8th-10th April, 2025 | London, UK

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FREE* FOR DRUG DEVELOPERS & RESEARCHERS

WELCOME

EXPERT SPEAKERS

AGENDA

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REGISTER YOUR PLACE

15th Annual

World CB & CDx Summit Europe

Navigate European Regulations to Accelerate Patient Access to Personalised Drugs

Accelerate Drug-Diagnostics to Market with Clinically Relevant Biomarkers to Ensure Patient Access to Effective Precision Medicines in Oncology, Neurology, Rare Diseases & Beyond

Join 30+ World-Class Speakers, Including:

Huw Bannister
Senior Director of Digital & Computational Pathology
AstraZeneca

Antje Lukas
Senior Director Regulatory Affairs Companion Diagnostic
Daiichi Sankyo Europe

James Hewitt
IVD Business Line Manager
TÜV SÜD

Kristina McGuire
Executive Director & Head, Precision Medicine Laboratory Operations & Companion Diagnostics
Regeneron

Naureen Starling
Medical Oncologist GI & Director of the Royal Marsden's Clinical Trials Unit, NIHR Professor of Gastrointestinal Oncology
Royal Marsden NHS Foundation Trust

Vincent Mikol
Global Head of Translational Precision Medicine
Sanofi

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Welcome to the 15th World Clinical Biomarkers & Companion Diagnostics Summit Europe

World CB & CDx Summit Europe
8th -10th April, 2025 | London, UK

European drug-diagnostic co-development continues to surge, with the launch of a new consortium to improve patient access to precision therapies, numerous approvals and collaborations, and advances in diagnostic testing for Alzheimer's, Multiple Sclerosis, cardiovascular disease, and rare genetic disorders.

With 2025 poised as a critical year for the field, the **15th World Clinical Biomarkers & Companion Diagnostics Summit Europe** returns to London in April, cementing its position as the industry's leading end-to-end forum for Europe's precision medicine community and reuniting key stakeholders **to accelerate precision drugs from discovery through to commercialisation for patients in need**.

Bringing a refreshed agenda format, this year's programme features two tracks dedicated to **Biomarker Discovery & Clinical Development** and **Drug-CDx Development & Commercialisation**. Expect to hear critical updates on:

- Novel biomarker discovery in rare, cardiovascular oncology, metabolic, and autoimmune disease to improve patient selection and monitoring
- Emerging technologies spanning genomics, liquid biopsies, digital pathology, multi-omics and multiplexing with improved access and scalability
- Expectations and workflows of notified and competent bodies to bolster IVDR adherence and regulatory approvals
- Commercialisation and market access insights across Europe to ensure a strong product launch

Join 200+ senior executives working in **Biomarkers**, **Translational Medicine**, **Precision Medicine** and **Companion Diagnostics** from across Europe to develop a robust precision medicine strategy for your small molecule, ADC, cell therapy, gene therapy and more with a European regulatory-compliant CDx and improve patient outcomes through accelerating drug-diagnostics to market.

WHAT TO EXPECT

200+ Attendees

45+ Expert Speakers

7+ Hours of Networking

2 Tracks of Brand-New Content

2025 AGENDA HIGHLIGHTS

PLENARY SESSIONS

- Leverage the surge in liquid biopsy and genomic innovations with insights spanning **ctDNA translation** to **sequencing commercialisation** to bolster improved and accessible cancer diagnosis and monitoring
- Cast your attention to the **expectations of notified bodies and regulators** across Europe to **streamline IVDR compliance** and stay alert in the face of country-specific filing nuances
- Look to the future with **novel *in vivo*** and **multiplexed technologies**, and scout the evolving roadmap towards approved precision medicines in the European market

BIOMARKER DISCOVERY & CLINICAL DEVELOPMENT TRACK

- Discover the latest digital innovations from **multi-omics** to **computational pathology** for more scalable and physician appropriate interventions
- Be the first to hear the latest advances in biomarker discovery and validation in **oncology**, **cardiovascular**, **metabolic**, **autoimmune** and **rare diseases** to improve patient selection and monitoring
- Join your peers from the following departments and applications: **Biomarker Discovery**, **Translational Medicine**, **Clinical Operations**, and **Medical Affairs**

CDx DEVELOPMENT & COMMERCIALISATION TRACK

- Bolster the **initiation**, **scale-up** and **regulatory responsibilities of co-development partnerships** to spark compliant and scalable strategic alliances for accelerated approvals
- Get updated on the launch planning and commercialisation pathways poising **access to the European market in 2025** across oncology and non-oncology indications
- Join fellow industry experts working in: **IVD Development**, **Commercialisation**, **Market Access & Value**, **Precision Medicine Alliances** and **Regulatory Affairs**

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Gain Exclusive Insights Spanning Discovery to Commercialisation

World CB & CDx Summit Europe
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Preclinical Development

Indications include:

- Oncology
- Cardiovascular
- Neurological
- Metabolic
- Autoimmune
- Rare Disease

Phase I-III

Insights from:

argenx, BRAIN HEALTH, MultiOmic, sanofi, The Royal Marsden, MYTHIC THERAPEUTICS, ADC THERAPEUTICS, Genomics England, novo nordisk, VIVAN THERAPEUTICS

Filing

Hear from:

AstraZeneca, REGENERON, Bristol Myers Squibb, BAYER, NOVARTIS, TÜV SÜD

Commercialisation

Speakers include:

Daiichi-Sankyo, Lilly, Johnson & Johnson, Genentech

Biomarker Development

CDx Viability, Use & Regulation

CDx Post-Launch Assessment

Technologies Spanning:

Genomics | Omics | Pathology | Cell Sequencing | Flow Cytometry | Spatial Biology

