com/company/charles-river-laboratories

Charles River will be attending the Oxford Global Biomarkers conference virtually and we are eager to connect with you. Please schedule a virtual meeting with us, and we will get in touch with you to set up a convenient time.

With multiple facilities in North America, the United Kingdom and mainland Europe, we provide clients with the consistent application of laboratory procedures, regardless of study location. Our comprehensive global portfolio of biomarker services covers a wide range of therapeutic areas translatable to the clinic while greatly accelerating candidate development and decreasing timelines.

Our extensive team assists with the discovery of biologically and scientifically relevant biomarkers, while measuring and interpreting their changes within the test system, relating them to the drug development program. From assay qualification to full validation, our experts propose fit-for-purpose validation fully adapted to the context of use (COU) of your biomarkers.

## Digital Science

www.digital-science.com
www.twitter.com/digitalsci
www.linkedin.com/company/digital-science

Digital Science is a technology company working to make research more efficient. We invest in, nurture and support innovative businesses and technologies that make all parts of the research process more open and effective. We believe that together, we can help researchers make a difference. Visit www.digital-science.com

## Indivumed GmbH

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www.twitter.com/Indivumed1
www.linkedin.com/company/indivumed-inc.

Indivumed is a physician-led, integrated global oncology company committed to unveiling complex mechanisms of cancer, in order to support precision oncology. Only a multi-omics approach can achieve this goal – and reliable multi-omics require especially high-quality biospecimens and data. Through its three divisions, IndivuServ, IndivuType, and IndivuTest, Indivumed offers specialized products and services that support customers in biomarker and target discovery, drug development, clinical trials, individualized therapy and more.

## Metabolon GmbH

www.metabolon.com
www.twitter.com/metabolon
www.linkedin.com/company/metabolon

Metabolon, Inc. is the world's leading health technology company advancing metabolomics for precision medicine and life sciences research. Its Precision Metabolomics™ is a powerful technology for assessing health and delivering biomarker discoveries, innovative diagnostic tests, and valuable data for genomics and population health initiatives. Metabolon's expertise is also accelerating research and product development across the pharmaceutical, biotechnology, consumer products, agriculture and nutrition industries, as well as academic and government organizations. The company was founded in 2000 and is based in Research Triangle Park, North Carolina. For more information, please visit www.metabolon.com or follow us on LinkedIn or Twitter.

## Novai

Tel: +44 207 1838 895
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www.linkedin.com/company/novai-tech

Novai is a biotechnology start-up, commercialising DARC Technology, an exploratory retinal biomarker for use in Age-related Macular Degeneration (AMD) and Glaucoma clinical studies. DARC combines an innovative patented biologic with a state-of-the-art AI algorithm and uses standard imaging equipment to identify cellular level disease activity.

DARC Technology can be used to measure the impact of current and future therapeutics and interventions by assessment of disease activity whilst identifying non-responders to existing and new interventions, resulting in the avoidance of costly, ineffective or un-required medical management. DARC helps to stratify patients in clinical trials, resulting in the creation of enriched patient cohorts, consisting of those at highest risk of rapid disease progression.

Following further analysis of Phase II data, several other indications may follow, including Multiple Sclerosis, Alzheimer's Disease, Parkinson's Disease and Diabetes Mellitus. Novai is interested in collaborating with potential partners to explore DARC's potential in CNS.

Website: www.novai.co.uk

## Oncimmune Ltd.

**Tel: +44 1157 840 500**
**Email: info@oncimmune.com**
**www.oncimmune.com**
**www.twitter.com/oncimmuneECDT**
**www.linkedin.com/company/oncimmune**

Oncimmune, a global leader in immunodiagnostics is focused on autoantibody biomarker profiling in immuno-oncology, autoimmune and infectious diseases. Through its ImmunoINSIGHTS™ technology platform, the company provides insights to discover and validate novel biomarkers, improve treatment responses and adverse event (irAE) prediction, patient screening and diagnostic accuracy. The headquarter is based in UK and operates in Germany and USA.

## Propath UK Ltd

**Tel: +44 (0)1432 354 052**
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**www.propath.co.uk**
**www.twitter.com/Propath_UK**
**www.linkedin.com/company/propath-uk-limited**

Propath are a leading specialist CRO providing histopathology, molecular pathology (IHC/IF/ISH, biomarker development, TCR) and NanoString gene expression and digital spatial profiling. For over

three decades we have successfully collaborated on thousands of studies with biopharmaceutical companies, from our GLP/GCP compliant facility, demonstrating our professionalism and commitment to client satisfaction. Today we are recognised as a leading specialist and collaborate with clients from across the globe.

Recognising the importance of Spatial Biology, we have invested in:

- NanoString GeoMx Digital Spatial Profiling platform. High parameter protein biomarker and Spatial Transcriptomics (Whole Transcriptome)
- Lunaphore COMET - hyper plex mIF (up to 40 plex)

Whilst adhering to deadlines is a given, our approach is to first invest time with our clients to understand the precise scientific objectives and then provide tailored solutions to achieve them. We believe that by working with you, rather than simply for you, we add significant value to your work.

## Radiomics

Email: info@radiomics.bio
www.radiomics.bio
www.twitter.com/radiomics_
www.linkedin.com/company/radiomics-bio

Founded in 2016 and based in Liège, Radiomics is a Belgian AI-powered research organisation for next-generation image analysis, based on the unique experience of its founders, pioneers in radiomic science. Oncology being Radiomics' initial focus area, we have developed promising applications in various other therapeutic areas, such the respiratory field. Radiomics uses its advanced image analysis technology based on AI, deep learning, machine learning, and federated learning to obtain quantitative biomarker measurements from medical imaging, in a repeatable, reliable, and relevant manner. Our goal is to support decision-making through insights and optimise pharmaceutical and biotech companies' clinical trials and drug development studies and provide clinicians with a patient-centred approach based on personalised medicine.

## Rules-Based Medicine (RBM, a Q2 Solutions Company)

Tel: (+01) 512 835 8026
Email: RBM_ClientServices@q2labsolutions.com
www.rbm.q2labsolutions.com
www.twitter.com/myriad_rbm

www.linkedin.com/company/rules-basedmedicine

Rules-Based Medicine (RBM), a Q2 Solutions Company, is the world's leading multiplexed immunoassay testing laboratory that solves complex drug development challenges with innovative biomarker services and a novel whole blood immunophenotyping device (TruCulture®). RBM's internally developed and manufactured immunoassays based on Multi-Analyte Profiling (MAP) and Single-Molecule Array (SimoaTM) ultrasensitive immunoassay technology provides translational and clinical researchers with reproducible and quantitative data for a few or hundreds of human proteins. The comprehensive menu provides extensive coverage of numerous pathways and delivers accurate pharmacodynamic and safety assessments. RBM's CLIA certified biomarker testing laboratory is located in Austin, TX.

Q2 Solutions is a leading global clinical trial laboratory services organization providing bioanalytical, genomics, vaccines, flow cytometry, anatomic pathology, immunoassay, companion diagnostics and central laboratory services with secure, enterprise-wide biospecimen and consent management solutions. With our industry-leading science, partnership approach and innovative solutions, we'll make sure our clients get the results that will turn patients' hope into the help they need


## Scailyte

www.scailyte.com
www.twitter.com/scailyte
www.linkedin.com/company/scailyte

Scailyte is an ETH Zürich spin-off with a best-in-class artificial intelligence platform for the discovery of complex disease patterns from single-cell data. Our solution provides unprecedented insight into the disease and patients' biology and enables the discovery of new clinically relevant biomarker signatures by uncovering human's hidden "single-cell" secrets. Scailyte's proprietary best-in-class data analysis platform ScaiVision™ associates multimodal single-cell datasets (RNA-/TCR-/BCR-seq, proteomics, etc.) with clinical endpoints, such as disease diagnosis, progression, severity, treatment response, and toxicity response to identify ultra-sensitive biomarker signatures and cell functionality states. The performance and clinically relevant applications of Scailyte's platform

ScaiVision have been demonstrated in well-established CAR-T cell therapies and various clinical projects in Oncology and Immunology

## The Science Behind

Tel: +44 (0)29 22644840
Email: contact@thesciencebehind.com
www.thesciencebehind.com
www.twitter.com/TheScienceBhind
www.linkedin.com/company/thesciencebehind

The Science Behind combines neuroscience, neurology and psychology expertise and hardware to provide a service that offers an array of electro-diagnostic markers to assess human brain excitability and functionality in health and disease. For those looking to measure target engagement, evaluate in-vivo markers for pharmacological activity and/or in-vivo markers for specific biological processes we can support trials with protocol design, delivery, data analysis and reporting.

## Yourgene Health

Tel: +44 (0)161 669 8122
Email: info@yourgene-health.com
www.yourgene-health.com
www.twitter.com/Yourgene_Health
www.linkedin.com/company/yourgene-health

Yourgene Health is a leading integrated technologies and services business, enabling the delivery of genomic medicine. The group works in partnership with global leaders in DNA technology to advance diagnostic science.

Yourgene Genomic Services is a global laboratory service network equipped to be a full life-cycle partner for clinical, research and pharmaceutical organisations to support partners at the preclinical, clinical, and post-market stages to develop, manufacture, obtain regulatory approval and commercialise new products and services.

Yourgene Health is headquartered in Manchester, UK with facilities in Taipei, Singapore, the US and Canada, and is listed on the London Stock Exchange's AIM market under the ticker "YGEN".

# DAY ONE | TRACK 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN ONCOLOGY & IMMUNO-ONCOLOGY

## Speaker Biographies and Session Information

The success of immune checkpoint blockade therapy has drastically advanced treatment of different types of cancer over recent years, however identification of patients who are responsive to these therapeutic strategies remain a major issue for enhancing the efficacy of these treatments. There is an unmet need in discovery and development of novel biomarkers to add predictive values for prosperous personalized medicine. This is vital for the success of therapeutic modalities and combination strategies. Our immuno-oncology track considers the latest biomarker strategies and case studies impacting oncology.

08.30 – 08.55
Conference Room 1

### Opening Keynote Address: Biomarker Strategies For Precision Oncology Development

Senior Rep,
**TBC**

Bio

08.55 – 09.20
Conference Room 1

### Biomarker-Guided Drug Development: Vertical Inhibition Of The MAPK Pathway In NRAS Mutant Melanomas

- Biomarker-driven pipeline-in-a-molecule development strategy
- Targeting MAPK aberrant solid tumors with a MEK inhibitor in combination with a RAF inhibitor

- Additive effects in NRAS mutant melanoma patient-derived models

ADEELA KAMAL, Senior Vice President, Biology & Translational Medicine,
**SpringWorks Therapeutics**

Dr. Adeela Kamal has 20+ years of experience in leading biotech/pharma organizations to develop targeted Oncology drugs from idea inception to marketing approval for both solid tumors and hematological malignancies. She is currently Senior VP, Biology & Translational Medicine at SpringWorks Therapeutics working on a portfolio of targeted Oncology drugs. Previously she was at Ferring Pharmaceuticals, MedImmune/AstraZeneca, Biogen and Conforma Therapeutics. Adeela completed her undergraduate degree in Biology at MIT, her Ph.D. in Molecular and Cell Biology at the University of Texas Southwestern Medical Center and a post-doctoral fellowship from Howard Hughes Medical Institute at UC San Diego.

09.20 – 09.50
Conference Room 1

## Why High-Plex Digital Spatial Profiling Needs To Be Part Of Biomarker Plans In Drug Discovery And Development

- Challenges with standard biomarker discovery and development approaches
- Biomarker discovery and development opportunities enabled by high-plex spatial biology technologies
- Forward thinking ideas

ESPY ANGUIANO, Scientific Market Development Director -BioPharma,
**Nanostring Technologies**

Bio

11.10 – 11.35
Conference Room 1

## The Value Of Model Selection In Preclinical Biomarker Discovery And In Vitro/In Vivo Translatability

An example on predictive biomarker exploration and validation for Debiopharm's WEE1 inhibitor Debio 0123:

- In vitro drug sensitivity screening: from a tissue-agnostic to an indication-specific approach
- Generating a predictive biomarker hypothesis: drug sensitivity versus -omics data
- How publicly accessible transcriptomics data (CCLE) compare to in-house generated data
- Translatability from in vitro-generated biomarker hypothesis to pre-clinical in vivo CDX/PDX models

JEANNETTE FUCHS, Associate Scientist,
**Debiopharm**

Jeannette Fuchs started her scientific career with basic research in Molecular Oncology at Marburg University. In this academic setting she dedicated her time to preclinical mouse models and developed a refined method to monitor tumor growth in vivo. During her Postdoc at Novartis she looked for novel drug combination partners to improve cancer therapies based on p53-reactivation. At the same time, she gained more insights into drug development processes and ever since felt called to use her experience in a more translational environment. Since fall 2020, Jeannette backs Debiopharm`s Personalized Medicine Team with her skills in the interrogation of large -omics data sets (Genomics, Transcriptomics, Proteomics). As an Associate Scientist, she now explores novel predictive biomarker candidates for Debiopharm`s pipeline drugs at pre-clinical and early clinical stage. In addition to the pre-clinical work, she is becoming increasingly engaged in clinical studies overviewing Personalized Medicine-related activities in ongoing studies and study setup.

11.35 – 12.05
Conference Room 1

## From Discovery To Therapy: The Power Of 10x Genomics Single Cell And Visium Spatial Analysis

- Access the resolution you need to explore complex tumor heterogeneity, distinct immune microenvironments and discover T cell responses to therapy with single cell and spatial multiomics
- Identify novel cell types and biomarkers, track clonal behavior, and monitor cells over time

NICOLA CAHILL, Science and Technology Advisor,
**10x Genomics**

Bio

12.05 – 12.30
Conference Room 1

## Characterisation Of GPR65 Antagonist In Macrophages By Gene Expression Profiling

- GPR65 as target for macrophage conditioning in cancer immunotherapy
- Gene expression profiling characterises effects of GPR65 antagonist in various models and aids biomarker identification

ALASTAIR CORBIN, Senior Scientist,
**Pathios Therapeutics**

Alastair is a Senior Scientist at Pathios Therapeutics. He obtained a DPhil in Cellular and Molecular Medicine from the University of Oxford where he utilised in vitro and in vivo approaches to probe monocyte and macrophage function in the context of intestinal inflammation. Following his DPhil and postdoctoral studies, he joined the Ipsen Bioinnovation drug discovery team to determine efficacy and binding properties of modified recombinant neurotoxins. Alastair advances Pathios' Immuno-Oncology pipeline by enabling in vitro and in vivo studies to investigate mechanism of action, biomarker discovery, PK/PD and efficacy.

12.30 – 13.00
Conference Room 1

## Utilizing Comprehensive Platforms For The Biomarker Protein Production And Antibody Development

- A panel of proprietary biomarkers and the monoclonal antibodies against these targets
- Advantages and strengths of our platforms and services
- The benefits of optimized CRO service workflow
- Working capacity of different platforms
- The lead times of different customized services
- Introduction of our additional antibody expression services, e.g. bispecific antibodies, scFv, VHH, Fab, IgM, etc.
- Experience and case study sharing of high-throughput antibody expression service
- Introduction of our platforms for monoclonal and polyclonal antibody developments

*Joining Online:* LINLIN ZHANG, Technical Specialist,
**Sino Biological**

Dr. Zhang is a technical specialist at Sino Biological Europe. Zhang worked as a project leader in the University of Lübeck before she joined Sino Biological Europe. Her research interests fall into the fields of protein structural biology, antiviral therapy, and virus-host interaction mechanisms. Dr. Zhang determined the crystal structure of the unliganded main protease of SARS-CoV-2, as well as its complex with an alpha-ketoamide peptidomimetic compound named 13b (Zhang et al., Science, 368, 409-412 (2020)).

14.00 – 14.30
Conference Room 1

## Using A Dual Proteomics And Multiplexed IF Approach For The Detection Of Biomarkers Predictive For Response To ICI-Therapy

- Identification of over 70 proteins differentially regulated in melanoma patients responding to therapy
- Several immune phenotypes, including T cell subsets and M1 TAMs, significantly increased in responders

ANNA JUNCKER-JENSEN, Principal Scientist,
**NeoGenomics**

Dr. Anna Juncker-Jensen is a Principal Scientist at NeoGenomics where she is responsible for providing scientific support for all aspects of multiplexed IF study execution. Furthermore, she oversees academic collaborations and publication strategies within Pharma Services at NeoGenomics. Anna received her PhD in cancer cell biology from University of Copenhagen and completed a post-doctoral fellowship at The Scripps Research Institute focusing on remodelling of the extracellular matrix and immune responses during tumour progression. Prior to joining NeoGenomics in 2017 she worked at NantBioscience leading several projects with responsibility for delivery of lead cancer drug candidates from discovery to the pre-clinical phase.

14.30 – 14.55
Conference Room 1

## Microsampling Technology For The Remote Detection Of Cytokines By Multiplex ELISA

- Validation of workflows for the extraction and analysis of cytokines from finger prick blood samples will be described
- We aim to detect cytokine changes in immunotherapy patients taking samples at home, to predict immune-related adverse events

HOLLY BUTTERWORTH, Senior Scientific Officer,
**Cancer Research UK Manchester Institute**

Holly is a Senior Scientific Officer in the Cancer Biomarker Centre of Cancer Research UK Manchester Institute and has worked in the institute since 2017 as a Scientist and Project Manager across multiple immunotherapy clinical studies and validation projects. She specialises in the validation of multiplex immunoassays for clinical research use with the primary aim of detecting cytokine changes in patients receiving combination checkpoint inhibitor or advanced cell therapy (e.g. CAR T Cell Therapy). She is particularly interested in exploring the feasibility of remote monitoring of immunotherapy patients in their own homes using minimally invasive dried blood spot samples, with the future aim of identifying clinically relevant biomarkers of immune-related adverse events.

14.55 – 15.25
Conference Room 1

## Precision Proteomics Enables Biomarker Identification And Characterization

- In this scientific seminar we will discuss our capabilities and we will present case studies elucidating the role of precision proteomics and Multiomics approaches in biomarker identification and personalized therapies

SARANTIS CHLAMYDAS, Scientific Director,
**Olink Proteomics**

Bio

16.30 – 17.20
Conference Room 1

## Workshop: Biomarker Analysis - Design And Validation Of Assays

## Presentation 1: Biomarker Assay Validation Strategies

STEPHANIE TRAUB, Associate Director,
**UCB**

Stephanie completed her PhD in the faculty of immunology at the University of Konstanz. Following that, she worked for 6 years in academia as postdoc in France and at Imperial College London. After this, she joined Medimmune, then LGC, where she led projects in both Biomarker assay development and translational medicine implementation. In 2014, Stephanie joined the Centre for Drug Development at Cancer Research UK, then in 2020 Stephanie joined UCB Pharma where she is responsible for the design of pharmacodynamic biomarkers and patient enrichment strategies for early phase clinical trials. She designs Biomarker strategies for novel, first in class agents, across multiple modalities and different therapeutic areas.

