

Biomarkers UK: In-Person

08 - 09 November 2021 | Manchester, UK

+ *Digital Day: 10 November 2021 | Online*

400+

LEADING PHARMA, BIOTECH AND
ACADEMIC DELEGATES ATTENDING
ON-SITE & VIRTUALLY

70+

PRESENTATIONS, CASE
STUDIES AND DISCUSSIONS

8

INTERACTIVE STREAMS ON
THE LATEST INNOVATIONS

Conference Brochure

KEY SPEAKERS INCLUDE



Adam Platt
AstraZeneca



Elizabeth Harrington
AstraZeneca



Alastair Brown
Heptares



Andrea Renninger
Bristol-Myers Squibb



Jarema Kochan
Turnstone Biologics



Mark Milton-Edwards
Teva

Book Online: www.oxfordglobal.co.uk/biomarkers-series-uk/

Join the Conversation: [#BiomarkersSeries21](https://twitter.com/BiomarkersSeries21)



Welcome Back to London Innov Biomarkers In-Person Network

Oxford Global is proud to present **Biomarkers UK: In-Person**, uniting senior-level experts to provide a focussed forum for thought-provoking discussion and to gain insights from the key figures in the community.

The comprehensive programme allows you to gain a forward-looking perspective on the latest technologies and strategies impacting biomarker research across multiple applications and therapeutic areas.

2021 sees the return of our popular discovery, diagnostics, preclinical and clinical streams designed to provide updates across multiple therapeutic areas, including key focusses on neuroscience, oncology, NASH and immunology. Benefit further from case studies on topical technology innovation in this space, from the latest in-vitro diagnostics and imaging tools through to data management strategies and proteomic markers.

Alongside the application-based streams, we also are pleased to once again bring together case studies on genomic markers to facilitate precision medicine, with deliberation of next-generation strategies as well as liquid biopsies and CTCs. New for this year, there is also a dedicated stream on digital pathology and digital biomarkers, reflecting the technological transformation healthcare is current undergoing.

The event will be returning in a hybrid format, with a revamped programme featuring cutting-edge presentations and a dedicated roundtable discussion room full of interactive, closed-door sessions, meaning there's more opportunities than ever for you to personalise your agenda for the sessions most of interest to you. Alongside the in-person talks, we're also pleased to bring you an array of digital content delivered by our state-of-the-art virtual conference platform.

We look forward to welcoming you there!

BROCHURE CONTENTS

- | | | | |
|-----|----------------------|-----|--|
| 02. | Welcome | 07. | Full Programme Agenda: Day One & Day Two |
| 03. | Attendees & Sponsors | 14. | Digital Day Agenda: (Coming Soon) |
| 04. | Session Topic Areas | 14. | Hybrid Event Format |
| 05. | Confirmed Speakers | | |



On-site Health & Safety

At Oxford Global, the safety and well-being of our clients is our top priority, and we are committed to ensuring that our congresses remain safe and successful. In anticipation of the return of our In-Person events in 2021, we have reviewed all areas of our congresses and a detailed plan is currently in place; from the registration process and networking activities, to the one-on-one meetings and set-up of our presentations.

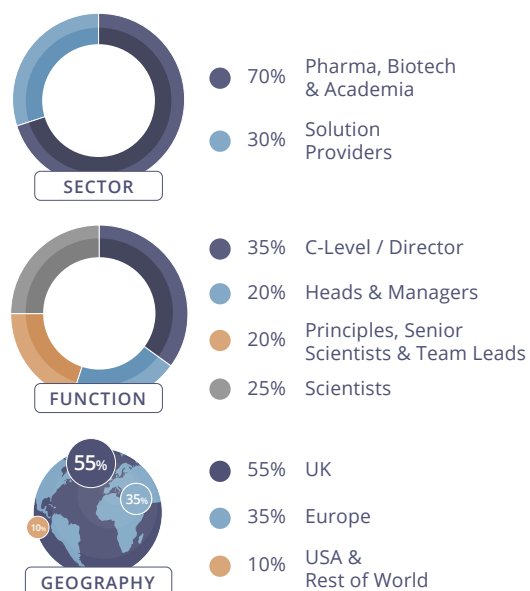
We are following all guidelines set out by the Association of Event Organisers and its stakeholders to ensure a safe return to live events. These guidelines have been approved by the UK government. We are confident that your participation will be in a safe and secure environment, and look forward to you joining us in 2021

WHO IS ATTENDING?