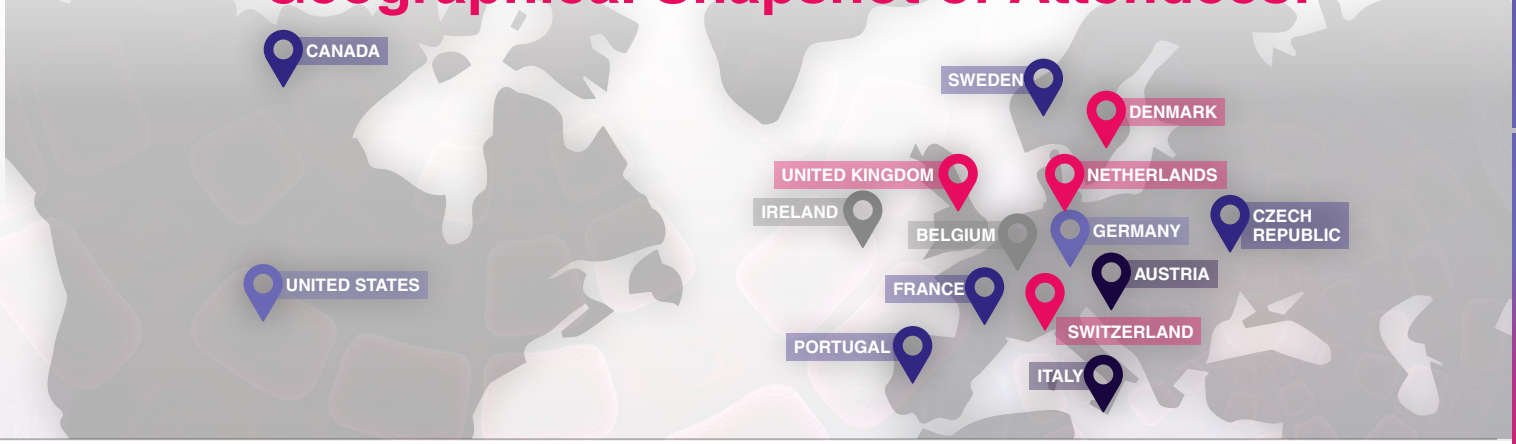
NEW for 2025:

Beyond Oncology Case Studies
Spanning Neurological, Metabolic, Cardiovascular, Autoimmune, & Rare Diseases

60%
Brand New Companies Joining the Speaker Faculty

Exploring Novel Technologies
Including Multi-Omics, *In Vivo* Screening & AI-Enabled Platforms

Geographical Snapshot of Attendees:



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Speaker Faculty

Monika Lamba Saini
Global Translational Pathology Leader
ADC Therapeutics
Education Committee Member, **Digital Pathology Association**

Pascal Bamford
Chief Clinical Officer
Akoya Biosciences

Cheryl McFarlane
Associate Director, Assay Development & Validation
Almac Diagnostic Services

Brett Swansiger
Chief Commercial Officer
ANGLE

Lindsey Bennie
Laboratory Manager
ARC Regulatory

Lien Dejager
Director, Head of Translational Biomarkers
argenx

Huw Bannister
Senior Director of Digital & Computational Pathology
AstraZeneca

Patrick Fivey
Director, Precision Medicine Policy
AstraZeneca

Roy Milner
Regulatory Affairs Project Director
AstraZeneca

Thomas Di Maio
Head of Diagnostic Europe & Canada
AstraZeneca

Philipp Schatz
Global Regulatory Lead, IVD
Bayer

Subrata Bose
Vice President & Head, General Clinical Imaging Services. CoE Diagnostic Imaging Data & AI, Radiology R&D
Bayer

Chris van Haag
Senior Director Global Strategic Partnerships
Biocartis

Mary Anne Williams
Senior Director, Regulatory Affairs
Bio-Techne

Sharon Liang
Executive Director, Head, Precision Medicine & Digital Health
Bristol Myers Squibb

Xinru Mao
Head of Pharma Services & Global IVD Business
Burning Rock

Antje Lukas
Senior Director, Regulatory Affairs Companion Diagnostic
Daiichi Sankyo Europe

Scott Reid
Vice President & Global Head of Companion Diagnostics
Discovery Life Sciences

Pierre Moulin
Chief Scientific Officer
Diagnexia Analytix

Lill-Brith von Arx
RWE Northern Europe Hub Lead
Eli Lilly & Co

Varun Pattani
Senior Director, Diagnostic Development, Clinical & Scientific Operations
Foundation Medicine

Speaker Faculty

Katia Bassett
Senior Director & Head of CDx Development, Translational Medicine
Genentech

James Duboff
Director, Strategic Partnerships
Genomics England

Katarzyna Witkowska
Strategic Partnerships Director
Genomics England

Kerri Fuller
Director, RII & ID PMed Operations
GSK

Marcus Hausch
Head of Commercial EUAA
Guardant Health

Beatriz Bellosillo
Head of the Molecular Biology Laboratory
Pathology Department of Hospital del Mar

Daniel Gehrlach
Director, Biomarkers
HMNC Brain Health

Ali Kuraishy
Head, Clinical Business Development
Illumina

Andrea Stevens
Senior Director Precision Medicine Access
Johnson & Johnson Innovative Medicine

Flora Berisha
Global Head of Diagnostic Partnering & Development
Johnson & Johnson Innovative Medicine

Leonie de Visser
Portfolio & Alliance Lead, Precision Medicine, EMEA Strategy & Operations
Johnson & Johnson Innovative Medicine

Robert Thong
Co-Founder & Chief Executive Officer
MultiOmic Health

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Vice President, Regulatory Affairs
Mythic Therapeutics

Donna Nichol
Senior Director, Market Development, Europe
Natera

Seán O'Dowd
Director of Regulatory Affairs, Precision Medicine
Novartis

Christian Ruzanski
Principal Scientist
Novo Nordisk

Antoine de Sagey
Director Commercial Strategy & Operations Diagnostic
Owkin

Alexandre Akoulitchev
Chief Scientific Officer
Oxford BioDynamics

Pahini Pandya
Founder & Chief Executive Officer
Panakeia Technologies

Catarina Veiga
Commercial Director, Pharma Business
Platomics

Shidong Jia
Founder & Chief Executive Officer
Predicine

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Regeneron

Mark Hellewell
International Product Manager
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Patrick Eimerman
Vice President, Business Development & Partnerships
SAGA Diagnostics