## Presentation 2: Assay Validation For Biomarker Qualification

- Exploratory, qualification, and regulatory definitions
- Appropriate scientific rigor
- Clinical utility as end goal

*Joining Online:* STEVEN PICCOLI, Associate Vice President,
**Sun Pharmaceutical Advanced Research Center**

Dr. Steven Piccoli joined SPARC (Sun Pharma Advanced Research Center) as Head of Clinical Biomarkers in April 2020 from GlaxoSmithKline, where he was Head of Clinical Biomarkers and Senior Director of Precision Medicine. He is a recognized expert in clinical biomarkers and precision medicine with extensive contributions to in vitro diagnostics and clinical chemistry and has led clinical and analytical teams in the pharmaceutical, biotechnology, and medical/companion diagnostics industries, at Novartis, Johnson & Johnson and Bristol-Myers Squibb. Earlier entrepreneurial efforts included founding a contract research organization to conduct medical device trials and accelerate in vitro diagnostic device (IVD) submissions in oncology to the FDA and directing the CLIA regulated patient testing reference laboratory of the CRO. In addition, he has served on FDA (CDRH) Medical Devices Panel in Immunology and is extensively engaged in public/private partnerships (Critical Path Institute, Predictive Safety Testing Consortium, Foundation of the National Institutes of Health, Biomarkers Consortium). Together with the PSTC, he is co-leading an initiative to advance and harmonize scientific and regulatory aspects of bioanalytical and biomarker qualification for regulatory submissions. He

obtained degrees in chemistry, biochemistry and molecular biology from Carnegie Mellon University, Washington University in St. Louis, and Princeton University.

## Panel Discussion: Scientific And Regulatory Considerations For The Qualification Of Biomarkers

*Moderator:* THOMAS JOOS, Deputy Managing Director,
**NMI Natural and Medical Sciences Institute at the University of Tübingen; Luminex**

Since 2013: Deputy Managing Director, NMI, 2008 - 2014 Director Strategic Alliances, EDI GmbH, Reutlingen (part time), 2000 - 2017 Head of Biochemistry Department, NMI, 1998 - 2000 Research Assistant, NMI, 1994 – 1998: Postdoctoral research, Dept. of Cell Biology, Max Planck Institute for Developmental Biology, Tübingen, 1994: Ph.D. degree (Dr. rer. nat), Dept. of Cell Biology, Max Planck Institute for Developmental Biology, Tübingen (under Prof. P. Hausen; Topic: "Integrin-α5 during early embroygenesis of Xenopus laevis", 04–08 1988: Molecular biology practical, Biochemistry Dept., the Brandeis University“ (under Prof. Andrew Szent-Györgyi), Waltham, Massachusetts, USA, 1984 – 1990: Study of Biochemistry, University of Tübingen. Dr. Joos is a member of the editorial board of "Drug Discovery Today", "Proteomics" and "Expert Review of Proteomics". He is a member of the Scientific Advisory Board of the Plasma Proteomics Institute in Washington, DC, USA and a member of the Scientific Advisory Board of Myriad RBM Inc. in Austin, Texas, USA. Dr. Joos is the author of >100 scientific papers. He is recognized worldwide as an expert and opinion leader in the technology field of biomarkers and their clinical applications and basic research. Dr. Joos is co-founder of SIGNATOPE GmbH, Reutlingen. SIGNATOPE develops innovative protein tests with which biomarkers for organ damage and drug interactions can be detected in all pharma-relevant species.

*Panellist:* STEPHANIE TRAUB, Associate Director,
**UCB**

Stephanie completed her PhD in the faculty of immunology at the University of Konstanz. Following that, she worked for 6 years in academia as postdoc in France and at Imperial College London. After this, she joined Medimmune, then LGC, where she led projects in both Biomarker assay development and translational medicine implementation. In 2014, Stephanie joined the Centre for Drug Development at Cancer Research UK, then in 2020 Stephanie joined UCB Pharma where she is responsible for the design of pharmacodynamic biomarkers and patient enrichment strategies for early phase clinical trials. She designs Biomarker strategies for novel, first in class agents, across multiple modalities and different therapeutic areas.

*Panellist: (Joining Online)* STEVE HOFFMANN, Associate Vice President, Research Partnerships Director, Biomarkers Consortium,
**Foundation for the National Institutes of Health**

Steve Hoffmann is an Associate Vice President in Research Partnerships and Director of the Biomarkers Consortium at the Foundation for the National Institutes of Health (FNIH). He provides strategic planning, programmatic management and research administration of a multi-faceted portfolio of established and emerging projects within the Biomarkers Consortium and Accelerating Medicines Partnership including projects including neuroscience, rare diseases, organ toxicity, infectious disease and other autoimmune and inflammatory diseases. Steve has a

broad background in the academic, government and industry sectors in the field of translational biomarkers, molecular immunology and precision medicine. Prior to joining FNIH, Steve worked as both a project and product manager, supporting protein diagnostics development at Meso Scale Discovery (MSD). Before MSD, Steve was a scientist in the Transplantation and Autoimmunity Branch of the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK) and led research efforts utilizing immune depletion and co-stimulatory blockade strategies for human renal and islet cell transplant trials. Steve holds a Master of Science degree in Pathology and Laboratory Medicine from the University of North Carolina at Chapel Hill and a Bachelor of Science degree in Biochemistry and Biophysics from the University of Pittsburgh.

*Panellist: (Joining Online)* STEVEN PICCOLI, Associate Vice President,
**Sun Pharmaceutical Advanced Research Center**

Dr. Steven Piccoli joined SPARC (Sun Pharma Advanced Research Center) as Head of Clinical Biomarkers in April 2020 from GlaxoSmithKline, where he was Head of Clinical Biomarkers and Senior Director of Precision Medicine. He is a recognized expert in clinical biomarkers and precision medicine with extensive contributions to in vitro diagnostics and clinical chemistry and has led clinical and analytical teams in the pharmaceutical, biotechnology, and medical/companion diagnostics industries, at Novartis, Johnson & Johnson and Bristol-Myers Squibb. Earlier entrepreneurial efforts included founding a contract research organization to conduct medical device trials and accelerate in vitro diagnostic device (IVD) submissions in oncology to the FDA and directing the CLIA regulated patient testing reference laboratory of the CRO. In addition, he has served on FDA (CDRH) Medical Devices Panel in Immunology and is extensively engaged in public/private partnerships (Critical Path Institute, Predictive Safety Testing Consortium, Foundation of the National Institutes of Health, Biomarkers Consortium). Together with the PSTC, he is co-leading an initiative to advance and harmonize scientific and regulatory aspects of bioanalytical and biomarker qualification for regulatory submissions. He obtained degrees in chemistry, biochemistry and molecular biology from Carnegie Mellon University, Washington University in St. Louis, and Princeton University.

17.20 – 17.45
Conference Room 1

## Panel Discussion: Biomarker Strategies In Neurodegenerative Therapeutics

*Panellists:* KIRA HOLMSTRÖM, Head of Biomarker Research,
**Herantis Pharma Plc**

Bio

*Panellists:* GERGELY TOTH, Chief Executive Officer & Chief Scientific Officer,
**Cantabio Pharmaceuticals**

Dr. Gergely Tóth (PhD, MBA) is the CEO, CSO and founder of Cantabio Pharmaceuticals Inc., a preclinical stage biopharmaceutical company focusing on developing novel disease modifying therapeutics mostly for the treatment of Alzheimer's and Parkinson's disease. Dr. Tóth is also an Honorary Associate Professor at the School of Pharmacy at University College London. Dr. Tóth received his PhD from the Department of Biomedical Sciences at Creighton University in 2001. He was a post-doctoral fellow at the Department of Molecular Biology at the University of California at Berkeley. Dr. Tóth also received an Executive MBA from the University of Cambridge (UK) in 2012. Dr. Tóth previously held various research roles in small and global biopharmaceutical companies in the U.S., where he mostly pursued drug discovery research for neurodegenerative diseases. In addition, he was a research fellow at the University of Cambridge between 210-215.

*Panellists:* JENNIFER BARNETT, Chief Executive Office,
**Monument Tx**

Jenny has an MA in Experimental Psychology from Oxford University, a PhD in the epidemiology of schizophrenia from the University of Cambridge and completed post-doctoral work at Massachusetts General Hospital and the Broad Institute of Harvard and MIT. She joined Cambridge Cognition in 2008 and worked in the clinical trial, healthcare and R&D functions before joining the senior management team in 2014 and becoming CSO in 2016. She has worked on the design and analysis of more than 100 cognitive trials and is the author of 60+ scientific publications and six patents. She has led IP strategy, KOL networking and the scientific validation of medical devices for regulatory approval.

# DAY ONE | TRACK 2: BIOMARKERS FOR DIAGNOSTICS & PRECISION MEDICINE

## Speaker Biographies and Session Information

**This year's programme has a substantial focus on biomarker analysis for precision medicine and how academia and industry can better work together to improve patient care. Further sessions look at novel diagnostic biomarkers impacting breast cancer, including initiatives for precision oncology development, the implementation of patient-centric biomarkers, and the impacts of the changing regulatory landscape on precision oncology development. With early diagnosis improving cancer outcomes, it's become clear that diagnostics are vital for the delivery of personalised therapies and constitute an increasingly important public health strategy..**

08.55 – 09.20
Conference Room 2

### Decoding The Mechanisms Of Metastasis And Therapy Resistance In Triple Negative Breast Cancer

- Reveal subclonal cell populations associate with tumor aggressive features
- Show that upon exposure to NAC, TNBC cells undergo distinct transcriptional reprogramming and enrich features for chemoresistance and metastasis
- Provide a potential first-in-class multi-gene assay for predictive chemotherapy response upfront for TNBC patients
- Show potential alternate therapeutics strategies for TNBC patients resistant to chemotherapy

VIJAY TIWARI, Professor and Group Head, Oncology Laboratory,
**Wellcome-Wolfson Institute for Experimental Medicine, Queen's University Belfast**

The research in Tiwari lab is aimed at achieving an integrated molecular and systems-level understanding of epigenetic and transcriptional code of TNBC metastasis and chemoresistance. To investigate these questions, the Tiwari lab employs a multidisciplinary approach combining cutting-edge genomics together with computational biology tools in sophisticated and defined animal and cellular models. Dr Tiwari is a member of HDRUK-Turing Wellcome Program in Health Data Science, European Association of Cancer Research and BBSRC pool of experts. Dr Tiwari's contributions are widely recognized by several high impact publications, invitation to reputed meetings and several recognized awards.

09.20 – 09.50
Conference Room 2

## Non-Invasive Biomarker Identification And Measurement Using Breath Biopsy®

- Development of Breath Biopsy OMNI, the first standardized platform for the identification and measurement of onbreath biomarkers
- Case studies demonstrating the analytical performance of OMNI for breath biomarker discovery and validation
- Strategies for moving breath testing from centralised analysis to point-of-care solutions

HUW DAVIES, Vice President of Global Sales,
**OwlStone Medical**

Dr Huw Davies has over 25 years experience working with novel technologies that enable the diagnosis and treatment of major human diseases. In his current role, Huw leads a global commercial team responsible for growing Owlstone Medical's Breath Biopsy® collaborations and service business with leading pharmaceutical companies and academic partners to identify and deploy novel non-invasive breath biomarkers for precision medicine and disease diagnosis. Prior to joining Owlstone, Huw was a Director of Business Development for Abcam Plc, the leading UK based antibody company where he was responsible for the negotiation and execution of licensing and supply agreements for Abcam's portfolio of research and diagnostic products and technologies. Prior to joining Abcam, he worked in various business development, management and scientific roles for start-up companies with novel biomarker technologies in the field of proteomics and metabolomics.

11.10 – 11.35
Conference Room 2

## If 98% Of Biomarkers Fail, Is It Time To Give Up Or Rethink Our Strategies?

- Millions are spent on Biomarker research in Academia and Industry but only a tiny fraction, less than 2%, achieve clinical adoption with the rest stalling or failing
- This talk will consider where we are failing in Biomarker research and how Academia and Industry can work better together to discover, validate and implement the Biomarkers we need to improve patient care
- It will also consider what features of Biomarkers make them most likely to succeedclare

CHRISTOPHER PETERS, Clinical Senior Lecturer,
**Imperial College London**

Christopher Peters went to medical school in Leeds and after completing basic surgical training moved to Cambridge to carry out a PhD with Professor Rebecca Fitzgerald. During his PhD he developed a four gene signature to predict outcome in oesophageal adenocarcinoma which was validated in 371 independent cases. He also set up the OCCAMS collaboration which went on to be selected to run the International Cancer Genome Consortium's Whole Genome sequencing project in oesophageal adenocarcinoma. OCCAMS has ongoing CRUK funding and has now recruited in excess of 3000 patients. After moving to London to complete his higher surgical training he was appointed as a Clinical Senior Lecturer and Consultant Upper GI surgeon at Imperial College London with a specialist interest in Biomarkers. His academic interest is molecular and clinical predictors of outcome in Oesophageal adenocarcinoma, and in particular

developing ways of combining the two to improve stratification of patients. As the Biomarker lead for the NIHR London IVD Co-operative he also has a programme built around trying to better understand which Biomarkers are likely to achieve clinical adoption- aiming to bridge the gap between the millions spent on Biomarker discovery and validation and the handful that achieve clinical success.

11.35 – 12.05
Conference Room 2

## 10 Things I Hate About Proteomics

The next generation of proteomics enables measurement of 7000 proteins at once. With this comes many new considerations and a similar number of myths that should be dispelled. In this talk you will learn about:

- Mitigation of challenges specific to massive scale proteomics
- Why the next generation of proteomics needs machine learning to remain impartial
- Common misconceptions about proteomics versus genuine limitations

STEPHEN A. WILLIAMS, Chief Medical Officer,
**Somalogic**

Steve Williams is currently responsible for Clinical R&D, Medical Affairs and Regulatory and Quality. He joined SomaLogic in 2009 as Chief Medical Officer responsible for the clinical application of the SomaScan® Platform and had roles in launching the Life Sciences commercial business, assay development and bioinformatics. Prior to SomaLogic, Dr. Williams co-founded the pharma consultancy Decisionability, LLC in 2007 and authored the book "Decisionability." From 1989-2007, he worked at Pfizer, Inc., initially in Experimental Medicine and later as Vice President and Worldwide Head of Clinical Technology. From 2003-2007, he was on the National Advisory Council for Biomedical Imaging and Bioengineering at the National Institutes of Health. He helped to launch the Alzheimer's Disease Neuroimaging (ADNI) study and to form the FDA-FNIH-PhRMA biomarker consortium. He led or co-led the PhRMA position papers on "proof of concept," surrogate endpoints and evidentiary standards for biomarkers and diagnostics. Dr. Williams has degrees in physiology, medicine and surgery, and a doctorate in medicine and physiology from Charing Cross and Westminster Medical School (now a part of Imperial College, London). He also obtained training in diagnostic imaging at the University of Newcastle Upon Tyne.

12.05 – 12.30
Conference Room 2

## Multiplexed Biomarker Analysis For Precision Medicine: Towards The Identification Of Biomarkers Of Nash/NAFLD Disease Progression

- Stratification of the ABOS cohort led to the stratification of about 800 patients in 3 distinct groups according to their liver status (NASH, NAFL, Healthy)
- A multi omics analysis was performed including proteomics and metabolomics (lipids, free fatty acids and oxysterols) from plasma/serum, miRNA sequencing from liver biopsies, RNA seq on a subset of samples from extreme phenotypes with unequivocal diagnosis
- Biomarkers candidates have been identified which are being further validated in additional independent cohorts

*Joining Online:* VINCENT MIKOL, Precision Medicine Head,
**Sanofi R&D**

Vincent Mikol completed a Ph.D. in Biophysics at the University of Strasbourg, France. He then moved to Sandoz (Switzerland) working on the engineering of antibodies with the aim to develop biological therapeutics which culminated in the approval of Simulect®. He joined a Sanofi predecessor company as head of structural biology (France). He continued his career with Sanofi focusing on drug design approaches which have led to several development candidates in various therapeutic areas including immunology, oncology (Sarclisa®), anti-infectives, cardiovascular and neuro-degeneration. As head of translational research in Sanofi France, he brought to practice the “back translation” concept. It has enabled us to identify new targets, to develop physiological relevant models, to find exploratory biomarkers of patient selection, of disease progression and drug response and to understand mechanism of action of compounds. In my current capacity as precision medicine head, I am applying these findings to accelerate drug development by aligning therapeutics to the patient at the right time of the disease process.

12.30 – 13.00
Conference Room 2

## Solution Provider Presentation

YUEHAN FENG, Director, Scientific Alliances,
**Biognosys AG**

Bio

14.00 – 14.30
Conference Room 2

## Solution Provider Presentation

Senior Representative,
**Proteome Sciences**

Bio

14.30 – 14.55
Conference Room 2

## Panel Discussion: Clinical Diagnostics & Clinical Biomarkers

- Taking hypotheses from research settings & testing in clinical
- Bringing in the need for CDx before clinical development

*Panellist:* CLARE BALENDRAN, Vice President, Head of Translational Medicine,
**Novo Nordisk**

Clare Balendran graduated from University of Nottingham and completed a PhD from University of Wales College of Medicine, UK. She developed her interest in molecular signalling as a postdoctoral fellow in the lab of Sir Philip Cohen, University of Dundee. After a short period in Biotech, Clare joined AstraZeneca, Sweden where she held roles in line and project leadership. In 2011 Clare joined Personalised Healthcare at AstraZeneca as an Associate Director where she was a pioneer of implementing Precision Medicine in Cardiovascular and Metabolic Diseases. Clare's interest developed into diagnostics and in 2015 she became a Diagnostic Director and delivered Ph3 patient selection strategies in Alzheimer's Disease and Paediatric Sickle Cell Disease. She successfully led an sPMA CDx co-submission in Oncology. Clare joined Novo Nordisk, Denmark in March 2019 as VP and now heads Translational and Precision Medicine Depts together with a Diagnostic Centre of Excellence.