400+ VPs, Directors & Senior Managers will be attending on-site and online, coming from leading healthcare, biotech, pharma and research institutions in the following fields and more:

- Biomarker Discovery
- Translational Science
- Clinical Development
- Assay Development
- Genomic Markers
- Diagnostics
- Personalised Medicine
- Preclinical Development
- Biomarker Validation
- Oncology Biomarkers
- Neuroscience
- Translational Medicine
- Digital Health
- Pathology

Projected Attendee Profile



These companies and many more:



Formal and informal meeting opportunities offer delegates the chance to discuss key solutions with leading service providers:

- Assay Kits & Platforms
- Biomarker Verification
- Companion Diagnostics
- Protein Biomarkers
- Clinical Research & Trial Development
- Genomic Technologies
- Imaging Tools
- Liquid Biopsy
- Plexing Platforms
- Immunoassays
- Data Management
- Biomarker Discovery & Development
- Digitalisation & Digital Technologies
- Molecular & Digital Pathology

WHO IS SPONSORING?

Platinum Sponsors



Gold Sponsors



Silver Sponsors



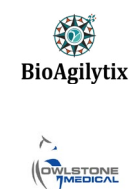
Bronze Sponsors



Network & Programme Sponsors



Webinar Sponsors



Biomarkers UK: In-Person features **2 days** of in-person cutting-edge presentations and knowledge-sharing, including **over 70** industry insights, sponsored presentations, think tank roundtable discussions and complimentary pre-event webinars, followed by a dedicated **Digital Day** delivered through our online event platform.

DAY ONE - 08 NOVEMBER

Biomarkers in Drug Discovery & Development – Therapeutic Areas: Oncology, Immuno-Oncology & Immunology

- Updates in predictive biomarkers for drug development
- Check point inhibitors and dual therapies in immuno-oncology
- Biomarker discovery in oncology and autoimmunity
- Translational biomarkers and patient stratification

Biomarkers for Detection, Monitoring & Diagnosis

- Early detection
- Blood biomarkers for early detection of cancer
- Diagnostic Development: Companion, Tissue & PoC
- Digital Biomarkers for disease detection and monitoring

Biomarkers for Clinical Development

- Biomarker trial design and data analysis
- Implementing clinical biomarkers in oncology, cardiology, neuroscience and inflammatory diseases
- Transforming clinical development through biomarker driven clinical trial design
- Use of cellular, transcriptomic and proteomic biomarkers in clinical trials

Digital Pathology & Biomarker Development

- Digital pathology in immuno-oncology and neuroscience biomarker development
- Bridging the gaps between research, development and clinical uptake
- Developing and validating digital biomarkers
- Overcoming challenges, including data analysis

DAY TWO - 09 NOVEMBER

Biomarkers in Drug Discovery & Development – Therapeutic Areas: Neuroscience & NASH

- Case studies in biomarker discovery and validation in neuroscience: schizophrenia; CNS
- Novel stem cell biomarkers for neurodegenerative disorders
- Emerging biomarkers to advance NASH drug development

New Biomarker Technologies & Data

- Immunoassays and screening processes
- Big data analytics and sampling techniques
- Imaging technologies, CNS imaging techniques and digital pathology
- Multiplexing technologies, Flow cytometry and Mass spectrometry

Biomarkers for Preclinical to Clinical Development

- Assay development & validation
- Translational biomarkers from preclinical to clinical phase studies
- Patient stratification and selection
- The role of safety and efficacy biomarkers

Genomic Markers in Drug Development & Precision Medicine

- Validating and verifying genomic markers in drug development
- Predictive and prognostic biomarkers for oncology and rare diseases
- Applying NGS, Single Cell Technologies and other Genomic Technologies in drug discovery and development

DIGITAL DAY - 10 NOVEMBER

Presentations & interactive sessions across all above topics, delivered through our virtual event platform

CONFIRMED SPEAKERS – DAY ONE



ADAM PLATT

Vice President, Head Translational Science & Experimental Medicine, Respiratory & Immunology AstraZeneca