Vincent Mikol
Global Head of Translational Precision Medicine
Sanofi

Anne-Laure Bauchet
Immunohistochemistry Team Manager & Translational Medicine Lead
Sanofi

Jess Lambe
Vice President & Managing Director of BioPharma Business Development
SOPHiA GENETICS

Professor Naureen Starling
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Royal Marsden NHS Foundation Trust

James Hewitt
IVD Business Line Manager
TÜV SÜD

Annick Sawala
Head of Translational Research
Vivan Therapeutics

Agenda at a Glance

World CB & CDx Summit Europe
8th -10th April, 2025 | London, UK

Pre-Conference Engagers
Register Your Interest to Attend

Conference Day One

Morning Check In & Light Breakfast

Shaping the Future of Precision Oncology with **Genomic Initiatives & Liquid Biopsy to Tackle Hard-to-Treat Cancers** for Unmet Patient Need

Morning Break & Structured Networking

Bolstering the Equitable **Access of Precision Therapies Through Innovative** Trials & Sequencing Initiatives to Reduce Treatment Disparities & Improve the Standard of Care for All Patients

Lunch Break & Networking

Biomarker Discovery & Clinical Development	**CDx Development & Commercialisation**
Leveraging **Digital Pathology & Multi-Omics** to Bolster Scalable & More Cost-Effective Biomarker Development	Improving **CDx Development Through Co-Development Partnerships** for Effective Care Pathways

Afternoon Networking Break

Biomarker Discovery & Clinical Development	**CDx Development & Commercialisation**
Shaping the Future of **Patient Selection & Monitoring** to Inform Treatment Regimes for Best-in-Class Cancer Therapies	**Strengthening Co-Development Partnerships** for Rapid Market Access to Maximise Therapeutic Reach

Conference Day Two

Morning Networking Coffee

Harmonising IVDR Compliance Across European Notified & Competent Bodies to Enhance Regulatory Clarity & Speed Towards Approval

Morning Networking Break

Biomarker Discovery & Clinical Development	**CDx Development & Commercialisation**
Strengthening Disease Management Through Biomarkers & Digital Innovations for **Improved Autoimmune & Rare Disease Treatment** Regimes Beyond Oncology	Optimising **Regulatory & Commercialisation Priorities within the Clinic** to Expedite Approval

Lunch Break & Networking

Biomarker Discovery & Clinical Development	**CDx Development & Commercialisation**
Pioneering **Integrating Blood-Based & Neuroinflammation Biomarkers** for Better Outcomes in **Neurological Diseases** to Improve Quality of Life Beyond Oncology	**Bolstering Access & Synchronising Commercialisation** for Precision Medicines Across Oncology & Non-Oncology Beyond Oncology

Afternoon Networking Break

From **Tumour-Specific Models to AI-Enabled Tools**: Enabling the Future of Precision Medicine Through Novel Technologies

Pre-Conference Day
Tuesday 8th April, 2025

World CB & CDx Summit Europe
8th -10th April, 2025 | London, UK

10.00 - 2.00

From Concept to Commercialisation: The Digital Canvas of Precision Medicine

Join your peers for a collaborative workshop focused on gathering insights and addressing shared challenges through presentations, interactive feedback sessions, and a panel discussion led by industry and Roche experts, exploring digital pathology and computational pathology in precision medicine.

Roche

3.00 - 5.00

Navigate Complex Biomarkers & Regulatory Challenges With Confidence With Foundation Medicine's Current & Future IVD Platforms

Unveil the blind spots in your biomarker strategy and gain the insights you need to move your therapy forward.

FOUNDATION MEDICINE®

Register your interest* to attend

*Attendance subject to availability and partner approval.

For T&Cs please visit the website.

"Amazing quality of speakers, underpinned by representation of different stakeholders from Pharma, IVD manufacturers and Notified Bodies, leading to valuable networking sessions."

Past Attendee, Director, **Pierre Fabre**

"Interesting breadth of talks and panel discussions, accompanied by meaningful interactions with potential CDx company partners."

Past Attendee, Director, Clinical Biomarkers, **Ipsen Pharma**

Conference Day One
Wednesday 9th April, 2025

7.30 **Check In & Light Breakfast**
One-on-One Partnering™ Zone Opens ONE PARTNERING

Flora Berisha
Global Head of Diagnostic Partnering & Development
Johnson & Johnson Innovative Medicine

8.20 **Chair's Opening Remarks**

Shaping the Future of Precision Oncology with Genomic Initiatives & Liquid Biopsy to Tackle Hard-to-Treat Cancers for Unmet Patient Need

Professor Naureen Starling
Medical Oncologist GI & Director of the Royal Marsden's Clinical Trials Unit, NIHR Professor of Gastrointestinal Oncology
Royal Marsden NHS Foundation Trust

8.30 **Advancing Faster Diagnosis of Pancreatic & Biliary Tract Cancers with Liquid Biopsies to Improve Clinical Impact & Optimise Patient Treatment Outcomes**

- Pancreatic and Bile Duct cancers can be associated with protracted diagnostic pathways
- Both diseases are associated with high levels of ctDNA detection
- Showcasing the potential for a liquid biopsy enhanced diagnostic pathway for faster, safer, accurate diagnosis of these challenging cancers

Varun Pattani
Senior Director, Diagnostic Development, Clinical & Scientific Operations
Foundation Medicine

8.50 **Identifying Key Blind Spots in Your Diagnostic Strategy: Considerations for Defining Complex Biomarkers**

- Explore key considerations for defining biomarkers as part of your CDx strategy
- Gain insights into the complexity of defining biomarkers like TMB, MSI, HRDSig, and CH
- Uncover potential blind spots in your CDx strategy and identify factors to consider in choosing a diagnostic partner

Katarzyna Witkowska
Strategic Partnerships Director
Genomics England

9.20 **Using the National Genomic Research Library Clinico-Genomic Data for Biomarker Discovery – Genomics England Use Cases**