*Panellist: (Invited)* AMANDA J. WOODROOFFE, Senior Vice President, General Manager, UK Labs,
**Precision For Medicine**

Bio

14.55 – 15.25
Conference Room 2

## Flexible, Scalable Genetic Screens And Other Methods For Novel Therapeutic Target And Biomarker Discovery

- Measurements of changes in gene activation and expression provide a basis to understand genetic changes causing biological responses
- Cell-to-cell gene disruption induced by CRISPR and other gene-perturbation technologies help tease out the drivers of these responses. Adaptations of these two screening approaches can be used to discover the genetic drivers responsible for phenotypic variabilities such as drug sensitivities and disease variation
- Other related technologies such as clonal barcoding and transcriptome profiling will also be discussed

PAUL DIEHL, Chief Operating Officer,
**Cellecta**

Bio

**Biomarkers increase the success rate of drug development programmes, thereby accelerating the availability of new therapeutics. It is vital to integrate biomarkers into all phases of drug development in order to progress these drugs through the clinic. Talks in this track provide examples of challenges and solutions for success in the clinical use of biomarkers, including translational approaches and patient stratification, alongside goals to transform clinical development through biomarker-driven clinical testing.**

08.55 – 09.20
Conference Room 3

## Minimally Invasive Assessment Of Molecular Profiles In Inflammatory Skin Disease

- Brief overview of non- and minimally invasive technologies for biomarker assessments in dermatology
- Examples from exploratory clinical trials
- Concluding remarks on pros and cons of these methods

MADS ROPKE, Senior Principal Clinical Pharmacologist,
**LEO Pharma A/S**

Affiliations: LEO Pharma A/S, Clinical Pharmacology. Department of Immunology and Microbiology, University of Copenhagen. Mads Røpke received his PhD at the University of Copenhagen, Denmark. After doing his postdoc on cellular immunology at University of Copenhagen he moved to DAKO A/S a diagnostic company. During his 3 years at DAKO he developed a number of diagnostic tools within oncology, most natably the HercepTest® that was delveloped in collaboration with Genentech for selecting patients for Herceptin™ treatment. He then moved to Maxygen, a biotech company focussing on developing protein therapeutics. Here he worked for eight years developing biomarkers in discovery models and clinical studies in the areas of multiple sclerosis, cancer and hemophilia. For the past 14 years he has worked for LEO Pharma A/S, initially in Research and for the last 11 years in development the department of Clinical Pharmacology. Here he is focusing on development and implementation of clinical biomarkers in the field of inflammatory skin diseases. His work is focused on the translational aspects of experimental clinical research of systemic and topical dermatological drugs. Mads teaches at University of Copenhagen and the Danish Technical University at courses in

pharmacology, Translational Medicine and Clinical Drug Development. In 2021 he joined the Department of Immunology and Microbiology at University of Copenhagen as part time Associate professor

09.20 – 09.50
Conference Room 3

## Including Direct Measurements Of Target Engagement And Activity In CNS Clinical Trials

- Overview of limitations and failures of recent clinical trials targeting the central nervous system
- Introduction to The Science Behind (the people, the technology, the network of expertise)
- Overview of electrodiagnostic biomarkers and examples of their application in measuring target engagement in early clinical trials
- Examples of cutting edge electrodiagnostic biomarker research in neurodegeneration
- Examples highlighting how electrodiagnostic markers can be integrated into clinical trials

ROISIN MCMACKIN, Clinical Research Consultant,
**The Science Behind**

Now a postdoctoral fellow at Trinity College Dublin's Academic Unit of Neurology, where she works within the Signal Analysis team, Dr Roisin McMackin obtained her PhD in Clinical Medicine for investigating electrophysiological biomarkers of ALS and is a junior non-clinical research fellow of the UK Motor Neurone Disease Association. Roisin's research applies the use of EEG and TMS to investigate the change in neural networks in ALS, build on current understanding of the mechanism of ALS and enhance categorisation of different clinical presentations of ALS. Her research and the use of TMS-EEG has broader application in measuring changes in other neurodegenerative diseases and the development of therapeutic drugs.

11.10 – 11.35
Conference Room 3

## Biomarkers In Drug Development: Applications In Cardiovascular Diseases

- Biomarkers for assessment of target engagement in early clinical studies
- Translational approaches and patient stratification
- Remote biomarker sampling for disease detection

*Joining Online:* PIA DAVIDSSON, Senior Director, Translational Science & Experimental Medicine,
**AstraZeneca**

Pia Davidsson was born on June 3 in Gothenburg (Sweden) 1962. She received her PhD degree in 1989 from the Department of Clinical Neuroscience at Gothenburg University for studies of glycoconjugates in human meningiomas. In 1998 she was appointed Assistant Professor in Clinical Neuroscience. The research areas were synaptic / regenerative function and pathology in neurodegenerative diseases. In 2003, Pia got a position at AstraZeneca/ Sweden in the biomarker discovery area for cardiovascular diseases, and later 2008 as pharmacokinetic/ pharmacodynamic project lead in preclinical development of biotherapeutics with focus on pharmacokinetic and/ pharmacodynamic characterization and modelling. In 2013, Pia was

appointed as Director for the Translational Biomarker team, and 2018 as Senior Director for Biomarkers Discovery and Development for cardiovascular, renal and metabolic diseases at AstraZeneca with accountabilities for discovery and development of biomarkers for early clinical studies.

11.35 – 12.05
Conference Room 3

## Biomarker Discovery From Gene Expression: Challenges And Solutions For Success

What you will learn:

- Challenges associated with analysing gene expression data
- Key study design considerations for biomarker discovery
- Best practices for training and validating a gene expression signature
- Making use of public data repositories and integrating different data types
- Innovative reporting of gene expression signatures using Almac's proprietary bioinformatics software solution – claraT

JONATHAN YOUNG, Senior Bioinformatics Scientist,
**Almac Group**

Dr Jonathan Young is a senior Bioinformatics Scientist in the Data Sciences R&D team at Almac Diagnostics. The Bioinformatics team develop and maintain NGS analysis pipelines to support NGS assays for both biomarker research and clinical trial use. Prior to joining Almac, Jonathan gained a BSc in Genetics, followed by an MSc in Biotechnology and a PhD in Microbial Metagenomics from Queen's University Belfast. He has previously worked in the diagnostic laboratories at the Royal Victoria Hospital Belfast and has worked as a Bioinformatics Scientist at Almac for 3 years.

12.05 – 12.30
Conference Room 3

## Exploring Biomarkers In NASH Clinical Trials

- Precision medicine biomarker needs in NASH
- Evaluation of monitoring potential of biomarkers to detect NASH disease development during treatment
- Example from semaglutide phase 2b study

LOUISE MAYMANN NITZE, Principal TranslationalMedicine Scientist,
**Novo Nordisk**

Louise M. Nitze has 15 years of pharmaceutical industry experience within R&D and a solid knowledge within drug discovery and clinical drug development. Her expertise is within target evaluation, clinical pharmacology, and translational medicine. In almost a decade, she has worked with gut hormones and their role in obesity, diabetes, and NASH. Her current focus is biomarkers, diagnostics, and precision medicine. Louise M. Nitze has an Industrial PhD in Natural Science from the University of Copenhagen in collaboration with Novo Nordisk A/S. She has a Master's in Molecular Biology from University of Copenhagen and conduced both her

Bachelor and Master project at the Danish Cancer Society where she characterized molecular and cellular effects of novel therapies.

12.30 – 13.00
Conference Room 3

## Using Explainable AI To Generate Highly Predictive And Interpretable Biomarker Signatures From Clinical Data

- Modern assay technology paired with powerful computational methods has changed the way we discover biomarker signatures
- At Abzu, we have developed a workflow based on explainable AI that extracts the best possible predictive models from high-dimensional data, even with small sample sizes
- See how our new, interpretable approach to machine learning generates high-performance predictions from challenging omics and multi-omics data sets, getting the most out of clinical and experimental data

SAMUEL DEMHARTER, Head of Bioinformatics,
**ABZU**

Sam got his PhD in Systems Biology from the Department of Computer Science at the University of Oxford. He has broad experience in pharma and biotech and built an extensive toolset for challenging projects. Sam cares most about explainable AI and omics analysis for biomarker discovery and target identification. He is also very friendly - come and chat!

14.00 – 14.30
Conference Room 3

## Supporting Development Of Cellular Therapies: Pre-Clinical To Clinical Testing

- CAR T cells have been revolutionary in treating certain types of haematological malignancy
- Pre-clinical in vitro and in vivo testing, coupled with biodistribution data, are crucial steps along the path to demonstrating efficacy of a candidate therapeutic
- We will describe the strategies used at CRL to support the development of a cellular therapeutic from pre-clinical testing through to clinical trials, and the steps required to uplift a pre-clinical assay to GCLP standards

CHRISTOPHER KIRKHAM, Team Leader Translational Biomarkers,
**Charles River Laboratories**

Chris is a Team Leader within the Translational Biomarkers group at the Portishead, UK, site of Charles River Laboratories. The Translation Biomarkers group specialises in readouts of immune modulation to pre-clinical and clinical phases of drug discovery programmes, with a particular focus on pharmacodynamic biomarkers. Chris was awarded his PhD in 2014 by the University of Leeds, UK.

14.30 – 14.55
Conference Room 3

## Insights Into A Non-Drug Interventional Trial Aiding In Clinical Qualification Of Prognostic And Monitoring Biomarkers For Liver Cirrhosis

- Liver cirrhosis due to NASH is a life-threatening condition with no licensed treatment
- This trial aims to confirm the prognostic value of established and some emerging biomarkers in this field

ISABELLA GASHAW, Principal Clinical Biomarker Lead Cardiometabolism,
**Boehringer Ingelheim**

Isabella is passionate about developing translational concepts to improve effectiveness of drug development for better patient care. She builds on more than 14 years of experience in research and development in pharmaceutical industry ranging from target identification to post launch activities. She is currently a principal translational and clinical biomarker lead for cardiometabolic diseases at Boehringer Ingelheim. In this role, she creates biomarker concepts and steers their qualification including implementation of these concepts in advanced chronic liver diseases across drug development stages. Before joining BI in February 2021, Isabella was employed with Bayer AG as director biomarker strategist for non-oncologic diseases. She has also worked in preclinical research in gynecologic and hematologic conditions. Prior embarking on drug discovery, Isabella was investigating molecular mechanisms of reproductive disorders in an academic environment. Isabella holds a PhD in Clinical Pharmacology from the Humboldt University in Berlin (Germany).

14.55 – 15.25
Conference Room 3

## Personalis NeXT Platform: Enabling Precision Oncology With Comprehensive Tumor Profiling Solutions For Tissue And Liquid Biopsy

- Combining sensitive DNA and RNA sequencing with advanced analytics, ImmunoID NeXTTM provides a multidimensional view of the tumor and microenvironment
- A melanoma cohort case study demonstrates how a composite biomarker strengthens the association with immunotherapy response
- NeXT PersonalTM, an ultrasensitive tumor-informed liquid biopsy assay, designed to detect molecular residual disease will be highlighted

ERIN NEWBURN, Director, Field Application Scientist,
**Personalis, Inc.**

Dr. Newburn joined Personalis as a Field Applications Scientist in 2013 with over 13 years of research experience in the areas of molecular biology, genetics, and biotechnology. As the Director, Field Applications Scientist, Erin's team has the responsibility of providing both pre- and post-sale technical support for the Personalis NeXT Platform including both the ImmunoID NeXT and NeXT Personal solutions. Erin completed her postdoctoral training at the National Institute of Mental Health (NIMH) investigating candidate susceptibility genes for major psychiatric illnesses. Erin received her Ph.D. from the Ohio State University in Integrated Biomedical Science as a Presidential Fellow.

16.30 – 16.55
Conference Room 3

## Panel Discussion: Implementing Patient-Centric Biomarkers In Clinical Trials

*Panellist:* THOMAS HACH, Executive Director Patient Engagement,
**Novartis**

Thomas Hach, MD, is Executive Director Patient Engagement for Cardiovascular, Renal & Metabolism (CRM) at Novartis. He is leading end-to-end patient engagement strategy and operations for the broad CRM portfolio at Novartis. Thomas also held positions of Global Brand Medical Director Neuroscience, Senior Global Health Advisor and Director Healthcare Systems. His passion and expertise are in precision medicine, preventative medicine, patient centricity and partnerships. He joined Novartis from Boehringer Ingelheim, where he was Global Senior Medical Director, Therapeutic Area Metabolism. Prior to that, he was an associate principal at McKinsey & Company, serving as a leader in the pharmaceuticals and healthcare practice. Dr. Hach conducted several years of research and clinical practice in diabetes/microcirculation at Karolinska Institutet, Sweden. At the beginning of his clinical career, he worked in orthopedic surgery in Sweden and Germany. He received his medical degree from University of Mainz, Germany.

*Panellist:* VIRGINIA PARKS, Clinical Pharmacologist,
**Servier**

Virginia Parks is a Clinical Pharmacologist with over 20 years of drug development experience across multiple therapeutic areas including neuroscience, cardiovascular, metabolic disorders, and rare diseases. She was recently director of digital strategy at Takeda. In this role, she was a key member of a team for an early phase asset in neuroscience, working on an initiative to develop a digital biomarker strategy. This included identification of wearable technology, analytics development and validation, patient engagement, and use of external data sources. She has recently co-authored an article on leveraging the laboratory biomarker experience in digital health technologies (doi.org/10.1111/cts.12865) Virginia is currently at Servier and has worked for Pfizer and Wyeth where she was primarily focused on leading early stage exploratory programs.

*Panellist:* ALEXANDRA SEVKO, Director, Translational Research,
**Prokarium**

Initially, I studied clinical laboratory diagnostics at medical college, Kyiv, Ukraine (1989 -1992). I continued working at the clinical labs throughout my education at Kyiv State University (biology, 1993-1999), Ph.D. program in oncology, Institute of Experimental Pathology, Oncology and Radiobiology (Kyiv, 1999 – 2004), and specialisation for clinical laboratory diagnostics, Postgraduate Medical Education Academy (Kyiv, 2004). My passion to cancer immunology research was instigated by Dr Michael Shurin, Director of the Division of Clinical Immunopathology at Pittsburgh University (PA, 2000), the host for my UICC ICRETT project. I am interested in addressing tumour microenvironment to deliver the success for cancer immunotherapy. I worked at German Cancer Research Centre, Prof. Viktor Umansky lab (2008 – 2012); UCL Cancer Institute, Prof. Henning Walczak lab (2012 – 2015); Adaptimmune Ltd, cell research/NextGen laboratory (2015 – 2021). Since 2021, I joined Prokarium, company who is pioneering the field of microbial immunotherapy, as a director of translational research.

16.55 – 17.20
Conference Room 3

## Regulatory Requirements For Drug/Companion Diagnostic Clinical Development And Marketing Authorization In The US And EU

- Precision Medicine: drug-diagnostic co-development
- CDx regulatory framework in the US
- Changes in the EU CDx regulatory Landscape: The impact of IVDR

*Joining Online:* SVETLANA MUKHINA, Associate Director Global Regulatory Affairs, CDx,
**Merck Group**

Bio

17.20 – 17.45
Conference Room 3

## Biopharmaceuticals & Companion Multiplex Precision Diagnostic Products

*Joining Online:* DAVID ZARLING, Chief Executive Officer,
**Colby Pharmaceuticals**

Bio

# DAY ONE | TRACK 4: DIGITAL PATHOLOGY & AI/MACHINE LEARNING FOR BIOMARKER RESEARCH

## Speaker Biographies and Session Information

**Digital technologies are poised to transform biomarker development and translational research, with a key technological advancement being within digital pathology. The field is rapidly gaining momentum, allowing for enhanced productivity and improved treatment decisions. This track provides innovative insights into AI and image analysis, multiplexed digital technologies, as well as an in-depth panel discussion on "Digital Pathology, Imaging & AI In Biomarker Research".**

08.55 – 09.20
Conference Room 4

### A Production System For Computational Pathology In A Pharma Context

- An overview how digital pathology & AI is used within translational sciences
- Details about users, needs, and solutions for a computational pathology system
- Examples to illustrate how such systems pave the way for efficient & targeted discovery of digital biomarkers

MARTIN GROHER, Senior Director Software Product Management,
**AstraZeneca Computational Pathology GmbH**

Martin has earned a PhD in medical image analysis from the Technical University of Munich and started to work on whole slide imaging in 2008 as a Postdoctoral researcher. He then co-founded a company in the digital pathology industry and led it for about 7 years as CEO, developing and marketing products for 3D histology reconstruction, slide image co-registration, and whole slide image labeling. Afterwards, he joined Definiens, one of the pioneers in AI for digital pathology to focus on applications tailored for pharma companies. In 2019 he joined Astrazeneca Computational Pathology to lead product management of imaging software, also covering the genomics software stack since June 2021.

09.20 – 09.50
Conference Room 4

### How To Develop A 6-Plex Chromogenic Mx Stain On An Automated Staining System

- Immunohistochemistry (IHC) detects proteins of interest within whole tissue sections, keeping cellular organization intact. Evolving from conventional IHC (single slide, single marker), multiplex IHC is an advancement in this technique that enables the detection of multiple markers of interest simultaneously in one tissue section
- The ability to analyze multiple markers is important as cells do not exist or act in isolation, and cellular responses involve the activation of several pathways that influence the nature of their responses
- Multiplexing can therefore be applied to address several types of research questions including, but not limited to, the spatial arrangement or quantity of different cell lineages, phenotyping of immune cells, evaluation of multiple effectors of signal transduction pathways, and the distribution of novel drugs. Performing (IHC) manually may spark dread due to the lengthy nature of the process
- In this talk, we would like to show you a flexible, consistent, fully automated workflow that decreases the hands-on time for up to 6-plex chromogenic stainingy

CHARLOTTE GRAY, Application Consultant,
**Leica Biosystems**

Immunohistochemistry (IHC) detects proteins of interest within whole tissue sections, keeping cellular organization intact. Evolving from conventional IHC (single slide, single marker), multiplex IHC is an advancement in this technique that enables the detection of multiple markers of interest simultaneously in one tissue section. The ability to analyze multiple markers is important as cells do not exist or act in isolation, and cellular responses involve the activation of several pathways that influence the nature of their responses. Multiplexing can therefore be applied to address several types of research questions including, but not limited to, the spatial arrangement or quantity of different cell lineages, phenotyping of immune cells, evaluation of multiple effectors of signal transduction pathways, and the distribution of novel drugs. Performing (IHC) manually may spark dread due to the lengthy nature of the process. In this talk, we would like to show you a flexible, consistent, fully automated workflow that decreases the hands-on time for up to 6-plex chromogenic staining. For research use only. Not for use in diagnostic procedures.

11.10 – 11.35
Conference Room 4

## Biomarkers Of Human Longevity

- Data Science and AI for Accelerating Ageing Research and R&D
- The Critical Catalyst for Practical Human Longevity and Precision Health
- Tangible Investment Decision Making and De-Risking in the Longevity Industry

DMITRY KAMINSKIY, General Partner,
**Deep Knowledge Group**

Dmitry Kaminskiy is an innovative entrepreneur, investor, author and philanthropist dedicated to impact investment and ethical business, with a focus on engineering the accelerated trajectory of progressive technological development for the benefit of humanity. Mr.Kaminskiy is a co-founder and managing partner of Deep Knowledge Group - a consortium of commercial and non-profit organizations active on many fronts in the realm of DeepTech and Frontier Technologies (AI, Longevity, Precision Medicine, FinTech, GovTech, InvestTech), ranging from scientific research to investment, entrepreneurship, analytics, policy and philanthropy. He leads the activities of the consortium's investment arms - Deep Knowledge Ventures, focused on DeepTech and advanced science projects, and Longevity.Capital, which prioritizes the convergence of Longevity and Artificial Intelligence. In addition to his business experience,

Dmitry is involved in several scientific endeavours. He has a major interest in anti-aging and healthy longevity, which is reflected in the full scope of his personal and professional activities. Dmitry Kaminskiy is author of the books 'Biomarkers of Human Longevity' and 'Longevity Industry 1.0 - Defining the Biggest and Most Complex Industry in Human History'.

12.05 – 12.30
Conference Room 4

## Panel Discussion: Digital Pathology, Imaging & AI In Biomarker Research

- What is the potential for interplay between AI based image analysis and spatial transcriptomics in drug discovery? Does the light image hold all of the answers?
- What role can AI play in analysing the vast repositories of transcriptomic data and how can this be leveraged to discover new biology and biomarkers. Can these be translated into the clinic through the use of immune histochemistry
- How can AI and image analysis be used to measure dose variable responses in heterogeneous cellular populations to sublethal doses of drug candidates in high throughput screening. Can biomarkers be discovered that predict resistance and out growth?

*Moderator:* GRAHAM BALL, Professor,
**Nottingham Trent University**

Prof Graham Ball is a Professor of Bioinformatics at Nottingham Trent University and founder-CSO of Intelligent Omics. Prof Ball specialises in the application of innovative artificial intelligence and machine learning methods to the analysis of complex data in the biomolecular, biomedical, and pharmacological domains. Prof Ball has led the development and validation of bioinformatics algorithms using Machine learning to mine molecular data for the last 20 years. He has focussed on applying these approaches to public data repositories leveraging actionable and translational features from the data. He has published 195 journal papers and 7 patents in this area. After a PhD (UN funded) modelling environmental systems, in 2000 he shifted his focus to analysis of proteomic and genomic data; searching for proteins and genes associated with cancer. His current research focuses on innovative computational methods that allow the identification of optimised biomarker panels, molecular systems of disease and druggable biology.

*Panellist:* SEAN WALSH, Chief Scientific Officer,
**Radiomics**

Seán is a co-founder of Radiomics and serves as Chief Scientific Officer. He is a medical physicist with key expertise in data science and a decade of experience in the fields of radiology and oncology. He has a proven track record of managing, processing, and discovering actionable insight from (federated) clinical data in multiple international cancer centres. Seán is primarily responsible for leading research activities within Radiomics, setting scientific priorities in accordance with the mission and goals of the company. The research team is driven by a commercial attitude of scientific excellence. Agility, innovation, and impact are core pillars to maintain a 'thought leadership' position for the company, advance science, and address the unmet clinical needs of the healthcare community. Seán obtained a PhD from the National University of Ireland, Galway before becoming a joint postdoctoral scholar at the University of Oxford and Maastro Clinic. He has a passion for sport.

*Panellist:* STEPHANIE ARNOLD, Senior Scientist,
**AstraZeneca**

Bio

*Panellist:* MARTIN GROHER, Senior Director Software Product Management,
**AstraZeneca Computational Pathology GmbH**

Martin has earned a PhD in medical image analysis from the Technical University of Munich and started to work on whole slide imaging in 2008 as a Postdoctoral researcher. He then co-founded a company in the digital pathology industry and led it for about 7 years as CEO, developing and marketing products for 3D histology reconstruction, slide image co-registration, and whole slide image labeling. Afterwards, he joined Definiens, one of the pioneers in AI for digital pathology to focus on applications tailored for pharma companies. In 2019 he joined Astrazeneca Computational Pathology to lead product management of imaging software, also covering the genomics software stack since June 2021.

*Panellist (Invited):* Senior Representative,
**Indica Labs**

Bio

12.30 – 13.00
Conference Room 4

## Streamlining The Highly Multiplexed Image Analysis Workflow

- How Indica Labs' industry leading digital pathology products HALO®, HALO AI™, HALO Link™, and HALO AP® fit together to provide a comprehensive workflow from bench to bedside
- Overview of highly multiplexed assays supported by HALO image analysis
- Evaluation of the tissue micro-environment by 17-plex immunofluorescence using the Orion Platform from RareCyte and HALO Image Analysis

NATASHA CARMELL, Manager, Life Science Applications (EMEA),
**Indica Labs**

Natasha has a background in cellular and molecular biology, receiving her PhD in Molecular Oncology from the University of Sheffield. Her thesis evaluated the identification of novel targets to augment chemotherapeutic potency in high-grade brain cancers. During this time Natasha developed a keen interest in IF, IHC and image analysis. After finishing her PhD, Natasha joined Indica Labs in 2019 as a Field Applications Scientist, and in 2021 she took on the role of Life Science Applications Manager where she leads the EMEA Applications team in sales and applications support of HALO, HALO AI, and HALO Link.

14.00 – 14.30
Conference Room 4

## Solution Provider Presentation

DANIEL JAMIESON, Chief Executive Officer,
**Biorelate**

Bio

14.30 – 14.55
Conference Room 4

## Application Of Machine Learning To The Discovery Of Biomarkers And Biological Drug Targets In Breast Cancer

- We utilise machine learning methods to interrogate public transcriptomic data repositories to identify robust biomarker sets associated with clinical questions and molecular pathways
- We further analyse these molecular data to build digital twins of pathways and identify drivers of pathways
- We evaluate these drivers for their efficacy as drug targets, for their risk of having off-target effects, and their association with druggable biology

GRAHAM BALL, Professor,
**Nottingham Trent University**

Prof Graham Ball is a Professor of Bioinformatics at Nottingham Trent University and founder-CSO of Intelligent Omics. Prof Ball specialises in the application of innovative artificial intelligence and machine learning methods to the analysis of complex data in the biomolecular, biomedical, and pharmacological domains. Prof Ball has led the development and validation of bioinformatics algorithms using Machine learning to mine molecular data for the last 20 years. He has focussed on applying these approaches to public data repositories leveraging actionable and translational features from the data. He has published 195 journal papers and 7 patents in this area. After a PhD (UN funded) modelling environmental systems, in 2000 he shifted his focus to analysis of proteomic and genomic data; searching for proteins and genes associated with cancer. His current research focuses on innovative computational methods that allow the

identification of optimised biomarker panels, molecular systems of disease and druggable biology.

# DAY TWO | TRACK 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN NEUROSCIENCE, NASH & CO-MORBIDITY

## Speaker Biographies and Session Information

**Biomarkers are in demand for disease diagnosis and the development of novel therapeutics. Biomarker discovery in neuroscience has been traditionally challenging due to the absence of robust molecular correlates and interpatient heterogeneity. This track provides insights into novel biomarker types impacting neuroscience, including the use of digital biomarkers when approaching neuroscience. In addition to neuroscience case studies, there is a push to revolutionise NASH diagnosis, monitoring and treatment via non-invasive biomarker development.**

09.35 – 10.00
Conference Room 1

### Quantification Of Distinct Oxidized States Of Dj-1 As Potential Biomarker For Parkinson's Disease

- A critical lack of biomarkers exists for early diagnosis of Parkinson's disease (PD) and to aid disease modifying drug development
- The DJ-1protein is genetically linked to the early on-set of familial PD and is implicated in idiopathic PD. Cys106 of DJ1, a critical residue controlling its functions, is highly reactive and oxidation-sensitive. As oxidative stress is one of the key hallmarks of PD, the ratio of DJ-1 redox isoforms may be an indicator of disease onset and progression
- We developed unique ELISAs to quantify distinct redox variants of C106 DJ-1 using novel antibodies of DJ-1 with the aim of having a more precise understanding of the relative redox states of C106-DJ-1 in disease conditions

GERGELY TOTH, Chief Executive Officer & Chief Scientific Officer,
**Cantabio Pharmaceuticals**

Dr. Gergely Tóth (PhD, MBA) is the CEO, CSO and founder of Cantabio Pharmaceuticals Inc., a preclinical stage biopharmaceutical company focusing on developing novel disease modifying therapeutics mostly for the treatment of Alzheimer's and Parkinson's disease. Dr. Tóth is also an Honorary Associate Professor at the School of Pharmacy at University College London. Dr. Tóth received his PhD from the Department of Biomedical Sciences at Creighton University in 2001. He was a post-doctoral fellow at the Department of Molecular Biology at the University of California at Berkeley. Dr. Tóth also received an Executive MBA from the University of Cambridge (UK) in 2012. Dr. Tóth previously held various research roles in small and global biopharmaceutical companies in the U.S., where he mostly pursued drug discovery research for

neurodegenerative diseases. In addition, he was a research fellow at the University of Cambridge between 210-215.

10.00 – 10.30
Conference Room 1

## Gold Solution Provider Presentation

Senior Representative,
**Bio-Techne**

Bio

11.50 – 12.15
Conference Room 1

## Using Digital Biomarkers To Apply A Stratified Approach To Neuroinflammation

- Psychiatry and neurology have experienced many late-stage drug development failures. We believe this stems in part from a lack of objective assessments used when categorising patients for clinical trials. This lack of objective inclusion criteria results in substantial biological heterogeneity within clinical trial samples, making it unlikely that any one drug will have a positive effect on all patients
- At Monument Therapeutics we use digital biomarkers to select patients with specific abnormalities in brain processes, and pair them with drugs known to positively affect these processes. Using this approach, we are developing biomarker-drug combinations to tackle areas of major unmet medical need, including schizophrenia and neuroinflammation

JENNIFER BARNETT, Chief Executive Officer,
**Monument Tx**

Jenny has an MA in Experimental Psychology from Oxford University, a PhD in the epidemiology of schizophrenia from the University of Cambridge and completed post-doctoral work at Massachusetts General Hospital and the Broad Institute of Harvard and MIT. She joined Cambridge Cognition in 2008 and worked in the clinical trial, healthcare and R&D functions before joining the senior management team in 2014 and becoming CSO in 2016. She has worked on the design and analysis of more than 100 cognitive trials and is the author of 60+ scientific publications and six patents. She has led IP strategy, KOL networking and the scientific validation of medical devices for regulatory approval.

12.15 – 12.45
Conference Room 1

## Simoa Technologies For Ultrasensitive Biomarker Detection, Future Proofing Your Bioanalysis

- 1000x fold sensitivity improvement over traditional immunoassay technologies
- Simoa quantification of low abundance proteins, minimally invasive low volume samples, and better stratification between comparator groups
- Quanterix SP-X, SR-X and HD-X
- Critical biomarker detection applicable to a wide range of therapeutic areas
- Assay Development and Custom Services

LINDSEY MARSH, Senior Field Applications Scientist,
**Quanterix**

Sr Field Application Scientist for Quanterix residing in the UK with previous experience in both research and industry. Our ultrasensitive technology solutions enable researchers to evaluate the continuum between health and disease. Responsibilities include providing post-sales trainings on HD-X, SR-X and SP-X platforms, pre-sales support within the UK, Ireland and Switzerland to present the technology to new clients and working with academic and industrial customers within Europe to ensure successful adoption of Simoa Technology.

12.45 – 13.15
Conference Room 1

## Challenges For Performing Regulatory Validations Of Neurological Biomarker Assays

- Bioanalytical challenges around measuring neurological biomarkers from a CRO perspective?
- Can we evolve our validations to be more aligned with context of use or should every validation be bespoke?
- Obstacles with commercial reagents, what can be done to overcome them?
- Case studies: the merits of applying performance based acceptance criteria vs relying on PK BMV guidelines, for validations using commercial reagents on a high sensitivity platform

LAUREN JORDAN, Senior Scientist,
**LGC Group**

Laura is a Senior Scientist/Regulated Project Manager within the biomarker group of our Immunoassay department at LGC, Fordham. Together with our team of Principal Scientists and technical specialists, we develop, characterise and validate biomarker assays across a range of different sensitivity platforms to support clinical trials. Prior to working at LGC, I completed my PhD at Cardiff University where my research was centred around understanding the cytokines involved in the destructive pathophysiology of bone in arthritis.

14.15 – 14.45
Conference Room 1

## Solution Provider Presentation

Senior Representative,
**Metabolon**

Bio

14.45 – 15.10
Conference Room 1

## FNIH Workshop

## Presentation 1: Impact and Innovation – The FNIH Biomarkers Consortium & Accelerating Medicines Partnership

DANA CONNORS, Senior Program Manager, Research Partnerships,
**Foundation for the National Institutes of Health**

Dana E. Connors, MSc, PMP is the Senior Scientific Program Manager for Cancer Research Partnerships at the Foundation for the National Institutes of Health. Drawing on experience in the biotechnology industry, non-profit and federal sectors, he works with the Cancer Steering Committee to set strategy and prioritize project pipelines and manages the activities of project teams and working groups to facilitate the advancement and execution of innovative cancer research and biomarker development. In his work with public-private biomedical research partnerships he engages participation from government, industry, academia, patient-advocacy, and private sector organizations to drive international scientific collaboration in multiple disease areas. Ongoing collaborations include analytical validation and clinical utility of liquid biopsy, project opportunities around immuno-oncology biomarkers, development of clinical trial metrics, and Minimal Residual Disease in blood-based cancers.

## Presentation 2: Advancing Novel Tools And Biomarker Validation For Neurodegenerative Diseases

WESLEY HORTON, Senior Project Manager,
**Foundation for the National Institutes of Health**

Wesley Horton is a Scientific Project Manager for Neuroscience at the Foundation for the National Institutes of Health. Wesley manages the Biomarker Consortium Neuroscience Steering Committee (BC NSC), Accelerating Medicines Partnership Schizophrenia (AMP SCZ), and various working groups operating under the BC NSC. Working across diverse stakeholders and building alliances, Wesley has successfully developed and launched multiple public-private partnerships in neuroscience enabling new solutions for drug development in Alzheimer's disease and rare neurodegenerative disorders. Prior to joining the FNIH team, Wesley worked for Georgetown University managing interventional Alzheimer's disease studies and developing clinical research programs in stroke, neurosurgery, and interventional radiology. He also spent time working with the United States Department of Defense in managing multi-center clinical trials to understand HIV and HIV-associated neurocognitive disorder.

15.10 – 15.35
Conference Room 1

## Presentation 3: AMP Schizophrenia: Biomarkers Of Clinical High Risk (CHR) And Disease Trajectory For Psychosis

LYNSEY BILSLAND, Head of Mental Health Translation,
**Wellcome Trust Foundation**

Bio

16.05 – 16.30
Conference Room 1

## FNIH Workshop Continued Presentation 4: Revolutionizing NASH Diagnosis, Monitoring And Treatment, A NIMBLE Approach For Success

*Joining Online:* HELEN HEYMANN, Senior Scientific Project Manager, Research Partnerships, Biomarkers Consortium,
**Foundation for the National Institutes of Health**

Helen Heymann, MMSc, is the Project Lead and Senior Scientific Project Manager for Metabolic Disorders in the Biomarkers Consortium at the Foundation for the National Institutes of Health (FNIH). In her current position Helen Heymann manages and develops multi-million dollars public-private partnership projects moving biomarkers towards qualification as drug development tools. She also leads and manages the Biomarkers Consortium Metabolic Disorders Steering Committee (MDSC), composed of over 40 members from industry, academia, NIH, FDA, and non-profits, to drive scientific collaboration, set strategy and prioritize the

program pipeline, and advise on the sound execution of projects. Helen Heymann also facilitates the generation through project development teams of the advancement and execution of innovative metabolic disorders projects. Prior to working at the FNIH, Helen Heymann held several positions working as a Program Manager at the United Development Program (UNDP), the Academy for Educational Development (AED), and Family Health International 360 (FHI360). Helen Heymann holds a Masters of Medical Sciences in Human Nutrition, University of Sheffield, UK and a Masters of Science in Social Policy and Planning, London School of Economics and Political Science (LSE), UK.

16.30 – 16.55
Conference Room 1

## Neurological Immune Biomarkers

*Joining Online:* SARAH HARRIS, Head, GI and Neurology Disease Teams, Translational Medicine, **Bristol Myers Squibb**

Bio

# DAY TWO | TRACK 2: NEW & EMERGING BIOMARKER TECHNOLOGIES

## Speaker Biographies and Session Information

**The biomarker field is constantly evolving, with an influx of new technologies impacting the rate of research. With these new technologies comes increased data management challenges, with companies looking for harmonised strategies for biomarker discovery. Join our technologies track to benefit from case-studies into novel technology applications, as well as our roundtable discussion on the future of early detection of cancer.**

08.35 – 09.35
Conference Room 2

### Workshop: Biomarker Challenges In Prostate Cancer (And The Consequences Elsewhere)

*Moderator:* MARK EMBERTON, Professor,
**UCL**

Mark Emberton is Professor of Intervention Oncology within the Division of Surgery and Dean of the Faculty of Medical Science at University College London. He is clinically active and holds the position of Honorary Consultant Urologist at University College London Hospitals NHS Trust where he works as a specialist in prostate cancer. His academic work has focused on developing novel diagnostic strategies and new therapies for men with prostate cancer. His research has resulted in the transformation of both the diagnostic and therapeutic pathways. These have been incorporated into international guidelines. He has published over 400 peer review papers, holds a large grant portfolio, and lectures widely around the world and holds international honorary professorships. He is a founding Pioneer of the charity Prostate Cancer UK.

### Presentation 1: The Methodological Challenges Of Biomarkers In Detection & The Validation Of Preclinical Disease

SHONIT PUNWANI, Professor of Magnetic Resonance and Cancer Imaging,
**UCL**

Bio

## Presentation 2: The Challenges In Developing A New Prostate Cancer Biomarker

GERT ATTARD, Endowed Chair in Urological Cancer,
**UCL**

Bio

## Presentation 3: Are We Ready To Re-Visit Prostate Cancer Screening?

- The role of imaging will be discussed
- The causes of failure of previous trials will be assessed
- Optimal trial design will be explored

MARK EMBERTON, Professor,
**UCL**

Mark Emberton is Professor of Intervention Oncology within the Division of Surgery and Dean of the Faculty of Medical Science at University College London. He is clinically active and holds the position of Honorary Consultant Urologist at University College London Hospitals NHS Trust where he works as a specialist in prostate cancer. His academic work has focused on developing novel diagnostic strategies and new therapies for men with prostate cancer. His research has resulted in the transformation of both the diagnostic and therapeutic pathways. These have been incorporated into international guidelines. He has published over 400 peer review papers, holds a large grant portfolio, and lectures widely around the world and holds international honorary professorships. He is a founding Pioneer of the charity Prostate Cancer UK.

09.35 – 10.00
Conference Room 2

## Roundtable Discussion: The Future Of Early Detection Of Cancer

How can we overcome the challenges to early detection of cancer? Specifically, in:

- Determining risk of developing cancer to tailor early detection strategies to those at elevated risk

- Developing technologies with the sensitivity to detect the earliest tumours and the specificity to minimize false positives
- Designing early detection clinical trials to provide robust evidence to change practice

*Moderator:* WENDY ALDERTON, Early Detection and ACED Programme Manager,
**University of Cambridge**

Dr Wendy Alderton is the Early Detection and ACED Programme Manager at the Cancer Research UK Cambridge Centre. Wendy is an experienced programme manager and biotechnology research leader. Her areas of expertise include oncology small molecule drug discovery gained at GlaxoSmithKline, Millennium Pharmaceuticals (UK), PIramed Ltd. She was formerly CSO at Abcodia, a UCL spin-out engaged in the development of novel tests for the early detection of cancer.