- National Genomic Research Library holds one of the largest collections of whole genome sequencing (WGS) data linked to clinical records across 200+ rare disease disorders and over 16 cancer types for consented participants
- NHS Genomics Medicine Service has commissioned WGS as standard of care for a number of indications, enabling future growth of the dataset
- Genomics England unique model, enabling use of consented data for clinical and research applications, enables true translation of research back to the clinic, driving the future of precision medicine in UK and around the world

Marcus Hausch
Head of Commercial EUAA
Guardant Health

9.40 **Advancing Precision Oncology in Europe with a Globally Validated Liquid Biopsy - Guardant360**

- Comprehensive biomarker testing and precision oncology uptake in Europe face adoption challenges due to regulatory, reimbursement and data hurdles
- Guardant Health's partnerships with leading cancer centers in the EU have accelerated Guardant360 adoption, expanding access to high-quality testing
- Guardant's successful UK pilot with The Royal Marsden demonstrates how local implementation of Guardant360 drives clinical adoption and improves patient access

10.10 **Morning Break & Structured Networking**
An opportunity to network, discuss and collaborate with like-minded leaders of the biomarker and CDx community

Bolstering the Equitable Access of Precision Therapies Through Innovative Trials & Sequencing Initiatives to Reduce Treatment Disparities & Improve the Standard of Care for All Patients

Annick Sawala
Head of Translational Research
Vivan Therapeutics

11.10 **From Precision Medicine to Personalised Medicine in Oncology: Predicting Effective Treatments Based on Complex Tumour Gene Signatures Using a Novel *In Vivo* Screening Technology**

- Genetic complexity: Tumours are driven by a network of oncogenic genetic alterations and tumour signatures are incredibly diverse across patient population
- Drosophila avatars: a rapid and cost-effective generation of in vivo models with genetically engineered complex tumour signatures for large-scale drug screening
- Utilising whole-exome sequencing and in vivo drug screening to uncover actionable insights into tumour-specific vulnerabilities: from standard of care ranking to novel combinations

Conference Day One
Wednesday 9th April, 2025

11.30 **Discover How SOPHiA GENETICS is Empowering Pharma Companies to Advance Precision Medicine with Next-Generation Genomics Solutions, Improving Patient Access to Innovative Therapies**

Jess Lambe
Vice President & Managing Director of BioPharma Business Development
SOPHiA GENETICS

- Learn how to unlock the potential of SOPHiA DDM™ to optimise late-stage clinical development by designing and deploying genomics solutions at scale
- Gain insights into the regulatory pathway of the SOPHiA DDM™ Platform and its validation path for broadening access to precision therapies
- Understand SOPHiA GENETICS' market-leading lab footprint and ability to truly democratise genomics
- Hear how SOPHiA GENETICS and AstraZeneca are joining forces to shape healthcare's future by standardising and decentralising a best-in-class liquid biopsy assay on a global scale

12.00 **Addressing Testing Disparities & Reinforcing Patient Access to Care for All**

Andrea Stevens
Senior Director Precision Medicine Access
Johnson & Johnson Innovative Medicine

- What are the best practices to engage with patient communities and ensure successful enrolment of under-represented groups?
- Adopting recruitment strategies that overcome biases in clinical trials and improve patient access to testing and monitoring
- What is the role of technology in overcoming healthcare access barriers for marginalised populations in the context of diagnostic testing?

12.20 **Precision Medicine at Scale: Innovation, Efficiency & Global Reach**

Ali Kuraishy
Head, Clinical Business Development
Illumina

- Learn about how Illumina can help drive success of your drug development pipeline, from discovery to commercialisation
- Learn about how the global reach of Illumina, from our instrument placements to the uptake of our TruSight Oncology comprehensive genomic profiling solution, can drive precision oncology at scale
- Learn about the benefits of a companion diagnostic partnership with Illumina – accessing our product development teams to drive innovative solutions, leveraging our clinical development teams to ensure uniform testing throughout the world and utilising our experienced regulatory teams to navigate the ever-changing global regulatory environment

12.50 **Lunch Break & Networking**
Dedicated One-on-One Partnering™ ONE PARTNERING™

TRACK A: Biomarker Discovery & Clinical Development

Kerri Fuller, Director, RII & ID PMed Operations, **GSK**

Leveraging Advanced Computing & AI to Enhance Predictive Accuracy & Bolster Scalable & More Cost-Effective Biomarker Development

1.45 Paving a Pathway Towards Computational & Digital Pathology for Enhanced Interpretation & More Targeted Intervention

- What is the role of Pharma in the adoption of computational pathology?
- Where has co-development been leveraged to create integrated digital pathology platforms?
- Navigating commercial implications regarding the need for computational algorithms for treatment identification, scanner deployment, site distribution, and expected market penetration

Huw Bannister, Senior Director of Digital & Computational Pathology, **AstraZeneca**

2.05 An Expert Pathology Network for Biomarker Development: Leveraging Digital Innovation for Scale & Precision

- Expert Pathology Network Integration: Leverage our global network of board-certified pathologists to deliver precise, high-quality biomarker insights
- Advanced Digital Pathology Analytics: Utilise state-of-the-art imaging and AI-driven analytics to streamline and enhance biomarker discovery
- Scalable and Cost-Effective Solutions: Accelerate clinical research with a tailored, scalable platform that reduces time-to-insight and optimises development costs

Pierre Moulin, Chief Scientific Officer, **Diagnexia Analytix**

TRACK B: CDx Development & Commercialisation

Katia Bassett, Senior Director & Head of CDx Development, Translational Medicine, **Genentech**

Improving CDx Development Through Co-Development Partnerships for Effective Care Pathways for Effective Care Pathways

1.45 An *In Vitro* Diagnostic Test for Dose Maintenance Setting in Patients Treated with an anti-TFPI antibody

Christian Ruzanski, Principal Scientist, **Novo Nordisk**

2.05 From Liquid Biopsy to Dynamic Monitoring: ctDNA Empowering Cancer Treatment Optimisation

- Explaining the unique value of liquid biopsy in patient selection and therapeutic monitoring
- Showcasing clinical applications of Burning Rock's CanCatch™ for MRD-guided treatment adjustments
- Sharing real-world examples of ctDNA monitoring in evaluating therapeutic response and enabling personalised treatment strategies
- Presenting case studies, including sensitive urinary cfDNA assays for bladder cancer detection and monitoring

Xinru Mao, Head of Pharma Services & Global IVD Business, **Burning Rock Dx**

Conference Day One
Wednesday 9th April, 2025

2.35 From Real-World Patient Data to Precision Therapeutics: A Case Study in Applying AI-Enabled Patient Endotyping & Multiple Omics Modalities to Diabetic Nephropathy

- What are the challenges of assembling real world patient cohorts and datasets to generate relevant multi-omics data?
- Identifying patient subpopulations using machine learning in a way that remains meaningful to physicians
- How AI-enabled techniques can enable patient stratifying biomarker models with high predictivity
- What are the key hurdles to determining drug targets that will be most relevant to specific patient subpopulations?