10.00 – 10.30
Conference Room 2

## What Beats The Beads – Multiplexed Immunoassays For Biomarker Assays

Bead based assays allows:

- To visualize the serological response towards a variety of Borrelia antigens from five different Borrelia species by simultaneously analyzing IgM and IgG levels using the INTELLIFLEX® Dual Reporter Assay
- To perform multiplex ACE2 RBD competition assay of SARSCoV-2 after vaccination or infection as an alternative to infectious live-virus neutralization tests
- The detection of hundreds of proteins and protein modifications from a minimal amount of sample to visualize intracellular signalling in tumour cells

THOMAS JOOS, Deputy Managing Director,
**NMI Natural and Medical Sciences Institute at the University of Tübingen; Luminex**

Since 2013: Deputy Managing Director, NMI, 2008 - 2014 Director Strategic Alliances, EDI GmbH, Reutlingen (part time), 2000 - 2017 Head of Biochemistry Department, NMI, 1998 - 2000 Research Assistant, NMI, 1994 – 1998: Postdoctoral research, Dept. of Cell Biology, Max Planck Institute for Developmental Biology, Tübingen, 1994: Ph.D. degree (Dr. rer. nat), Dept. of Cell Biology, Max Planck Institute for Developmental Biology, Tübingen (under Prof. P. Hausen; Topic: "Integrin-α5 during early embroygenesis of Xenopus laevis", 04–08 1988: Molecular biology practical, Biochemistry Dept., the Brandeis University“ (under Prof. Andrew Szent-Györgyi), Waltham, Massachusetts, USA, 1984 – 1990: Study of Biochemistry, University of Tübingen. Dr. Joos is a member of the editorial board of "Drug Discovery Today", "Proteomics" and "Expert Review of Proteomics". He is a member of the Scientific Advisory Board of the Plasma Proteomics Institute in Washington, DC, USA and a member of the Scientific Advisory Board of Myriad RBM Inc. in Austin, Texas, USA. Dr. Joos is the author of >100 scientific papers. He is recognized worldwide as an expert and opinion leader in the technology field of biomarkers and their clinical applications and basic research. Dr. Joos is co-founder of SIGNATOPE GmbH, Reutlingen. SIGNATOPE develops innovative protein tests with which biomarkers for organ damage and drug interactions can be detected in all pharma-relevant species.

11.50 – 12.15
Conference Room 2

## Biomarker Data Curation In A Changing Biopharmaceutical Development Environment

As the use of different data sources is moving into the focus of biopharmaceutical development, it is time to rethink the role of data management. Together with the use of real-world data and external patient data, the use of biomarker data for clinical decisions is changing the paradigm of clinical drug development. Data management and statistics play an important role in this transformation.

RICHARDUS VONK, Vice President, Head Oncology Statistics and Data Management,
**Bayer AG**

Vice-President, Head of Oncology Statistics and Data Management Bayer AG, Berlin, Germany
Richardus is a data and statistics afficionado and is recognized as a leading advocate of quantitative pharmaceutical development, a field in which he has over 30 years of experience. He regularly speaks about how an increased ability to derive actions from data determines the success of drug development programs and leads to a competitive advantage. Richardus advances data-driven decisions in pharmaceutical development to the next level, aligning the latest scientific research with operational requirements.

12.15 – 12.45
Conference Room 2

## Highly Reproducible Multiplexed Immunofluorescence Assays: From Discovery To Translational Research

- Multiplexing immunofluorescence imaging enables the analysis of the whole tissue microenvironment
- How the COMET™ performs automated staining and imaging
- How COMET™ allows to achieve high-quality, reproducible and uniform results.

BASTIAN NICOLAI, Product Manager,
**Lunaphore**

Bio

12.45 – 13.15
Conference Room 2

## Sensitive Biomarker Discovery Via Representation Learning On Single-Cell Data

- Single-cell data presents a rich source of information for biomarker discovery

- Representation learning finds relevant patterns in data
- The ScaiVision platform uses representation learning for biomarker discovery
- ScaiVision performs best-in-class (compared to other single cell algorithms)
- ScaiVision can extract a biomarker signature from the trained models
- Using ScaiVision on clinical data (use cases)

MARTIJN VAN ATTEKUM, Technical Lead,
**Scailyte AG**

Martijn van Attekum is trained as a medical doctor and obtained a PhD in oncology. He has worked on a variety of biomedical AI topics, such as protein feature prediction or patient stratification using image analysis. At Scailyte, Martijn has developed ScaiVision, the AI-driven discovery platform for ultra-sensitive biomarkers from single-cell omics and clinical data modalities.

14.15 – 14.45
Conference Room 2

## Exploring Biomarkers Research With Dimensions

Research is being published at a higher rate than ever, so keeping on top of the latest developments in biomarkers research is challenging. Our technology helps you identify the most relevant publications, and discover information that may be missed, giving you a comprehensive overview of cutting edge developments. Our automated extraction of information, unique content coverage, and interactive data visualisation capabilities help you interrogate research information to quickly identify connections and trends in biomarkers research, helping inform your future strategy

SUZE KUNDU, Head of Engagement, Chemistry Specialist,
**Digital Science, Dimensions Life Sciences and Chemistry**

Dr Suze Kundu has a BSc in Chemistry, a MSc in Analytical Chemistry and a PhD in Materials Chemistry from University College London. A passionate educator, she has also studied for a PGCE in Senior School Science, and an MEd in University Learning and Teaching while teaching at Imperial College London. After six years lecturing in the Department of Materials at Imperial College London and at the University of Surrey's Chemical and Process Engineering Department, she is now the Head of Engagement at the technology company Digital Science, where she continues to research interesting topics within chemistry and materials science, but also the wider research landscape with their flagship software solution, dimensions.

14.45 – 15.10
Conference Room 2

## Panel Discussion: From The Real World To Real Time Biomarker Data

- Review of the real world of biomarker data and what value it brings
- New Developments in Biomarker RWD and Innovations
- Need for Real Time Biomarker Data
- Impact of Real Time Biomarker Data

*Panellist:* MIIKA AHDESMÄKI, Director, Early Computational Oncology R&D

**AstraZeneca**

Bio

*Panellist:* SONIA RODRIGUES, Executive Director Oncology Regulatory Science and Strategy, Hematology Head,
**AstraZeneca**

Bio

*Panellist: (Invited)* RICHARDUS VONK, Vice President, Head Oncology Statistics and Data Management,
**Bayer AG**

Vice-President, Head of Oncology Statistics and Data Management Bayer AG, Berlin, Germany
Richardus is a data and statistics afficionado and is recognized as a leading advocate of quantitative pharmaceutical development, a field in which he has over 30 years of experience. He regularly speaks about how an increased ability to derive actions from data determines the success of drug development programs and leads to a competitive advantage. Richardus advances data-driven decisions in pharmaceutical development to the next level, aligning the latest scientific research with operational requirements.

15.10 – 15.35
Conference Room 2

## Flow Cytometry In Clinical Drug Development

- Flow cytometry in pre-clinical and clinical development
- Application of Flow for biomarker and bioanalytical applications
- Development and validation of Flow Cytometry assays
- Biomarker validation strategy

SION LEWIS, Principal Scientist,
**UCB**

Sion is a Principal Scientist and Flow Cytometry Subject Matter Expert in the Translational Biomarker and Bioanalysis Department at UCB, supporting preclinical and clinical stage assets across a range of modalities. Drawing on over 20 years experience in Immunology, Immuno-Oncology and Stem Cell Biology in Clinical/Academic, Biotech and Biopharma environments. Sion specialises in Flow Cytometry Biomarker discovery and validation, with experience in developing diagnostic, prognostic, immunophenotyping, pharmacodynamic and target occupancy/engagement biomarkers. Sion has a PhD in Biochemical Engineering from University College London and an MSc. in Biomedical Sciences Research from King's College London.

16.05 – 16.30
Conference Room 2

## Spatial Biology For Drug Development

- Application of spatial biology in drug development for drug disposition, safety, efficacy, model characterisation and disease understanding

STEPHANIE LING, Associate Director, Integrated Imaging, Imaging and Data Analytics, CPSS, **AstraZeneca**

Bio

# DAY TWO | TRACK 3: BIOMARKERS FOR CLINICAL DEVELOPMENT & PRECISION MEDICINE

## Speaker Biographies and Session Information

**Biomarkers are vital for enabling precision therapies, particularly within the oncology field. Precision medicine holds promise for improving many aspects of healthcare, with a better understanding of underlying mechanisms of disease and improved approaches for prevention, diagnosis and treatment of diseases. This track looks at the importance of making meaningful clinical use of biomarkers and explores the importance of collaboration in precision medicine.**

09.35 – 10.00
Conference Room 3

### Importance Of Collaboration In Precision Medicine

- What is Precision Medicine and its benefits
- Role of diagnostic Precision Medicine
- Perspectives from the pharmaceutical industry
- Challanges and potential solutions

GABRIELE ALLEGRI, Global Commercial Head,
**Precision Medicine, Johnson & Johnson**

Values-driven leader with 15+ years of international experience (Turkey, Italy, France, Germany and the US) with proven progressive leadership experience in sales, marketing, market access and general management in Healthcare sector, Gabriele Allegri is leading Global Commercial Strategy and Access Precision Medicine in Janssen. In his role is leading companion and complementary diagnostics (Co Dx) for all Therapeutic Areas (TAs), for all stages of commercialization, from project evaluation to commercialization and launch planning in all global markets. With a MS in Management Engineering, achieved in Italy, France and Germany, Gabriele Allegri began his career in the US in startup company focusing on Big Data. Two years later, he returned to Europe and began working for the consulting firm Accenture, in the Sophia Antipolis Innovation Center. He joined Janssen in 2005 Gabriele holds a university degree in Industrial and Management Engineering and an MBA from the SDA Bocconi Milano, Italy.

10.00 – 10.30
Conference Room 3

## Getting Precisely What You Need From Your Biomarker Led Clinical Trials

A review of key practical considerations for success including:

- Scientifically focussed choice of analytes & platforms: translation from preclinical to clinical
- Clinical sample strategy: format, integrity, management & logistics
- Biomarker assay validation for clinical trial assays – regulatory requirements
- Data analysis, management, and integration of complex datasets

AMANDA J. WOODROOFFE, Senior Vice President, General Manager, UK Labs,
**Precision for Medicine**

Bio

11.50 – 12.15
Conference Room 3

## What Makes Clinical Trials Patient Centric: Biomarker Perspective

- Main drivers for biomarker patient centricity
- Key advantages and limitations of patient centric sampling
- Important considerations for sample collection and data interpretation

DMITRI MIKHAILOV, Director, Head Biomarker Coordination,
**Novartis**

Dmitri Mikhailov is the Global Head of Biomarker Study Coordination, Translational Medicine at Novartis. Dmitri's team is responsible for clinical biomarker study setup across multiple therapeutic areas, and for developing new processes and technologies to improve clinical study conduct. As part of his role, Dmitri represents Novartis on the Patient Centric Sampling IQ consortium, developing best practices for new generation clinical trials. Dmitri is also the global lead for Novartis Human Tissue Network, the company wide effort to develop risk-based strategy and efficient processes to enable translational research using human samples. Dmitri joined Novartis in 2003 and had several positions of increasing responsibility in early biology, lead discovery, safety pharmacology and drug repositioning. Dmitri Mikhailov holds Ph.D. in Biology and M.S. in Physics & Applied Math.

12.15 – 12.45
Conference Room 3

## Autoantibodies As Biomarkers Of Disease, Response And Adverse Events

The presentation will cover an introduction to Oncimmune and the ImmunoINSIGHTS autoantibody profiling service. Autoantibody biomarker data will be presented in:

- Immuno-Oncology response and irAEs to checkpoint inhibitors, bispecific antibodies, cancer vaccines and oncolytic viruses

- Autoimmune disease characterisation and response in SLE, Sjögren's disease and systemic sclerosis
- Infectious diseases - COVID-19 and the autoimmune reactions SARS-CoV-2 invokes

MIKE FISHER, Vice President, Head of Business Development,
**Oncimmune**

Mike has a PhD in medicinal chemistry and 25 years' experience of life sciences business development, commercialisation, project management and government relations. He has worked in both the public and private sectors, focusing on the diagnostics industry for the past 15 years. Mike joined Oncimmune in 2017 and drove the adoption strategy for EarlyCDT Lung in the UK and Europe before taking on the business development responsibility for ImmunoINSIGHTS, Oncimmune's companion diagnostics work with the biopharmaceutical industry. Mike Joined Oncimmune from Abcodia, where he was Director of Strategic Alliances, focusing on biomarker validation for early detection of cancer and other diseases. Between 2005 and 2008, Mike was the UK government's Life Sciences Industry Advisor for North America, based in Cambridge MA, where he liaised between US corporates and the Department of Health, NICE and MHRA. Prior to moving to the US Mike worked in life science economic development where he raised over £10m for infrastructure projects to support biotech commercialisation and provided internationalisation consultancy to life science companies.

12.45 – 13.15
Conference Room 3

## Hypoxia Biomarkers: Personalising Cancer Treatment By Targeting Hypoxia. Mantra Diagnostics Ltd.

- Measuring hypoxia in solid tumours
- Directed cancer therapy choices
- Advance personalised cancer medicine
- Improved patient outcomes

JOELY IRLAM-JONES, Research Associate/Direcor,
**University of Manchester**

Joely Irlam-Jones, a Research Associate at the University of Manchester and Director and CEO of ManTRa Diagnostics, a spin-out company from the University of Manchester that is developing patient stratification solutions to personalise medicine and improve cancer treatment outcomes. The team have developed tumour-site-specific gene expression signatures which indicate the oxygen status of the tumour.

14.15 – 14.45
Conference Room 3

## Unprecedented Sensitivity And Specificity For Analysis Of Short Nucleic Acids And Rare Sequence Variants

We present an exceedingly sequence specific and sensitive method to analyse short nucleic acids called Two-Tailed PCR (2T-PCR) that is particularly suitable for microRNA and rare sequence variant analyses. 2T-PCR takes advantage of a target-specific primer composed of two hemiprobes, complementary to two different parts of the target molecule, connected by a hairpin structure. The introduction of short hemiprobes that sense the target sequence confers exceeding specificity while maintaining the very high sensitivity of PCR. Highly similar targets can be distinguished with superior precision irrespectively of the position of the variant nucleotide. Further, the target molecule can be as short as some 15 bases, making 2T-PCR the preferred method for microRNA profiling, analysis of forensic samples, ancient material, formalin fixed, and paraffin embedded (FFPE) material, and rare sequence variants in cell-free DNA. 2T-PCR is readily multiplexed and is compatible with real-time as well as digital PCR, making it the preferred method for pharmacokinetic and pharmacodynamic (PK/PD) studies for the development of advance therapy and medicinal products (ATMPs).

MIKAEL KUBISTA, Founder and Chief Executive Officer,
**TATAA**

Dr Kubista was one of the pioneers in the molecular analyses space inventing several methods and technologies used, most recently the Two-Tailed PCR for the analysis of short nucleic acids and rare sequence variant detection. In 2001 Kubista set up TATAA Biocenter, originally as training center, which has developed to the prime provider of molecular analyses services to the pharmaceutical and diagnostic industries, with ISO 17025 accreditation and GLP/GCP compliance. In 2019 TATAA was named “Best Nucleic Acid Analysis Service provider – Europe” by Global Health & Pharma. Kubista co-authored the MIQE and dMIQE guidelines for qPCR and dPCR analyses and he is member of the CEN/ISO working group developing guidelines for molecular diagnostics. Kubista also heads the Department of Gene Expression at the institute of Biotechnology, BIOCEV, Czech Academy of Sciences.

14.45 – 15.10
Conference Room 3

## Precision Medicine 2.0 - Biosignatures, Patients And Personalization

- Precision Medicine And Patient Engagement
- Complexity needs to be appreciated and managed
- Don’t forget the human touch

THOMAS HACH, Executive Director Patient Engagement,
**Novartis**

Thomas Hach, MD, is Executive Director Patient Engagement for Cardiovascular, Renal & Metabolism (CRM) at Novartis. He is leading end-to-end patient engagement strategy and operations for the broad CRM portfolio at Novartis. Thomas also held positions of Global Brand Medical Director Neuroscience, Senior Global Health Advisor and Director Healthcare Systems. His passion and expertise are in precision medicine, preventative medicine, patient centricity and partnerships. He joined Novartis from Boehringer Ingelheim, where he was Global Senior Medical Director, Therapeutic Area Metabolism. Prior to that, he was an associate principal at McKinsey & Company, serving as a leader in the pharmaceuticals and healthcare practice. Dr. Hach conducted several years of research and clinical practice in diabetes/microcirculation at Karolinska Institutet, Sweden. At the beginning of his clinical career, he worked in orthopedic surgery in Sweden and Germany. He received his medical degree from University of Mainz, Germany.

15.10 – 15.35
Conference Room 3

## Microfluidics And Clinical Oncology Research

- Technological developments such as droplet-based digital PCR and optimized
- NGS allow the highly sensitive and precise detection of circulating tumor DNA (ctDNA) within liquid biopsies, several biomarkers have now been developed to track ctDNA
- ctDNA allows for efficient patient monitoring in different cancers both for advanced and early cancers

VALERIE TALY, Group Leader and CNRS Research Director,
**INSERM, Centre de recherche des Cordeliers, Université Paris Cité**

V. Taly is a CNRS research director and group leader of the Translational Research And Microfluidics group within the MEPPOT team (Personalized medicine, pharmacogenomics and therapeutic optimization) located in the Cordeliers Research Center (CRC). Her group performs interdisciplinary researches aiming at developing and validating microfluidic tools for cancer research in close collaboration with clinicians and researchers in oncology. Since 2008, she developed droplet-based digital procedures for Cancer diagnosis. Recently, her research has been dedicated to the clinical validation of droplet-based microfluidics for the discovery and non-invasive monitoring of Cancer biomarkers, as well as the development of original tools and procedures for their detection with applications in personalized medicine, cancer recurrence detection and cancer diagnostics. She is co-founder of EMULSEO and METHYS DX start up companies.

16.05 – 16.30
Conference Room 3

## EV-microRNAs As Liquid Biopsy Tool For Therapy Response Prediction In Hematological Malignancies

MICHIEL PEGTEL, Head of the Liquid Biopsy Center,
**Cancer Center Amsterdam**

Bio

# DAY TWO: GENOMIC MARKERS FOR DISCOVERY & DEVELOPMENT

## Speaker Biographies and Session Information

**There is an unmet need in the discovery and development of genomic biomarkers which are vital for identifying unknown genes that influence the risk of disease. This field holds promise for improving many aspects of healthcare, with a better understanding of underlying mechanisms of disease and improved approaches to prevention, diagnosis and treatment of diseases. Our Genomic markers track considers advances in liquid biopsies, CTCs and other genomic technologies that are impacting drug development.**

09.35 – 10.00
Conference Room 4

### Accelerating The Delivery Of Genomic Medicine

- What are the current barriers to the delivery of genomic medicine into routine healthcare settings?
- How can mainstreaming of genomics accelerate drug development and biomarker discover?
- What can we learn from the pandemic to expedite progress in other fields?

PHILIP BEER, Vice President, Head of Research and Translational Medicine,
**Step Pharma**

Philip is a physician scientist with expertise in drug development and biomarker discovery. He followed his initial training as a haematologist with 8 years' research in Cambridge and Vancouver, focused on understanding genotype-phenotype correlations in haematological cancers and developing improved preclinical models of leukaemia. Since then, Philip has worked cross-sector in academic, healthcare and biotech roles with a unified goal of accelerating oncology drug development and ensuring that each patient receives the most suitable therapy.

11.50 – 12.15
Conference Room 4

### Panel Discussion: Enabling Precision Oncology

- How genomics, transcriptomics, and proteomics are being combined in the quest to optimise precision oncology
- Advancing biomarker discovery and oncology clinical development programs

- Application in basic clinical sample studies
- Application in translational research (clinical trials)

*Moderator: (Invited)* ERIN NEWBURN, Director, Field Application Scientist, ERIN NEWBURN, Director, Field Application Scientist,
**Personalis, Inc.**

Dr. Newburn joined Personalis as a Field Applications Scientist in 2013 with over 13 years of research experience in the areas of molecular biology, genetics, and biotechnology. As the Director, Field Applications Scientist, Erin's team has the responsibility of providing both pre- and post-sale technical support for the Personalis NeXT Platform including both the ImmunoID NeXT and NeXT Personal solutions. Erin completed her postdoctoral training at the National Institute of Mental Health (NIMH) investigating candidate susceptibility genes for major psychiatric illnesses. Erin received her Ph.D. from the Ohio State University in Integrated Biomedical Science as a Presidential Fellow.

*Panellist:* MARTIN MILLER, Senior Director,
**AstraZeneca**

In late 2021, Martin Miller joined Early Computational Oncology (ECO) in Translational Medicine in Oncology R&D at AstraZeneca. Within ECO, Martin leads the Computational Biology efforts focussing on understanding and characterising resistance mechanisms to cancer immunotherapies. Before joining AZ, Martin was a Group Leader at Cancer Research UK, Cambridge Institute at the University of Cambridge. Martin did his PhD in Bioinformatics at the Technical University of Denmark and a post doc in Computational Oncology at Memorial Sloan Kettering Cancer Center. Martin's research is focussed on understanding how cancer cells manipulate the tumour microenvironment (TME) and escape anti-tumour control mechanisms. Martin leads the cross-functional immunogenomic analysis efforts in Translational Medicine at AZ to deliver critical insights into tumour and patient characteristics that underpin sensitivity and resistance to immunotherapies.

*Panellist:* MICHIEL PEGTEL, Head of the Liquid Biopsy Center,
**Cancer Center Amsterdam**

Bio

*Panellist:* JEREMY P. SEGAL, Director, Molecular and Cytogenetic Pathology, Associate Professor of Pathology
**University of Chicago**

Jeremy Segal, MD, PhD is the director of Molecular and Cytogenetic Pathology and Associate Professor of Pathology at The University of Chicago. He completed his MD and PhD at Weill Cornell and Rockefeller University in New York City and Molecular Genetic Pathology fellowship at University of Pennsylvania prior to joining UChicago in 2013. At UChicago, Dr. Segal is focused on the clinical development and implementation of advanced genomic testing methodologies to help diagnose and manage patients with solid tumors and hematological malignancies. He is also Co-Founder of the Genomics Organization for Academic Laboratories (GOAL), a consortium effort dedicated to the advancement of genomic testing at academic and non-profit laboratories.

12.15 – 12.45
Conference Room 4

## Translational Medicine To Revolutionize Dermatologic Care

- Identify biomarkers of specific diseases and disease subsets
- Track and predict drug responses
- Stratify and select patients based on multi-omic skin profiles

TERRY ARNOLD, Senior Director of Medical Affairs,
**DermTech**

Terry Arnold is the DermTech Senior Director of Medical Affairs, leading our field team of Medical Science Liaisons. He is a nationally-certified Physician Assistant who spent more than 20 years in the dermatology specialty and four years in internal medicine practice. Terry has served in leadership positions on the local, state and national levels with professional organizations, non-profit agencies, and consumer advocacy groups. Prior to joining DermTech he held positions of increasing responsibility at a major biopharmaceutical company as a member of their Field Medical team and as a Scientific Director. His areas of interest include melanoma and non-melanoma skin cancer, inflammatory skin diseases, and dermatologic manifestations of internal disease. Terry is a graduate of the U.S. Air Force Academy, a veteran of Operation Desert Shield and Operation Iraqi Freedom, and has been awarded the Meritorious Service Medal and Air Force Commendation Medal.

12.45 – 13.15
Conference Room 4

## Solution Provider Presentation Exploring

VOLODIMIR OLEXIOUK, Team Lead, AI & Analytics,
**BioLizard**

During his PhD, Volodimir obtained extensive experience in multi-omics data integration crossing the field of genomics, translatomics and proteomics in order to identify novel coding entities across multiple model organisms. Next to multi-omics data mining, software applications and a public repository were developed in order to translate analytical findings to a broader scientific and clinical context, leading to a 4 month internship at DUKE-NUS, Singapore. After his PhD, Volodimir joined the center of medical genetics as a postdoc (UZGent), where he focused on data analytics in the context of oncology, with an emphasis on single cell

technologies. Later, he ventured into the consultancy world focusing on providing ML, AI and software expertise across a wide range of sectors, such as banking, insurance, energy and public sector. As the team lead of AI and analytics, Volodimir provides expertise within multi-omics data analytics, predictive analytics, biomarker discovery, (bio)statistics, single cell, MLOPs, deep learning and AI.

14.15 – 14.45
Conference Room 4

## Solution Provider Presentation Exploring

Senior Representative,
**Merck**

Bio

14.45 – 15.10
Conference Room 4

## Validating An Automated, Multiplexed NGS Assay For Rapid Turnaround Time

- How the Genexus integrated sequencer reduces TAT
- What targets are covered by the Oncomine Precision Assay panel
- What special considerations are required for this validation

COREY ROGERS, Genomic Development Specialist,
**Hospital of the University of Pennsylvania**

phil Rogers, Ph.D., is a Genomic Development Specialist at the Hospital of the University of Pennsylvania's Center for Personalized Diagnostics. His work involves the development and validation of new molecular assays for the diagnosis, prognosis, and treatment of hospital patients. He also works to establish proper quality control metrics for assay workflows, troubleshoot assay errors, and train staff members. Corey received his Bachelor of Science in Biology from La Salle University before attending Thomas Jefferson University in Philadelphia to earn his Ph.D. in Biochemistry and Molecular Pharmacology. His thesis involved understanding the molecular mechanisms of programmed cell death in the context of cancer. Prior to his current position, Corey worked as a Research Scientist to develop and validate diagnostic assays in the field of reproductive medicine.

15.10 – 15.35
Conference Room 4

## Goal Consortium Efforts In NGS Oncology Testing

- Understand the traditional barriers to development of NGS oncology diagnostics at academic medical centers in the US
- Learn about the formation of the Genomics Organization for Academic Laboratories (GOAL)
- Learn about current and future GOAL initiatives and future possibilities

JEREMY P. SEGAL, Director, Molecular and Cytogenetic Pathology, Associate Professor of Pathology,

**University of Chicago**

Jeremy Segal, MD, PhD is the director of Molecular and Cytogenetic Pathology and Associate Professor of Pathology at The University of Chicago. He completed his MD and PhD at Weill Cornell and Rockefeller University in New York City and Molecular Genetic Pathology fellowship at University of Pennsylvania prior to joining UChicago in 2013. At UChicago, Dr. Segal is focused on the clinical development and implementation of advanced genomic testing methodologies to help diagnose and manage patients with solid tumors and hematological malignancies. He is also Co-Founder of the Genomics Organization for Academic Laboratories (GOAL), a consortium effort dedicated to the advancement of genomic testing at academic and non-profit laboratories.

16.05 – 16.30
Conference Room 4

## EV-microRNAs As Liquid Biopsy Tool For Therapy Response Prediction In Hematological Malignancies

MICHIEL PEGTEL, Head of the Liquid Biopsy Center,
**Cancer Center Amsterdam**

Bio

# Biomarkers UK: In-Person

## DAY ONE: 03 MAY 2022 | LONDON, UK

## DAY ONE: 03 MAY 2022

**08:20** **Oxford Global Welcome Address & Chairperson's Opening Address**

**08:30**

**Opening Keynote Address: Importance Of Collaboration In Precision Medicine**

- What is Precision Medicine and its benefits
- Role of diagnostic Precision Medicine
- Perspectives from the pharmaceutical industry
- Challanges and potential solutions

GABRIELE ALLEGRI, Global Commercial Head,
**Precision Medicine, Johnson & Johnson**

### CONFERENCE ROOM 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN ONCOLOGY AND IMMUNO-ONCOLOGY

**Morning Track Chair:** To Be Announced
**Afternoon Track Chair:** ADEELA KAMAL, Senior Vice President, Biology & Translational Medicine, **SpringWorks Therapeutics**

### CONFERENCE ROOM 2: BIOMARKERS FOR DIAGNOSTICS & PRECISION MEDICINE

**Track Chair:** GABRIELE ALLEGRI, Global Commercial Head, **Precision Medicine, Johnson & Johnson**

### CONFERENCE ROOM 3: BIOMARKERS FOR CLINICAL DEVELOPMENT

**Track Chair:** VIJAY TIWARI, Professor and Group Head, Oncology Laboratory, **Wellcome-Wolfson Institute for Experimental Medicine, Queen's University Belfast**

### CONFERENCE ROOM 4: DIGITAL PATHOLOGY & AI/MACHINE LEARNING FOR BIOMARKER RESEARCH

**Track Chair:** MARTIN GROHER, Senior Director Software Product Management, **AstraZeneca Computational Pathology GmbH**

**08:55**

**Biomarker-Guided Drug Development: Vertical Inhibition Of The MAPK Pathway In NRAS Mutant Melanomas**

- Biomarker-driven pipeline-in-a-molecule development strategy
- Targeting MAPK aberrant solid tumors with a MEK inhibitor in combination with a RAF inhibitor
- Additive effects in NRAS mutant melanoma patient-derived models

ADEELA KAMAL, Senior Vice President, Biology & Translational Medicine,
**SpringWorks Therapeutics**

**Decoding The Mechanisms Of Metastasis And Therapy Resistance In Triple-Negative Breast Cancer**

- Reveal subclonal cell populations associate with tumor aggressive features
- Show that upon exposure to NAC, TNBC cells undergo distinct transcriptional reprogramming and enrich features for chemoresistance and metastasis
- Provide a potential first-in-class multi-gene assay for predictive chemotherapy response upfront for TNBC patients
- Show potential alternate therapeutics strategies for TNBC patients resistant to chemotherapy

VIJAY TIWARI, Professor and Group Head, Oncology Laboratory, **Wellcome-Wolfson Institute for Experimental Medicine, Queen's University Belfast**

**Minimally Invasive Assessment Of Molecular Profiles In Inflammatory Skin Disease**

- Brief overview of non- and minimally invasive technologies for biomarker assessments in dermatology
- Examples from exploratory clinical trials
- Concluding remarks on pros and cons of these methods

MADS ROPKE, Senior Principal Clinical Pharmacologist,
**LEO Pharma A/S**

**A Production System For Computational Pathology In A Pharma Context**

- An overview how digital pathology & AI is used within translational sciences
- Details about users, needs, and solutions for a computational pathology system
- Examples to illustrate how such systems pave the way for efficient & targeted discovery of digital biomarkers

MARTIN GROHER, Senior Director Software Product Management,
**AstraZeneca Computational Pathology GmbH**

**09:20**

**Why High-Plex Digital Spatial Profiling Needs To Be Part Of Biomarker Plans In Drug Discovery And Development**

- Challenges with standard biomarker discovery and development approaches
- Biomarker discovery and development opportunities enabled by high-plex spatial biology technologies
- Forward thinking ideas

ESPY ANGUIANO, Scientific Market Development Director -BioPharma,
**Nanostring Technologies**

**Non-Invasive Biomarker Identification And Measurement Using Breath Biopsy®**

- Development of Breath Biopsy OMNI, the first standardized platform for the identification and measurement of on-breath biomarkers
- Case studies demonstrating the analytical performance of OMNI for breath biomarker discovery and validation
- Strategies for moving breath testing from centralised analysis to point-of-care solutions

HUW DAVIES, Vice President of Global Sales,
**OwlStone Medical**

**Including Direct Measurements Of Target Engagement And Activity In CNS Clinical Trials**

- Overview of limitations and failures of recent clinical trials targeting the central nervous system
- Introduction to The Science Behind (the people, the technology, the network of expertise)
- Overview of electrodiagnostic biomarkers and examples of their application in measuring target engagement in early clinical trials
- Examples of cutting edge electrodiagnostic biomarker research in neurodegeneration
- Examples highlighting how electrodiagnostic markers can be integrated into clinical trials

ROISIN MCMACKIN, Clinical Research Consultant,
**The Science Behind**

**How To Develop A 6-Plex Chromogenic Mx Stain On An Automated Staining System**

- Immunohistochemistry (IHC) detects proteins of interest within whole tissue sections, keeping cellular organization intact. Evolving from conventional IHC (single slide, single marker), multiplex IHC is an advancement in this technique that enables the detection of multiple markers of interest simultaneously in one tissue section
- The ability to analyze multiple markers is important as cells do not exist or act in isolation, and cellular responses involve the activation of several pathways that influence the nature of their responses
- Multiplexing can therefore be applied to address several types of research questions including, but not limited to, the spatial arrangement or quantity of different cell lineages, phenotyping of immune cells, evaluation of multiple effectors of signal transduction pathways, and the distribution of novel drugs. Performing (IHC) manually may spark dread due to the lengthy nature of the process
- In this talk, we would like to show you a flexible, consistent, fully automated workflow that decreases the hands-on time for up to 6-plex chromogenic staining

CHARLOTTE GRAY, Application Consultant,
**Leica Biosystems**

**09:50** **Morning Coffee & Refreshments, 1-2-1 Meetings x4, Poster Presentation Sessions**

# Biomarkers UK: In-Person

## DAY ONE: 03 MAY 2022 | LONDON, UK

| | CONFERENCE ROOM 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN ONCOLOGY AND IMMUNO-ONCOLOGY | CONFERENCE ROOM 2: BIOMARKERS FOR DIAGNOSTICS & PRECISION MEDICINE | CONFERENCE ROOM 3: BIOMARKERS FOR CLINICAL DEVELOPMENT | CONFERENCE ROOM 4: DIGITAL PATHOLOGY & AI/MACHINE LEARNING FOR BIOMARKER RESEARCH |
|---|---|---|---|---|
| 11:10 | **The Value Of Model Selection In Preclinical Biomarker Discovery And In Vitro/In Vivo Translatability**<br>An example on predictive biomarker exploration and validation for Debiopharm's WEE1 inhibitor Debio 0123:<br>• In vitro drug sensitivity screening: from a tissue-agnostic to an indication-specific approach<br>• Generating a predictive biomarker hypothesis: drug sensitivity versus -omics data<br>• How publicly accessible transcriptomics data (CCLE) compare to in-house generated data<br>• Translatability from in vitro-generated biomarker hypothesis to pre-clinical in vivo CDX/PDX models<br>JEANNETTE FUCHS, Associate Scientist, **Debiopharm** | **If 98% Of Biomarkers Fail, Is It Time To Give Up Or Rethink Our Strategies?**<br>• Millions are spent on Biomarker research in Academia and Industry but only a tiny fraction, less than 2%, achieve clinical adoption with the rest stalling or failing<br>• This talk will consider where we are failing in Biomarker research and how Academia and Industry can work better together to discover, validate and implement the Biomarkers we need to improve patient care<br>• It will also consider what features of Biomarkers make them most likely to succeed<br>CHRISTOPHER PETERS, Clinical Senior Lecturer, **Imperial College London** | **Biomarkers In Drug Development: Applications In Cardiovascular Diseases**<br>• Biomarkers for assessment of target engagement in early clinical studies<br>• Translational approaches and patient stratification<br>• Remote biomarker sampling for disease detection<br>*(Joining Online)* PIA DAVIDSSON, Senior Director, Translational Science & Experimental Medicine, **AstraZeneca** | **Biomarkers Of Human Longevity**<br>• Data Science and AI for Accelerating Ageing Research and R&D<br>• The Critical Catalyst for Practical Human Longevity and Precision Health<br>• Tangible Investment Decision Making and De-Risking in the Longevity Industry<br>DMITRY KAMINSKIY, General Partner, **Deep Knowledge Group** |
| 11:35 | **From Discovery To Therapy: The Power Of 10x Genomics Single Cell And Visium Spatial Analysis**<br>• Access the resolution you need to explore complex tumor heterogeneity, distinct immune microenvironments and discover T cell responses to therapy with single cell and spatial multiomics<br>• Identify novel cell types and biomarkers, track clonal behavior, and monitor cells over time<br>NICOLA CAHILL, Science and Technology Advisor, **10xGenomics** | **10 Things I Hate About Proteomics**<br>The next generation of proteomics enables measurement of 7000 proteins at once. With this comes many new considerations and a similar number of myths that should be dispelled. In this talk you will learn about:<br>• Mitigation of challenges specific to massive scale proteomics<br>• Why the next generation of proteomics needs machine learning to remain impartial<br>• Common misconceptions about proteomics versus genuine limitations<br>STEPHEN A. WILLIAMS, Chief Medical Officer, **Somalogic** | **Biomarker Discovery From Gene Expression: Challenges And Solutions For Success**<br>What you will learn:<br>• Challenges associated with analysing gene expression data<br>• Key study design considerations for biomarker discovery<br>• Best practices for training and validating a gene expression signature<br>• Making use of public data repositories and integrating different data types<br>• Innovative reporting of gene expression signatures using Almac's proprietary bioinformatics software solution – claraT<br>JONATHAN YOUNG, Senior Bioinformatics Scientist, **Almac Group** | *Delegates are welcome to attend co-located sessions* |
| 12:05 | **Panel Discussion: Biomarker Strategies In Neurodegenerative Therapeutics**<br>• Enabling technologies and Imaging approaches to improve target engagement and early diagnostic biomarkers<br>• How best to incorporate biomarkers into drug development and clinical trials for neurodegenerative diseases<br>• Recent advancements in developing biomarkers for clinical utility<br>**Panellists:**<br>KIRA HOLMSTRÖM, Head of Biomarker Research, **Herantis Pharma Plc**<br>GERGELY TOTH, Chief Executive Officer & Chief Scientific Officer, **Cantabio Pharmaceuticals**<br>JENNIFER BARNETT, Chief Executive Officer, **MonumentTx** | **Multiplexed Biomarker Analysis For Precision Medicine: Towards The Identification Of Biomarkers Of Nash/NAFLD Disease Progression**<br>• Stratification of the ABOS cohort led to the stratification of about 800 patients in 3 distinct groups according to their liver status (NASH, NAFL, Healthy)<br>• A multi omics analysis was performed including proteomics and metabolomics (lipids, free fatty acids and oxysterols) from plasma/serum, miRNA sequencing from liver biopsies, RNA seq on a subset of samples from extreme phenotypes with unequivocal diagnosis<br>• Biomarkers candidates have been identified which are being further validated in additional independent cohorts<br>*(Joining Online)* VINCENT MIKOL, Precision Medicine Head, **Sanofi R&D** | **Exploring Biomarkers In NASH Clinical Trials**<br>• Precision medicine biomarker needs in NASH<br>• Evaluation of monitoring potential of biomarkers to detect NASH disease development during treatment<br>• Example from semaglutide phase 2b study<br>LOUISE MAYMANN NITZE, Principal Translational Medicine Scientist, **Novo Nordisk** | **Panel Discussion: Digital Pathology, Imaging & AI In Biomarker Research**<br>• Developing predictive biomarkers using computational pathology<br>• Pros and cons of immune-histochemistry techniques<br>• The robustness and process of validation of algorithms<br>• What is the potential for interplay between AI based image analysis and spatial transcriptomics in drug discovery? Does the light image hold all of the answers?<br>• What role can AI play in analysing the vast repositories of transcriptomic data and how can this be leveraged to discover new biology and biomarkers. Can these be translated into the clinic through the use of immuno histochemistry.<br>• How can AI and image analysis be used to measure dose variable responses in heterogeneous cellular populations to sublethal doses of drug candidates in high throughput screening. Can biomarkers be discovered that predict resistance and out growth?<br>**Moderator:** GRAHAM BALL, Professor, **Nottingham Trent University**<br>**Panellists:**<br>SEAN WALSH, Chief Scientific Officer, **Radiomics**<br>STEPHANIE ARNOLD, Senior Scientist, **Astra Zeneca**<br>MARTIN GROHER, Senior Director Software Product Management, **AstraZeneca Computational Pathology GmbH** |