Robert Thong, Co-Founder & Chief Executive Officer, **MultiOmic Health**

2.35 Roche RxDx Collaboration in Oncology: Achievements in Drug/CDx Co-Development

- Roche RxDx partnerships are the cornerstone of our R&D strategy
- Roche and Foundation Medicine (FMI) collaborate on drug and CDx co-development through shared expertise in oncology and cancer genomic profiling
- Case Study: ITOVEBI (inavolisib), an isoform-specific PI3K inhibitor, received US FDA co-approval with FMI's FoundationOne Liquid CDx assay after a positive Ph3 readout

Katia Bassett, Senior Director & Head of CDx Development, Translational Medicine, **Genentech**

2.55 Ensuring Global Patient Care: Evaluating Strategies for CDx Development & Regulatory Approvals in Precision Medicine Programs

- Developing effective biomarker strategies: technical and platform considerations
- Navigating regulatory changes and achieving compliance with IVDR
- Strategic commercial considerations for emerging market access

Mary Anne Williams, Senior Director, Regulatory Affairs, **Bio-Techne**

2.55 Developing Biomarker Assays With Commercialisation in Mind

- Many therapeutics require co-development of a diagnostic test to select and enrich for biomarker-positive patient populations
- Discovery's approach of utilising laboratory-developed tests to support early phase development permits rapid development and deployment to support patient management
- We will present a brief overview of the Discovery process with an emphasis on regulatory compliance and commercial foresight if a regulated CDx is required

Scott Reid, Vice President & Global Head of Companion Diagnostics, **Discovery Life Sciences**

3.25 Afternoon Networking Break
Dedicated One-on-One Partnering™ ONE PARTNERING™

Shaping the Future of Patient Selection & Monitoring to Inform Treatment Regimes for Best-in-Class Cancer Therapies

3.55 Roundtable Discussion: Advancing Patient Selection & Monitoring Across Therapeutics Modalities in Precision Oncology for Improved Clinical Outcomes

- How can you optimise the use of tumour and blood-based biomarkers for dynamic patient selection?
- How to address challenge of biomarker heterogeneity within solid tumors and its impact on accurate patient stratification
- Why is biomarker assay standardisation critical for clinical adoption, and what collaborative efforts can streamline this process?

Sharon Liang, Executive Director, Head, Precision Medicine & Digital Health, **Bristol Myers Squibb**

4.15 H&E-Based Molecular Profiling: From Bench to Bedside in the Era of Precision Medicine & AI

- Revolutionising molecular diagnostics: AI analysis of H&E images delivers biomarker insights in minutes, preserving tissue while reducing turnaround times
- Platform versatility: Applications spanning drug discovery, clinical trials, and patient care to address diverse stakeholder needs
- Real-world impact: Case studies highlighting validation, regulatory success, and implementation demonstrate the transformation potential for precision medicine

Pahini Pandya, Founder & Chief Executive Officer, **Panakeia Technologies**

Strengthening Co-Development Partnerships for Rapid Market Access to Maximise Therapeutic Reach

3.55 Panel Discussion: Advancing Partnerships with Novel & Digital Technologies to Ensure Compliant, Scalable Solutions for Global Precision Medicine Applications

- What is the role of strategic partnerships in effectively devising biomarker and CDx strategies?
- How can we ensure the integration of testing technologies in clinical and healthcare settings?
- What is the future of novel and digital technologies?
- How can you ensure the compliance and scalability of pathology?

Panel Moderator: Antje Lukas, Senior Director Regulatory Affairs Companion Diagnostic, **Daiichi Sankyo Europe**

Monika Lamba Saini, Global Translational Pathology Leader, **ADC Therapeutics** & Education Committee Member, **Digital Pathology Association**

Shane McGann, Vice President, Regulatory Affairs, **Mythic Therapeutics**

James Duboff, Director, Strategic Partnerships, **Genomics England**

Conference Day One
Wednesday 9th April, 2025

4.25 The Renaissance of Circulating Tumour Cells (CTC) for Translational Research & Clinical Trials

- The Renaissance was a period in Europe, from the 14th to the 17th centuries, marked by a "rebirth of art, culture, and learning". Today, CTCs are experiencing a "rebirth in clinical research" due to the increased sensitivity of downstream analysis methodologies
- In the era of HER2 targeted therapies including ADCs, detecting HER2 status changes in previously HER2-negative primary breast cancer patients may identify patients who could benefit from HER2-targeted treatments despite their primary tumour's HER2-negative status
- 16–40% of Glioblastoma patients are classified as inoperable and ctDNA is found in less than 10% of glioma patients. CTCs isolated using the Parsortix system can enable genetic, transcriptomic, and proteomic profiling to help classify patients into molecular subgroups for targeted therapies and enrollment into clinical trials
- Longitudinal pan-cancer NGS analysis of CTC-DNA and cfDNA from a single blood sample, demonstrates multi-parametric utility to capture tumour heterogeneity, reveals tumoral evolution, and provides indicators of cancer resistance mechanisms in clinical trials

Brett Swansiger, Chief Commercial Officer, **ANGLE**

4.25 Overcoming IVDR Compliance Challenges in Early Clinical Development

- IVDR requires robust scientific validity, analytical performance, and clinical performance data, with pharma sponsors now needing to conduct a performance study in parallel to their phase I/II clinical trial in all EU member states participating in the IMP trial
- This more complex technical package is coupled with an expanded documentation file per device and subsequently requires increased specialist regulatory knowledge and capacity within the sponsor's project team and/or additional external support
- To address these pain points, ARC has established a boutique accredited laboratory and sponsor delegation service, capable of analytical validation and sample analysis from global patients, across a range of technologies, with regulatory compliance and patient safety at the forefront

Lindsey Bennie, Laboratory Manager, **ARC Regulatory**

4.55 Strategic Development of a Selection Test for Targeted Therapy: A Case Study

- Test development process: selection of appropriate tool and platform; analytical validation
- Determination of positive cut-off and its iterative refinement to adapt to emerging data throughout development
- Bridging the test across development phases to ensure consistency and compliance with trial and regulatory requirements

Anne-Laure Bauchet, Immunohistochemistry Team Manager & Translational Medicine Lead, **Sanofi**

4.55 A Match Made in Oncology: Optimising Co-Development Partnerships for the Accelerated Approval of Precision Oncology Therapies

- How soon should biopharma and diagnostic providers initiate collaboration to optimise the development of companion diagnostics for precision oncology?
- How and when to initiate performance studies to collect and establish data for the CDx
- What are the key challenges in scaling up co-development partnerships for precision oncology therapies, and how can these challenges be mitigated?
- What is the impact and opportunity of dual-pharmaceutical alliances on the co-development of precision therapies?

Antje Lukas, Senior Director Regulatory Affairs Companion Diagnostic, **Daiichi Sankyo Europe**

5.15 Progress on Multiplexed IHC CDx

- After long promise, multiplexing has matured from research to selection device driven by several late-stage clinical programs
- The combination of staining reagents and digital quantitation with advanced controls and calibrants have yielded systems that are highly reproducible and accurate
- This evolution has the potential to address the coming wave of new targeted ADC/IO therapies, positively improving trial outcomes and patient care

Pascal Bamford, Chief Clinical Officer, **Akoya Biosciences**

5.15 A Laboratory Evaluation of a Simple, Rapid NGS-Based LBx Kitted Assay to Profile NSCLC

- Review the importance of LBx testing to help guide access to precision therapies and clinical trials for NSCLC
- Discussing relevant laboratory criteria when considering an NGS assay for in-house LBx testing
- Review a performance evaluation and workflow assessment of Pillar Biosciences' oncoReveal® Essential LBx kit

Beatriz Bellosillo, Head of the Molecular Biology Laboratory, **Pathology Department of Hospital del Mar**

5.45 Chair's Closing Remarks & End of Day One

6.00 Sip & Sail
Join Roche Diagnostics in Celebrating 40 Years of VENTANA Solutions

Conference Day Two
Thursday 10th April, 2025

7.30 **Morning Networking Coffee**

8.20 **Chair's Opening Remarks**

Harmonising IVDR Compliance Across European Notified & Competent Bodies to Enhance Regulatory Clarity & Speed Towards Approval

8.30 **Panel Discussion: Strengthening the Interface between Competent & Notified Bodies to Define a Unified Path Towards IVDR Compliance for Streamlined Approvals**

- What are the current and future expectations for CDx conformity? How closely are the new UK regulations expected to mirror or diverge from IVDR?
- How are stakeholders harmonizing the interpretation of performance studies, from a technical and regulatory perspective?
- How is the changing global landscape of laboratory developed tests expected to impact biomarker driven trials?

Panel Moderator:

Patrick Fivey
Director, Precision Medicine Policy
AstraZeneca

Roy Milner
Regulatory Affairs Project Director
AstraZeneca

Philipp Schatz
Global Regulatory Lead, IVD
Bayer

James Hewitt
IVD Business Line Manager & Senior Specialist (CDx)
TÜV SÜD

9.00 **Transforming Patient Access in Cancer Care: A New Collaborative Era**

- Evolving Precision Medicine: Explore how patients are losing opportunities for targeted therapy at each step of the Precision Medicine pathway and the need for change
- Partnership and Collaboration: Understand the combined efforts of Roche and J&J to enhance patient access through early screening, diagnostic development, value propositions, and speeding up the adoption of innovative healthcare technologies
- Integration of Diagnostic & Treatment Pathways: Discuss comprehensive patient support programs, enhanced data sharing, ethical considerations, and educational resources to streamline patient access and improve outcomes
- Case Study on Lung Cancer: Address the challenges in the lung cancer patient pathway, including unequal diagnostic access, late-stage diagnoses, ineffective reimbursement strategies, and the commitment of Roche and J&J to bridge these gaps through multidisciplinary care and innovative solutions

Mark Hellewell
International Product Manager
Roche Personalised Healthcare Solutions - Oncology

Leonie de Visser
Portfolio & Alliance Lead, Precision Medicine, EMEA Strategy & Operations
Johnson & Johnson Innovative Medicine

9.30 **Navigating the Challenges of Changing Diagnostic Regulations in Clinical Trials**

Kristina McGuire
Executive Director & Head, Precision Medicine Laboratory Operations & Companion Diagnostics
Regeneron

- Overview of the evolving diagnostic regulations and their impact on patient enrolment and recruitment
- Awareness of the complexities of diagnostic testing outside of oncology
- Importance of global alignment in the diagnostic regulations for clinical trial execution
- Strategies for the industry to align on intent, impact, and change for effective clinical trial execution
- Ensuring the availability of quality diagnostic tests for patients amidst regulatory changes

9.50 **Adapting Clinical Development to an MRD-Integrated Treatment Landscape**

Donna Nichol
Senior Director, Market Development, Europe
Natera

- Signatera™ MRD testing is transforming cancer care across tumour types in the US, with growing global adoption in clinical trials. Its impact on patient management is an increasingly important consideration for clinical development strategy
- Analyses from Phase 3 studies demonstrated that MRD-based patient selection can reveal treatment benefits not observed in unselected populations. Incorporating MRD may enable more efficient trial designs by enriching for high-risk patients, accelerating event-driven readouts, expanding development into earlier settings, and informing early go/no-go decisions
- Natera supports the integration of MRD into clinical development and offers additional multi-omic and real-world data (RWD) solutions to inform strategy across the drug development lifecycle