# Biomarkers UK: In-Person

## DAY ONE: 03 MAY 2022 | LONDON, UK

### CONFERENCE ROOM 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN ONCOLOGY AND IMMUNO-ONCOLOGY

**12:30**

**Utilizing Comprehensive Platforms For The Biomarker Protein Production And Antibody Development**

- A panel of proprietary biomarkers and the monoclonal antibodies against these targets
- Advantages and strengths of our platforms and services
- The benefits of optimized CRO service workflow
- Working capacity of different platforms
- The lead times of different customized services
- Introduction of our additional antibody expression services, e.g. bispecific antibodies, scFv, VHH, Fab, IgM, etc.
- Experience and case study sharing of high-throughput antibody expression service
- Introduction of our platforms for monoclonal and polyclonal antibody development

*(Joining Online)* LINLIN ZHANG, Technical Specialist, **Sino Biological**

**Using A Dual Proteomics And Multiplexed IF Approach For The Detection Of Biomarkers Predictive For Response To ICI-Therapy**

- Identification of over 70 proteins differentially regulated in melanoma patients responding to therapy
- Several immune phenotypes, including T cell subsets and M1 TAMs, significantly increased in responders

ANNA JUNCKER-JENSEN, Principal Scientist, **NeoGenomics**

**14:30**

**Microsampling Technology For The Remote Detection Of Cytokines By Multiplex ELISA**

- Validation of workflows for the extraction and analysis of cytokines from finger prick blood samples will be described
- We aim to detect cytokine changes in immunotherapy patients taking samples at home, to predict immune-related adverse events

HOLLY BUTTERWORTH, Senior Scientific Officer, **Cancer Research UK Manchester Institute**

### CONFERENCE ROOM 2: BIOMARKERS FOR DIAGNOSTICS & PRECISION MEDICINE

**An Integrated MS Proteomics Platform From Biomarker Discovery To Customized Assay Panels**

- State-of-the-art mass spectrometry platform for unbiased biomarker discovery and development of customized assay panels across various biological specimen
- Sub-protein resolution allows quantification of proteoforms such as post-translational modifications, isoforms and mutations
- Discovery of biomarker signatures through quantitative profiling of paired CSF-plasma samples from an Alzheimer's Disease cohort

YUEHAN FENG, Director, Scientific Alliances, **Biognosys AG**

**Solution Provider Presentation**

Senior Representative, **Proteome Sciences**

**Panel Discussion: Clinical Diagnostics & Clinical Biomarkers**

- Taking hypotheses from research settings & testing in clinical development
- Bringing in the need for CDx before clinical development - developing cdx and biomarker development
- Managing and mitigating and qualification and validation of biomarkers
- Clinical end points from phase 1-3 & translatability of the end points
- Implications on translation and precision medicine

**Moderator:** AMANDA J. WOODROOFFE, Senior Vice President, General Manager, UK Labs, **Precision For Medicine**

**Panellists:**
CLARE BALENDRAN, Vice President, Head of Translational Medicine, **Novo Nordisk**
*(Joining Online)* VINCENT MIKOL, Precision Medicine Head, **Sanofi R&D**

### CONFERENCE ROOM 3: BIOMARKERS FOR CLINICAL DEVELOPMENT

**Using Explainable AI To Generate Highly Predictive And Interpretable Biomarker Signatures From Clinical Data**

- Modern assay technology paired with powerful computational methods has changed the way we discover biomarker signatures
- At Abzu, we have developed a workflow based on explainable AI that extracts the best possible predictive models from high-dimensional data, even with small sample sizes
- See how our new, interpretable approach to machine learning generates high-performance predictions from challenging omics and multi-omics data sets, getting the most out of clinical and experimental data

SAMUEL DEMHARTER, Head of Bioinformatics, **ABZU**

**Supporting Development Of Cellular Therapies: Pre-Clinical To Clinical Testing**

- CAR T cells have been revolutionary in treating certain types of haematological malignancy
- Pre-clinical in vitro and in vivo testing, coupled with biodistribution data, are crucial steps along the path to demonstrating efficacy of a candidate therapeutic
- We will describe the strategies used at CRL to support the development of a cellular therapeutic from pre-clinical testing through to clinical trials, and the steps required to uplift a pre-clinical assay to GCLP standards

CHRISTOPHER KIRKHAM, Team Leader Translational Biomarkers, **Charles River Laboratories**

**Insights Into A Non-Drug Interventional Trial Aiding In Clinical Qualification Of Prognostic And Monitoring Biomarkers For Liver Cirrhosis**

- Liver cirrhosis due to NASH is a life-threatening condition with no licensed treatment
- This trial aims to confirm the prognostic value of established and some emerging biomarkers in this field

ISABELLA GASHAW, Principal Clinical Biomarker Lead Cardiometabolism, **Boehringer Ingelheim**

### CONFERENCE ROOM 4: DIGITAL PATHOLOGY & AI/MACHINE LEARNING FOR BIOMARKER RESEARCH

**Streamlining The Highly Multiplexed Image Analysis Workflow**

- How Indica Labs' industry leading digital pathology products HALO®, HALO AI™, HALO Link™, and HALO AP® fit together to provide a comprehensive workflow from bench to bedside
- Overview of highly multiplexed assays supported by HALO image analysis
- Evaluation of the tissue micro-environment by 17-plex immunofluorescence using the Orion Platform from RareCyte and HALO Image Analysis

NATASHA CARMELL, Manager, Life Science Applications (EMEA), **Indica Labs**

**Using Causal-Reasoning Knowledge Graphs For Biomarker Identification**

With the rise of high throughput technologies and accumulating research data in biomedical sciences, knowledge graphs are powerful tools to understand and derive useful insights from this big data. At Biorelate we use state-of-the-art natural language processing techniques to mine information from various literature sources including clinical trials and drug-target databases. We then annotate this data with several clinical concepts and derive causal interactions and confidence scores. The end result is a comprehensive knowledge graph with directed interactions and a rich library of annotations. We use our knowledgebase to identify different classes of biomarkers for diseases based on graph properties.

DANIEL JAMIESON, Chief Executive Officer, **Biorelate**

**Application Of Machine Learning To The Discovery Of Biomarkers And Biological Drug Targets In Breast Cancer**

- We utilise machine learning methods to interrogate public transcriptomic data repositories to identify robust biomarker sets associated with clinical questions and molecular pathways
- We further analyse these molecular data to build digital twins of pathways and identify drivers of pathways
- We evaluate these drivers for their efficacy as drug targets, for their risk of having off-target effects, and their association with druggable biology

GRAHAM BALL, Professor, **Nottingham Trent University**

**13:00** **Lunch Break, 1-2-1 Meetings x3, Poster Presentation Session**

**14:00**

# Biomarkers UK: In-Person

## DAY ONE: 03 MAY 2022 | LONDON, UK

### CONFERENCE ROOM 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN ONCOLOGY AND IMMUNO-ONCOLOGY

**Precision Proteomics Enables Biomarker Identification And Characterization**

- In this scientific seminar we will discuss our capabilities and we will present case studies elucidating the role of precision proteomics and Multiomics approaches in biomarker identification and personalized therapies

SARANTIS CHLAMYDAS, Scientific Director,
**Olink Proteomics**

### CONFERENCE ROOM 2: BIOMARKERS FOR DIAGNOSTICS & PRECISION MEDICINE

**Flexible, Scalable Genetic Screens And Other Methods For Novel Therapeutic Target And Biomarker Discovery**

- Measurements of changes in gene activation and expression provide a basis to understand genetic changes causing biological responses
- Cell-to-cell gene disruption induced by CRISPR and other gene-perturbation technologies help tease out the drivers of these responses. Adaptations of these two screening approaches can be used to discover the genetic drivers responsible for phenotypic variabilities such as drug sensitivities and disease variation
- Other related technologies such as clonal barcoding and transcriptome profiling will also be discussed

PAUL DIEHL, Chief Operating Officer,
**Cellecta**

### CONFERENCE ROOM 3: BIOMARKERS FOR CLINICAL DEVELOPMENT

**Personalis NeXT Platform: Enabling Precision Oncology With Comprehensive Tumor Profiling Solutions For Tissue And Liquid Biopsy**

- Combining sensitive DNA and RNA sequencing with advanced analytics, ImmunoID NeXTTM provides a multidimensional view of the tumor and microenvironment
- A melanoma cohort case study demonstrates how a composite biomarker strengthens the association with immunotherapy response
- NeXT PersonalTM, an ultrasensitive tumor-informed liquid biopsy assay, designed to detect molecular residual disease will be highlighted

ERIN NEWBURN, Director, Field Application Scientist,
**Personalis, Inc.**

### CONFERENCE ROOM 4: DIGITAL PATHOLOGY & AI/MACHINE LEARNING FOR BIOMARKER RESEARCH

*Delegates are welcome to attend co-located sessions*

14:55

15:25 **Afternoon Break, 1-2-1 Meetings x3, Poster Presentation Sessions**

### CONFERENCE ROOM 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN ONCOLOGY AND IMMUNO-ONCOLOGY & DEGENERATIVE DISEASES

**1 Hour Workshop:** Biomarker Analysis - Design And Validation Of Assays

**Presentation 1:** Assay Validation For Biomarker Qualification

- Exploratory, qualification, and regulatory definitions
- Appropriate scientific rigor
- Clinical utility as end goal

16:30 *(Joining Online)* STEVEN PICCOLI, Associate Vice President,
**Sun Pharmaceutical Advanced Research Center**

**Presentation 2:** Biomarker Assay Validation Strategies

STEPHANIE TRAUB, Associate Director, **UCB**

**Panel Discussion: Scientific And Regulatory Considerations For The Qualification Of Biomarkers**

16:55 **Moderator:** THOMAS JOOS, Deputy Director
**NMI Natural and Medical Sciences Institute at the University of Tübingen; Luminex**

**Panellists**:
STEPHANIE TRAUB, Associate Director, **UCB**
*(Joining Online)* STEVE HOFFMANN, Associate Vice President, Research Partnerships Director, Biomarkers Consortium, **Foundation for the National Institutes of Health**
*(Joining Online)* STEVEN PICCOLI, Associate Vice President, **Sun Pharmaceutical Advanced Research Center**

### CONFERENCE ROOM 2: BIOMARKERS FOR CLINICAL DEVELOPMENT

**Panel Discussion: Implementing Patient-Centric Biomarkers In Clinical Trials**

- Defining Patient-centric Clinical Trials
- Achieving patient centricity within their drug development process
- Approaches to supporting and increasing patient engagement

**Panellists:**
THOMAS HACH, Executive Director Patient Engagement, **Novartis**
VIRGINIA PARKS, Clinical Pharmacologist, **Servier**
ALEXANDRA SEVKO, Director, Translational Research, **Prokarium**

**Regulatory Requirements For Drug/Companion Diagnostic Clinical Development And Marketing Authorization In The US And EU**

- Precision Medicine: drug-diagnostic co-development
- CDx regulatory framework in the US
- Changes in the EU CDx regulatory Landscape: The impact of IVDR

*(Joining Online)* SVETLANA MUKHINA, Associate Director Global Regulatory Affairs, CDx,
**Merck Group**

*Delegates are welcome to attend co-located sessions*

17:20

**Biopharmaceuticals & Companion Multiplex Precision Diagnostic Products**

*(Joining Online)* DAVID ZARLING, Chief Executive Officer,
**Colby Pharmaceuticals**

17:45 **Drinks Reception**

18:45 **End of Day One**

# Biomarkers UK: In-Person

DAY TWO: 04 MAY 2022 | LONDON, UK

## DAY TWO: 04 MAY 2022

**Biomarker Directors Breakfast (Sign Up Required)**

08:00

*Exclusive to Director-level attendees, the Biomarkers Directors Breakfast provides an opportunity for leaders in the community to engage with their peers and discuss the latest big ideas transforming biomarker research. Discussion is designed to be a free-flowing and open exchange of views about issues of topical interest.*

**Conference Room 3: 1 Hour Breakfast Workshop:** Biomarker Challenges In Prostate Cancer (And The Consequences Elsewhere)

**Moderator:**
MARK EMBERTON, Professor, **UCL**

08:35

**Presentation 1: The Methodological Challenges Of Biomarkers In Detection & The Validation Of Preclinical Disease**
SHONIT PUNWANI, Professor of Magnetic Resonance and Cancer Imaging, **UCL**

**Presentation 2: The Challenges In Developing A New Prostate Cancer Biomarker**
GERT ATTARD, Endowed Chair in Urological Cancer, **UCL**

**Presentation 3: Are We Ready To Re-Visit Prostate Cancer Screening?**
MARK EMBERTON, Professor, **UCL**

- The role of imaging will be discussed
- The causes of failure of previous trials will be assessed
- Optimal trial design will be explored

### CONFERENCE ROOM 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN NEUROSCIENCE, NASH & CO-MORBIDITY

**Morning Chair:** GERGELY TOTH, Chief Executive Officer & Chief Scientific Officer, **Cantabio Pharmaceuticals**
**Afternoon Track Chair:** To Be Announced

09:35

**Quantification Of Distinct Oxidized States Of Dj-1 As Potential Biomarker For Parkinson's Disease**

- A critical lack of biomarkers exists for early diagnosis of Parkinson's disease (PD) and to aid disease modifying drug development
- The DJ-1protein is genetically linked to the early on-set of familial PD and is implicated in idiopathic PD. Cys106 of DJ-1, a critical residue controlling its functions, is highly reactive and oxidation-sensitive. As oxidative stress is one of the key hallmarks of PD, the ratio of DJ-1 redox isoforms may be an indicator of disease onset and progression
- We developed unique ELISAs to quantify distinct redox variants of C106 DJ-1 using novel antibodies of DJ-1 with the aim of having a more precise understanding of the relative redox states of C106-DJ-1 in disease conditions

GERGELY TOTH, Chief Executive Officer & Chief Scientific Officer,
**Cantabio Pharmaceuticals**

10:00

**Assessment Of The Ella Immunoassay Platform**

- ELLA platform overview
- Closed cartridge assessment, using two biomarker kits
- Open cartridge assessment, highlighting assay development of a biomarker assay
- Comparison of the ELLA platform with other LBA technologies

JOBY JOSE, Principal Scientist,
**UCB Biopharma UK**

### CONFERENCE ROOM 2: NEW & EMERGING BIOMARKER TECHNOLOGIES

**Track Chair:** CHRISTOPHER PETERS, Clinical Senior Lecturer, **Imperial College London**

**Roundtable Discussion: The Future Of Early Detection Of Cancer**

How can we overcome the challenges to early detection of cancer? Specifically in:

- Determining risk of developing cancer to tailor early detection strategies to those at elevated risk
- Developing technologies with the sensitivity to detect the earliest tumours and the specificity to minimize false positives
- Designing early detection clinical trials to provide robust evidence to change practice

**Moderator:**
WENDY ALDERTON, Early Detection and ACED Programme Manager, **University of Cambridge**

**What Beats The Beads – Multiplexed Immunoassays For Biomarker Applications**

Bead based assays allows:

- To visualize the serological response towards a variety of Borrelia antigens from five different Borrelia species by simultaneously analyzing IgM and IgG levels using the INTELLIFLEX® Dual Reporter Assay
- To perform multiplex ACE2 RBD competition assay of SARS-CoV-2 after vaccination or infection as an alternative to infectious live-virus neutralization tests
- The detection of hundreds of proteins and protein modifications from a minimal amount of sample to visualize intracellular signalling in tumour cells

THOMAS JOOS, Deputy Director,
**NMI Natural and Medical Sciences Institute at the University of Tübingen; Luminex**

### CONFERENCE ROOM 3: BIOMARKERS FOR CLINICAL DEVELOPMENT & PRECISION MEDICINE

**Morning Track Chair:** THOMAS HACH, Executive Director Patient Engagement, **Novartis**
**Afternoon Track Chair:** STEPHANIE TRAUB, Associate Director, **UCB**

**EV-microRNAs As Liquid Biopsy Tool For Therapy Response Prediction In Hematological Malignancies**

MICHIEL PEGTEL, Head of the Liquid Biopsy Center,
**Cancer Center Amsterdam**

**Getting Precisely What You Need From Your Biomarker Led Clinical Trials**

A review of key practical considerations for success including:

- Scientifically focussed choice of analytes & platforms: translation from preclinical to clinical
- Clinical sample strategy: format, integrity, management & logistics
- Biomarker assay validation for clinical trial assays – regulatory requirements
- Data analysis, management, and integration of complex datasets

AMANDA J. WOODROOFFE, Senior Vice President, General Manager, UK Labs,
**Precision for Medicine**

### CONFERENCE ROOM 4: GENOMIC MARKERS FOR DISCOVERY & DEVELOPMENT

**Morning Track Chair:** To Be Announced
**Afternoon Track Chair:** JEREMY P. SEGAL, Director, Molecular and Cytogenetic Pathology, Associate Professor of Pathology, **University of Chicago**

**Accelerating The Delivery Of Genomic Medicine**

- What are the current barriers to the delivery of genomic medicine into routine healthcare settings?
- How can mainstreaming of genomics accelerate drug development and biomarker discover?
- What can we learn from the pandemic to expedite progress in other fields?

PHILIP BEER, Vice President, Head of Research and Translational Medicine,
**Step Pharma**

*Delegates are welcome to attend co-located sessions*

# Biomarkers UK: In-Person

## DAY TWO: 04 MAY 2022 | LONDON, UK

10:30 — **Morning Break, 1-2-1 Meetings x4, Poster Presentation Sessions**

### CONFERENCE ROOM 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN NEUROSCIENCE, NASH & CO-MORBIDITY

**Using Digital Biomarkers To Apply A Stratified Approach To Neuroinflammation**

- Psychiatry and neurology have experienced many late-stage drug development failures. We believe this stems in part from a lack of objective assessments used when categorising patients for clinical trials. This lack of objective inclusion criteria results in substantial biological heterogeneity within clinical trial samples, making it unlikely that any one drug will have a positive effect on all patients
- At Monument Therapeutics we use digital biomarkers to select patients with specific abnormalities in brain processes, and pair them with drugs known to positively affect these processes. Using this approach we developing biomarker-drug combinations to tackle areas of major unmet medical need, including schizophrenia and neuroinflammation

JENNIFER BARNETT, Chief Executive Officer, **Monument Tx**

**Simoa Technologies For Ultrasensitive Biomarker Detection, Future Proofing Your Bioanalysis**

- 1000x fold sensitivity improvement over traditional immunoassay technologies
- Simoa quantification of low abundance proteins, minimally invasive low volume samples, and better stratification between comparator groups
- Quanterix SP-X, SR-X and HD-X
- Critical biomarker detection applicable to a wide range of therapeutic areas
- Assay Development and Custom Services

LINDSEY MARSH, Senior Field Applications Scientist, **Quanterix**

**Challenges For Performing Regulatory Validations Of Neurological Biomarker Assays**

- Bioanalytical challenges around measuring neurological biomarkers from a CRO perspective?
- Can we evolve our validations to be more aligned with context of use or should every validation be bespoke?
- Obstacles with commercial reagents, what can be done to overcome them?
- Case studies: the merits of applying performance based acceptance criteria vs relying on PK BMV guidelines, for validations using commercial reagents on a high sensitivity platform

LAUREN JORDAN, Senior Scientist, **LGC Group**

### CONFERENCE ROOM 2: NEW & EMERGING BIOMARKER TECHNOLOGIES

**Biomarker Data Curation In A Changing Biopharmaceutical Development Environment**

As the use of different data sources is moving into the focus of biopharmaceutical development, it is time to rethink the role of data management. Together with the use of real-world data and external patient data, the use of biomarker data for clinical decisions is changing the paradigm of clinical drug development. Data management and statistics play an important role in this transformation.

RICHARDUS VONK, Vice President, Head Oncology Statistics and Data Management, **Bayer AG**

**Highly Reproducible Multiplexed Immunofluorescence Assays: From Discovery To Translational Research**

- Multiplexing immunofluorescence imaging enables the analysis of the whole tissue microenvironment
- How the COMET™ performs automated staining and imaging
- How COMET™ allows to achieve high-quality, reproducible and uniform results.

BASTIAN NICOLAI, Product Manager, **Lunaphore Technologies S.A.**

**Sensitive Biomarker Discovery Via Representation Learning On Single-Cell Data**

- Single-cell data presents a rich source of information for biomarker discovery
- Representation learning finds relevant patterns in data
- The ScaiVision platform uses representation learning for biomarker discovery
- ScaiVision performs best-in-class (compared to other single cell algorithms)
- ScaiVision can extract a biomarker signature from the trained models
- Using ScaiVision on clinical data (use cases)

MARTIJN VAN ATTEKUM, Technical Lead, **Scailyte AG**

### CONFERENCE ROOM 3: BIOMARKERS FOR CLINICAL DEVELOPMENT & PRECISION MEDICINE

**What Makes Clinical Trials Patient Centric: Biomarker Perspective**

- Main drivers for biomarker patient centricity
- Key advantages and limitations of patient centric sampling
- Important considerations for sample collection and data interpretation

DMITRI MIKHAILOV, Director, Head Biomarker Coordination, **Novartis**

**Autoantibodies As Biomarkers Of Disease, Response And Adverse Events**

The presentation will cover an introduction to Oncimmune and the ImmunoINSIGHTS autoantibody profiling service.

Autoantibody biomarker data will be presented in:

- Immuno-Oncology response and irAEs to checkpoint inhibitors, bispecific antibodies, cancer vaccines and oncolytic viruses
- Autoimmune disease characterisation and response in SLE, Sjögren's disease and systemic sclerosis
- Infectious diseases - COVID-19 and the autoimmune reactions SARS-CoV-2 invokes

MIKE FISHER, Vice President, Head of Business Development, **Oncimmune Ltd**

**Hypoxia Biomarkers: Personalising Cancer Treatment By Targeting Hypoxia. Mantra Diagnostics Ltd.**

- Measuring hypoxia in solid tumours
- Directed cancer therapy choices
- Advance personalised cancer medicine
- Improved patient outcomes

JOELY IRLAM-JONES, Research Associate/Direcor, **University of Manchester**

### CONFERENCE ROOM 4: GENOMIC MARKERS FOR DISCOVERY & DEVELOPMENT

**Panel Discussion: Enabling Precision Oncology**

- How genomics, transcriptomics, and proteomics are being combined in the quest to optimise precision oncology
- Advancing biomarker discovery and oncology clinical development programs
- Application in basic clinical sample studies
- Application in translational research (clinical trials)

**Moderator**: ERIN NEWBURN, Director, Field Application Scientist, **Personalis, Inc.**

**Panellists:**

MARTIN MILLER, Senior Director, **AstraZeneca**

MICHIEL PEGTEL, Head of the Liquid Biopsy Center, **Cancer Center Amsterdam**

JEREMY P. SEGAL, Director, Molecular and Cytogenetic Pathology, Associate Professor of Pathology, **University of Chicago**

**Translational Medicine To Revolutionize Dermatologic Care**

- Identify biomarkers of specific diseases and disease subsets
- Track and predict drug responses
- Stratify and select patients based on multi-omic skin profiles

TERRY ARNOLD, Senior Director of Medical Affairs, **DermTech**

**How To Biomarker: A Biolizard View On Biomarker Identification And Common Pitfalls**

- Next generation biomarkers: from omics to precision medicine
- Characteristics of highly effective biomarkers and common pitfalls
- Importance of machine learning in biomarker discovery
- Case studies of BioLizards approach in Biomarker discovery

VOLODIMIR OLEXIOUK, Team Lead, AI & Analytics, **BioLizard NV**

13:15 — **Lunch Break, 1-2-1 Meetings x3, Poster Presentation Sessions**

# Biomarkers UK: In-Person

## DAY TWO: 04 MAY 2022 | LONDON, UK

| | CONFERENCE ROOM 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN NEUROSCIENCE, NASH & CO-MORBIDITY | CONFERENCE ROOM 2: NEW & EMERGING BIOMARKER TECHNOLOGIES | CONFERENCE ROOM 3: BIOMARKERS FOR CLINICAL DEVELOPMENT & PRECISION MEDICINE | CONFERENCE ROOM 4: GENOMIC MARKERS FOR DISCOVERY & DEVELOPMENT |
|---|---|---|---|---|
| 14:15 | **Solution Provider Presentation**<br><br>Senior Representative,<br>**Metabolon** | **Exploring Biomarkers Research With Dimensions**<br><br>Research is being published at a higher rate than ever, so keeping on top of the latest developments in biomarkers research is challenging. Our technology helps you identify the most relevant publications, and discover information that may be missed, giving you a comprehensive overview of cutting edge developments. Our automated extraction of information, unique content coverage, and interactive data visualisation capabilities help you interrogate research information to quickly identify connections and trends in biomarkers research, helping inform your future strategy.<br><br>SUZE KUNDU, Head of Engagement, Chemistry Specialist,<br>**Digital Science, Dimensions Life Sciences and Chemistry** | **Unprecedented Sensitivity And Specificity For Analysis Of Short Nucleic Acids And Rare Sequence Variants**<br><br>We present an exceedingly sequence specific and sensitive method to analyse short nucleic acids called Two-Tailed PCR (2T-PCR) that is particularly suitable for microRNA and rare sequence variant analyses. 2T-PCR takes advantage of a target-specific primer composed of two hemiprobes, complementary to two different parts of the target molecule, connected by a hairpin structure. The introduction of short hemiprobes that sense the target sequence confers exceeding specificity while maintaining the very high sensitivity of PCR. Highly similar targets can be distinguished with superior precision irrespectively of the position of the variant nucleotide. Further, the target molecule can be as short as some 15 bases, making 2T-PCR the preferred method for microRNA profiling, analysis of forensic samples, ancient material, formalin fixed and paraffin embedded (FFPE) material, and rare sequence variants in cell-free DNA. 2T-PCR is readily multiplexed and is compatible with real-time as well as digital PCR, making it the preferred method for pharmacokinetic and pharmacodynamic (PK/PD) studies for the development of advance therapy and medicinal products (ATMPs).<br><br>(1) Two-tailed RT-qPCR: a novel method for highly accurate miRNA quantification. P Androvic, L Valihrach, J Elling, R Sjoback, M Kubista. Nucleic Acids Research, Volume 45, Issue 15, 2017, Page e144<br><br>MIKAEL KUBISTA, Founder and Chief Executive Officer,<br>**TATAA** | **Customised Assays For Pcr Free Absolute Quantification Of Mirnas Directly From Body Fluids On The Smcxpro® Platform: An Example Of Mirna-122 As A Liver Toxicity Assay**<br><br>JUAN J. DÍAZ-MOCHÓN, Chief Executive Officer,<br>**DESTINA Genomics Ltd** |
| | Metabolon | DIGITAL science | TATAA BIOCENTER | MERCK |
| 14:45 | **FNIH Workshop**<br>**Presentation 1: Impact and Innovation - The FNIH Biomarkers Consortium & Accelerating Medicines Partnership**<br><br>DANA CONNORS, Senior Program Manager, Research Partnerships, **Foundation for the National Institutes of Health**<br><br>**Presentation 2: Advancing Novel Tools And Biomarker Validation For Neurodegenerative Diseases**<br><br>WESLEY HORTON, Senior Project Manager, **Foundation for the National Institutes of Health**<br><br>**Presentation 3: AMP Schizophrenia: Biomarkers Of Clinical High Risk (CHR) And Disease Trajectory For Psychosis** | **Panel Discussion: From The Real World To Real Time Biomarker Data**<br><br>• Review of the real world of biomarker data and what value it brings<br>• New Developments in Biomarker RWD and Innovations<br>• Impact of Real Time Biomarker Data and how it would change the drug development paradigm<br><br>**Moderator:** RICHARDUS VONK, Vice President, Head Oncology Statistics and Data Management, **Bayer AG**<br><br>**Panellists:**<br>MIIKA AHDESMÄKI, Director, Early Computational Oncology R&D, **AstraZeneca**<br><br>SONIA RODRIGUES, Executive Director Oncology Regulatory Science and Strategy, Hematology Head, **AstraZeneca** | **Precision Medicine 2.0 - Biosignatures, Patients And Personalization**<br><br>• Precision Medicine And Patient Engagement<br>• Complexity needs to be appreciated and managed<br>• Don't forget the human touch<br><br>THOMAS HACH, Executive Director Patient Engagement,<br>**Novartis** | **Validating An Automated, Multiplexed NGS Assay For Rapid Turnaround Time**<br><br>• How the Genexus integrated sequencer reduces TAT<br>• What targets are covered by the Oncomine Precision Assay panel<br>• What special considerations are required for this validation<br><br>COREY ROGERS, Genomic Development Specialist,<br>**Hospital of the University of Pennsylvania** |
| 15:10 | *(Joining Online)* LYNSEY BILSLAND, Head of Mental Health Translation,<br>**Wellcome Trust Foundation** | **Flow Cytometry In Drug Development**<br><br>• Flow cytometry in pre-clinical and clinical development<br>• Application of Flow for biomarker and bioanalytical applications<br>• Development and validation of Flow Cytometry assays<br>• Biomarker validation strategy<br><br>SION LEWIS, Principal Scientist,<br>**UCB Biopharma** | **Microfluidics And Clinical Oncology Research**<br><br>• Technological developments such as droplet-based digital PCR and optimized<br>• NGS allow the highly sensitive and precise detection of circulating tumor DNA (ctDNA) within liquid biopsies Several biomarkers have now been developed to track ctDNA<br>• ctDNA allows for efficient patient monitoring in different cancers both for advanced and early cancers<br><br>VALERIE TALY, Group Leader and CNRS Research Director,<br>**INSERM, Centre de recherche des Cordeliers, Université Paris Cité** | **Goal Consortium Efforts In NGS Oncology Testing**<br><br>• Understand the traditional barriers to development of NGS oncology diagnostics at academic medical centers in the US<br>• Learn about the formation of the Genomics Organization for Academic Laboratories (GOAL)<br>• Learn about current and future GOAL initiatives and future possibilities<br><br>JEREMY P. SEGAL, Director, Molecular and Cytogenetic Pathology, Associate Professor of Pathology,<br>**University of Chicago** |
| 15:35 | **Afternoon Coffee & Refreshments** | | | |

# Biomarkers UK: In-Person

## DAY TWO: 04 MAY 2022 | LONDON, UK

| | CONFERENCE ROOM 1: BIOMARKERS: IDENTIFICATION, VALIDATION & TRANSLATION IN NEUROSCIENCE, NASH & CO-MORBIDITY | CONFERENCE ROOM 2: NEW & EMERGING BIOMARKER TECHNOLOGIES | CONFERENCE ROOM 3: BIOMARKERS FOR CLINICAL DEVELOPMENT AND PRECISION MEDICINE |
|---|---|---|---|
| 16:05 | **FNIH Workshop Continued: Presentation 4: Revolutionizing NASH Diagnosis, Monitoring And Treatment, A NIMBLE Approach For Success**<br><br>*(Joining Online)* HELEN HEYMANN, Senior Scientific Project Manager, Research Partnerships, Biomarkers Consortium, **Foundation for the National Institutes of Health** | **Spatial Biology For Drug Development**<br><br>• Application of spatial biology in drug development for drug disposition, safety, efficacy, model characterisation and disease understanding<br><br>STEPHANIE LING, Associate Director, Integrated Imaging, Imaging and Data Analytics, CPSS,<br>**AstraZeneca** | *Delegates are welcome to attend co-located sessions* |
| 16:30 | **Nfl As A Marker Of Concurrent And Future Active Disease In Relapsing Multiple Sclerosis: An Analysis Of Data From The Phase 3 Ozanimod Clinical Trials**<br><br>• Neurofilament light chain (NfL) is a structural component of the neuron and axon cytoskeleton<br>• It is released into the cerebrospinal fluid (CSF) and bloodstream after neuronal injury and degeneration in multiple sclerosis (MS) and various other neurodegenerative disorders, including ALS, AD, Guillain-Barré-syndrome, and HD<br>• Measurement of serum neurofilament light chain concentration (sNfL) may become a convenient, cost effective and meaningful adjunct for multiple sclerosis (MS)- both prognostically as well as to monitor disease activity in response to treatment<br>• Presentation will summarize the relationship between plasma NfL levels and RMS disease activity in phase 3 ozanimod trials<br><br>*(Joining Online)* SARAH HARRIS, Head, GI and Neurology Disease Teams, Translational Medicine,<br>**Bristol Myers Squibb** | *Delegates are welcome to attend co-located sessions* | *Delegates are welcome to attend co-located sessions* |
| 16:55 | **End Of Conference** | | |

# Biomarkers UK: In-Person

POST-EVENT WORKSHOP: 05 MAY 2022 | LONDON, UK

## Advanced Sciences:
## Spatial Biology GeoMx DSP Best Practices

Join NanoString for the continuing Advanced Sciences Series – The Spatial Biology GeoMx DSP Best Practices Town Hall and Workshop

The first in-person event focused on Pharma and Contract Research Organizations (CROs) and held in conjunction with Oxford Global's Biomarker UK conference. Both current GeoMx DSP owners and interested Biopharma and CROs are invited.

*If you cannot attend the workshop in-person, you can register to receive a link to the livestream.*

nanoString®

REGISTER

## Workshop Agenda | 05 May 2022

| | |
|---|---|
| 08:30 | **Registration** |
| 09:00 | **Welcome Remarks, Agenda Overview, Town Hall & Workshop Goals**<br><br>LESLIE ABAD, Assoc Dir Global Pharma and CRO Market Development, **NanoString Technologies** |
| 09:10 | **Expert Approaches to Design and Execution of GeoMx Studies in a CRO Laboratory**<br><br>ALBAN BESSEDE, Chief Executive Officer, **Explicyte**<br>KELLY HUNTER, Chief Scientific Officer, **Propath UK**<br>CORINNE RAMOS, Director of R&D, **ImaBiotech** |
| | **Break** |
| 10:30 | **Pharma Perspectives on GeoMx Experimental Design and Execution**<br><br>SPEAKER TBA |
| | **Break** |


## VENUE INFORMATION


**Novotel London West**
1 Shortlands, Hammersmith, W6 8DR, London, UK
Tel: (+44) 20 8741 1555
E-mail: **H0737-RE@accor.com**

Novotel London West has one of the largest numbers of dedicated events spaces of any London hotel. With 33 conference, meeting and events spaces capable of hosting functions for up to 2,000 delegates, no other conference, event, convention or exhibition venue in London is as versatile or well-equipped to deliver the perfect event. Their 630 spacious ensuite bedrooms are the ideal place for relaxing and unwinding after a busy day.

The hotel is just a 3-minute walk from Hammersmith Underground Station and less than 20-minutes travel from Central London or Heathrow, escaping the Central London Congestion Zone and is ideally located to access all the main shopping areas and amenities of Central London. Detailed travel directions can be found at: **www.oxfordglobal.co.uk/biomarkers-series-uk/plan-your-visit/.**

Oxford Global has secured a number of bedrooms at the Novotel London West at a reduced conference rate:

**02/05/2022 – £155 including VAT and breakfast**

**03/05/2022 – £155 including VAT and breakfast**

Should you wish to book a room, please email our **help@oxfordglobal.co.uk**. The final cut-off date to book bedrooms is **Friday 1st April 2022** – any bookings after this date are subject to availability and rates. Please note that any cancellations within 7 days prior to arrival are subject to cancellation charges.

# BIOMARKERS SERIES ACROSS 2022

Join leaders, experts and researchers, connecting global pharma, biotech and academia for high-level discussions on the latest innovations. Covering Biomarkers, Genomic Markers, Digital Biomarkers, CTCs & Liquid Biopsies, Flow Cytometry & Multiplex Tools and more.

### Biomarkers UK: In-Person
03 - 04 May 2022 | London, UK

### Biomarkers US: In-Person
03 - 04 October 2022 | San Diego, USA

### Biomarkers Analysis Europe: In-Person
November 2022 | Berlin, Germany

### Clinical & Translational Biomarkers: Online
03 November 2022 | GMT (UTC+0)

### Biomarkers for NASH Symposium
07 December 2022 | Online: GMT (UTC+0)

Members of our Biomarkers Series Community have access to all these events. Please click here for more information.

## Biologics Series
Proteins & Antibodies |Peptides & Oligonucleotides | Bispecifics in Discovery & Development | Antibody Engineering | Vaccines

## Cell Series
Cell Culture & Bioprocessing | Cell Therapy Analytics | Cell & Gene Therapy Manufacturing Advanced Therapy Development

## Discovery Series
Organ Modelling | Drug Discovery Neuroscience Discovery | Discovery Chemistry

## Formulation & Delivery Series
Formulation & Drug Design
Inhalation & Respiratory Drug Delivery
RNA Therapeutics & Delivery
Pharmaceutical Lyophilization

## Immuno Series
Advances in Immuno-Oncology
Autoimmunity & Immunology
Tumor Microenvironment
Preclinical Immuno-Oncology

## NextGen Omics Series
Next Gen Sequencing | Single Cell Analysis
Genome Editing | Digital PCR | Spatial Biology

## PharmaTec Series
Pharmaceutical IT | AI in Drug Development
SmartLabs & Laboratory Informatics
Pharmaceutical Mobile Robotics
Pharma Manufacturing & Automation

Visit www.oxfordglobal.co.uk/calendar/ to explore our diverse portfolio of events across 2022.

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www.oxfordglobal.co.uk/biomarkers/