10.20 **Morning Break & Networking**
Dedicated One-on-One Partnering™

Conference Day Two
Thursday 10th April, 2025

TRACK A: Biomarker Discovery & Clinical Development

Kerri Fuller, Director, RII & ID PMed Operations, **GSK**

Strengthening Disease Management Through Biomarkers & Digital Innovations for Improved Autoimmune & Rare Disease Treatment Regimes

11.20 Use of -Omics Data for Drug Development in Immune & Inflammatory Diseases

- Indication selection using pharmacological and transcriptomics data from preclinical disease model
- Transcriptomics and proteomics data from clinical studies provide insights on mechanism of action of new drug candidates
- Correlation between transcriptomics data and clinical outcome

Vincent Mikol, Global Head of Translational Precision Medicine, **Sanofi**

11.40 Tumour-Informed & Tumour-Agnostic MRD Solutions for Clinical Drug Development

- Personalised MRD detection informed by baseline tissue, blood, or urine samples
- Tumour-agnostic MRD detection independent of baseline sample availability
- Integrated into clinical trials with high-impact publications in NEJM and Nature Medicine

Shidong Jia, Founder & Chief Executive Officer, **Predicine**

11.50 Next-Gen MRD: Increasing Access to Ultrasensitive ctDNA Assessment for Biomarker Discovery, Development, & CDx Programs

- The Pathlight MRD test is an ultrasensitive, cost-effective approach to MRD detection and quantification to <1 PPM using WGS proprietary dPCR methods to track structural variants
- Structural Variants (SVs) are highly prevalent across indications and are an ideal pan-cancer biomarker for determining MRD status
- Clinical studies in breast and ovarian cancers demonstrate improved detection of ctDNA at baseline, during neoadjuvant treatment, post-surgery, and during follow-up, with long lead times to clinical relapse

Patrick Eimerman, Vice President, Business Development & Partnerships, **SAGA Diagnostics**

12.20 Addressing the Diagnostic Gap: The Need for Customised IVD Solutions for Rare Diseases

- Navigating the IVD landscape for rare diseases: Exploring strategies for addressing the challenges faced when IVDs are unavailable
- Market considerations: Discussing the implications of CE marking termination on IVD development
- Assay validation considerations: Examining the complexities of cross-validation of assays across regions and the difference between validating biomarker assays used for exploratory versus diagnostic purposes

Lien Dejager, Director, Head of Translational Biomarkers, **argenx**

TRACK B: CDx Development & Commercialisation

Katia Bassett, Senior Director & Head of CDx Development, Translational Medicine, **Genentech**

Optimising Regulatory & Commercialisation Priorities within the Clinic to Expedite Approvals

11.20 Panel Discussion: Navigating IVDR: Biomarker Test Compliance in Clinical Trials

- How patient recruitment can be impacted by IVDR
- What strategies are pharma/labs using to overcome IVDR challenges?
- How biomarker testing will look (centralised vs decentralised) in the future

Panel Moderator: Catarina Veiga, Commercial Director, Pharma Business, **Platomics**

Sharon Liang, Executive Director, Head, Precision Medicine & Digital Health, **Bristol Myers Squibb**

Seán O'Dowd, Director of Regulatory Affairs, **Precision Medicine, Novartis**

Shane McGann, Vice President, Regulatory Affairs, **Mythic Therapeutics**

11.50 Planning for Success When Developing & Validating Assays for Global Clinical Trials

- Key considerations for the development and analytical validation of assays for clinical stratification
- Regulatory compliance of clinical trial assays across global jurisdictions (EU, US and China)
- Quality control, surveillance of assay performance and clinical trial monitoring

Cheryl McFarlane, Associate Director, Assay Development & Validation, **Almac Diagnostic Services**

12.20 Decentralised Testing to Improve Patient Outcomes

- Many cancer patients still lack timely access to molecular results needed to guide targeted therapy decisions
- Local rapid testing is a cost and sample effective triage tool to help physicians make fast treatment decisions
- Fast, decentralised testing can accelerate clinical trial enrollment by quick identification of eligible patients

Chris van Haag, Senior Director Global Strategic Partnerships, **Biocartis**

Conference Day Two
Thursday 10th April, 2025

12.50 Lunch & Break & Networking
Dedicated One-on-One Partnering™ ONE PARTNERING

Integrating Blood-Based & Neuroinflammation Biomarkers for Better Outcomes in Neurological Diseases to Improve Quality of Life

1.50 Roundtable Discussion: Identifying & Developing Biomarkers for Patients with Neurological Disorders to Deliver Treatment Sooner & Improve Long-Term Patient Outcomes

- Why do neurological biomarkers face higher rates of failure in clinical validation compared to oncology, and what lessons from successful oncology biomarkers can be adapted to address these bottlenecks?
- How to ensure the scalability and reproducibility of biomarker assays for neurological conditions in the transition from research settings to routine clinical practice
- How to address the variability in biomarker expression across different stages of neurological diseases and incorporate dynamic biomarkers for longitudinal patient monitoring

2.20 Bringing Precision to Psychiatry: Pioneering Genetic CDx-Use in Major Depressive Disorder

- The Unmet Need in Psychiatry: Psychiatry has lagged behind oncology and immunology in adopting CDx, despite the clear potential to address the biological heterogeneity of disorders like MDD
- Our Innovative CDx Platform anticify™: Using statistical genetics, we've developed tools to stratify MDD patients into biologically distinct subtypes, enabling personalised treatment strategies
- Clinical Validation of CDx in Psychiatry: Post-hoc analysis shows our CDx candidate accurately predict responses to CRHR1 antagonists, breathing new life into previously shelved treatments
- IVDR's impact on a small EU biotech company co-developing Rx + CDx: Change of study design to dodge IVDR requirements (pivoting to a prospective-retrospective approach); Choosing UK over EU as study location
- The Future Vision: With ongoing clinical programs for Cortibon and Nelivabon, our work sets the stage for applying CDx across psychiatry

Daniel Gehrlach, Director, Biomarkers, **HMNC Brain Health**

Bolstering Access & Synchronising Commercialisation for Precision Medicines Across Oncology & Non-Oncology

1.50 Leveraging AI & Digital Pathology to Advance Biomarker Diagnostics in Clinical Trials & Routine Practice

- How AI-driven diagnostics can deliver transformative value to patients and pharma by improving patient identification in clinical routine and clinical trials
- Case study: Accelerating gBRCA genetic testing for high-risk patients with BRACAnalysis - Key learnings and progress
- Strategies to increase digital pathology adoption

Antoine de Sagey, Director Commercial Strategy & Operations Diagnostic, **Owkin**

Thomas di Maio, Head of Diagnostic Europe & Canada, **AstraZeneca**

2.20 Genomics & Diagnostic Data for Disease Population Sequencing Using Secondary Health Data

- Purpose-built repositories for real-world data use
- Linking between registries for granular analysis of health data
- Use cases of integration of genomic and diagnostics into RWE study designs

Lill-Brith von Arx, RWE Northern Europe Hub Lead, **Eli Lilly & Co**

2.40 Afternoon Networking Break
Dedicated One-on-One Partnering™ ONE PARTNERING

Conference Day Two
Thursday 10th April, 2025

From Tumour-Specific Models to AI-Enabled Tools: Enabling the Future of Precision Medicine Through Novel Technologies

Alexandre Akoulitchev
Chief Scientific Officer
Oxford BioDynamics

3.10 **EpiSwitch® 3D Genomic Liquid Biopsy: Diagnostic, Prognostic & Predictive Clinical Biomarkers**

- EpiSwitch PSE: accurate detection of prostate cancer
- EpiSwitch CiRT: prediction of response to immune checkpoint inhibitors
- EpiSwitch Data Knowledge

Subrata Bose
Vice President & Head, General Clinical Imaging Services. CoE Diagnostic Imaging Data & AI, Radiology R&D
Bayer

3.50 **Challenges in AI Application Development for Clinical Use to Progress Precision Medicines**

- 80% of development cycle time is spent on preparing the data algorithm ready
- How to address the lack of high-quality, annotated clinical datasets for training AI models in precision medicine while ensuring patient privacy and data security
- What is the best approach for clinical validation and integrating AI-based tools into existing clinical workflows?

4.00 **Chair's Closing Remarks & End of 15th World Clinical Biomarkers & Companion Diagnostics Summit Europe**

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Partnership Opportunities

World CB & CDx Summit Europe
8th -10th April, 2025 | London, UK

Your Comprehensive, Industry-Dedicated & Europe-Centric Platform to Foster New & Existing Relationships within the Precision Medicine Community

Novel technologies and clinical biomarkers are set to trailblaze precision medicines breakthroughs for unmet patient need in oncology, rare, neurological, and autoimmune diseases. But, as European biopharma continue to navigate translational, regulatory and commercialisation bottlenecks, they need partnerships and collaboration with diagnostics developers!

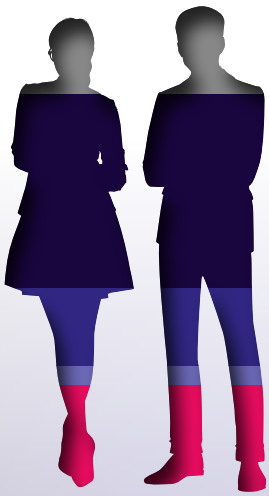
Uniting 200+ strategic biopharma leaders in London, the **15th World Clinical Biomarkers & Companion Diagnostics Summit Europe** is your premium connection-making platform to accelerate co-development strategies and partnerships within the growing European market.

Highlighting end-to-end precision medicine progress, companies partner with this legacy meeting to enhance visibility of their expert solutions and pioneering technologies. Esteemed by drug development leaders, we facilitate pivotal connections with the most innovative CDx and assay developers, empowering them to bring unique companion diagnostics to the European market.

4 Reasons To Prioritise Partnering

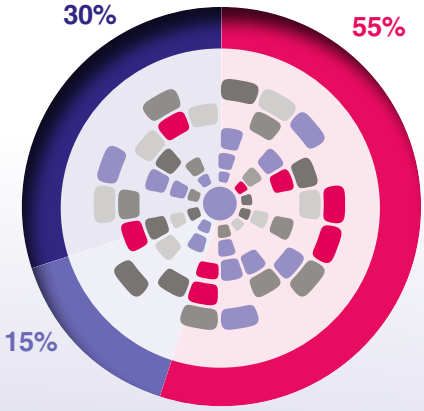
1. Gain actionable market insights with over 22 case study-led sessions and high-value Q&A discussions
2. Position your company as a trusted thought leader within the European industry and generate new partnership opportunities
3. Demonstrate your solutions to boost your visibility and influence in the growing European CDx market
4. Connect and build relationships with both existing and potential clients leading precision therapies for oncology, neurological, autoimmune, cardiovascular, metabolic, and rare diseases
5. Find the right partners, schedule face to face meetings and leverage your meeting history to efficiently collaborate with colleagues using the One-on-One Partnering™ platform

SENIORITY OF ATTENDEES*



- Chief, President & VP – 18%
- Director & Head – 40%
- Manager – 16%
- Scientist – 4%
- Other – 22%

TYPES OF COMPANIES ATTENDING*



- Drug Developers
- Academia & Research Institutes
- Equipment & Service Providers

*Statistics Taken from the 14th World Clinical Biomarkers & CDx Summit Europe

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DISCOVER and leverage first-hand technical and strategic insights from leading biopharma striving for **improved patient selection and monitoring with novel biomarkers** and improved technologies

BUILD your understanding into the evolving IVDR filing and commercialisation challenges, strategies, and solutions to truly capitalise on the **precision medicines paradigm in oncology, autoimmune, rare disease** and **CNS indications**

ENGAGE with 200+ precision medicine peers with in-person networking opportunities to build complementary collaborations and partnerships to **fuel co-development and propel your clinical progress**

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