PATRICK FIVEY

Precision Medicine Policy Lead - Global Oncology R&D, AstraZeneca



JAREMA KOCHAN

Head Of Biomarkers, Diagnostics And Assay Development, Turnstone Biologics



ANDREA RENNINGER

Director, Global Regulatory Lead, Precision Medicine, Bristol-Myers Squibb



RUSSELL GARLAND

Group Leader for Translational Biomarkers, Charles River



CHRISTOPHER PETERS

Clinical Senior Lecturer & Consultant Upper GI Surgeon, Imperial College London



NADIA GODIN-HEYMANN

Director, Precision Medicine Lead, AstraZeneca



EMMA LEIRE

Team Leader, Translational Science Immune Monitoring, Achilles Therapeutics



MARK MILTON-EDWARDS

Head of Product & Health Solutions - Digital Health, Teva



TUC AHMAD

Director, Companion Diagnostics, Labcorp



TIMOTHY SANGSTER

Executive Director, Bioanalytical Sciences, Celerion



MATT HUMPHRIES

NPIC Research Operations Manager, Leeds Teaching Hospitals NHS Trust



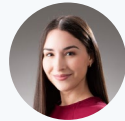
MAX BYLESJO

Technical Director, Fios Genomics



CHERYL MCFARLANE

Assay Development & Validation Manager, Almac



INES NEACHOU

Imaging Scientist, Indica Labs



ANNE-SOPHIE PAILHES-JIMENEZ

Head R&D, ANGLE



ANNA JUNCKER-JENSEN

Principal Scientist, Associate Director, NeoGenomics, Inc



AMELIE VIRATHAM

Field Application Specialist, Akoya Biosciences



MICHAEL RHODES

Senior Director Advanced Applications, Nanostring Technologies



ARMAN RAHMAN

Head of Tissue Imaging Facility, Precision Oncology Ireland, University College Dublin



BRUNO GOMES

Head of Biomarkers Oncology, Roche



CONFIRMED SPEAKERS – DAY ONE



YASMINE MAKHLOUF

Lead Data Scientist, Precision Medicine Centre of Excellence, QUB



ELTON REXHEPAJ

Principal Scientist, Sanofi



STEPHEN WILLIAMS

Chief Medical Officer, SomaLogic



CHRIS BAGNALL

Associate Principal Scientist, Biomarker Strategy and Applications, Ultivue, Inc.



HANS-ULRICH SCHILDHAUS

Professor, University of Goettingen



MELANIE ANDERSON

Principal Scientist, MSD



MARIJANA RUCEVIC

Scientific Director, Olink



GEOFF DANCE

Field Application Scientist, Europe, Sengenics



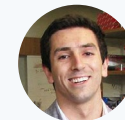
FABIAN SCHEIDER

Service Project Lead, R&D, Visiopharm



DAVID KRIGE

Vice President, Translational Medicine, PsiOxus



OMER BAYRAKTAR

Team Leader, Wellcome Sanger Institute



DOMENICO MERANTE

Global Clinical Development Lead, Vifor Pharma



PHILIP ARLEN

President and Chief Executive Officer, Precision Biologics



ANDREAS VOSS

Medical Director, Apis Assay Technologies



BENJAMIN DIZIER

Head of In Vitro Diagnostics, UCB



ANIA GASPO

Therapeutic Area Expert, Oncology, Cerba Research



JÖRG-M. HOLLIDT

General Manager & Chief Executive Officer, engine the biomarker company



WENDY ALDERTON

Early Detection ACED Programme Manager, CRUK Cambridge Centre, University of Cambridge



MARTIN BONE

International Alliance for Cancer Early Detection Programme Manager, Cancer Research UK Manchester Institute



ALASTAIR BROWN
Vice President, Translational Sciences, Sosei Heptares



CLARE JONES
Head of R&D, Talisman Therapeutics



CLAIRE SEAL
Principal Scientist, F-Star Biotechnology



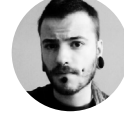
ANDERS STAHLBERG
Group Leader, University of Gothenburg



GRAHAM BALL
Professor of Bioinformatics, Nottingham Trent University



GERBEN BOUMA
Head of Translational Science – C3 DPU, GlaxoSmithKline



HUBERT AVIOLAT
Senior Scientist, AbbVie



DARREN HODGSON
Global Project Leader & Executive Director Translational Medical Strategy, AstraZeneca



THOMAS HACH
Executive Director Patient Engagement, Novartis



ARCHANA VIJAYAKUMAR
Research Scientist, Fibrosis, Gilead



JOSE ANTONIO LÓPEZ GUERRERO
Head of the Molecular Biology Laboratory Service, Instituto Valenciano de Oncología



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



JACK ROBERTSON
Translational Pathology Image Analysis Lead, Oncology R&D, Indica Labs



MAIK PRUESS
Senior Field Application Scientist, Personalis



TOBIAS PAPROTKA
Director Of Research and Development, Eurofins Genomics



MARSILIO ADRIANI
Principal Scientist, Lead Translational Science, 4D Pharma



GAYLE MARSHALL
Lead Biomarker Scientist, Medicines Discovery Catapult



SAM RODRIQUES
Team Leader, Francis Crick Institute



XUEMEI ZHAO
Principal Scientist, MSD



TIM AITMAN
Professor of Molecular Pathology & Genetics, University of Edinburgh



BEVIN GANGADHARAN
Research Scientist, University of Oxford



NIR BARZILAI
Director of the Institute of Aging Research, Albert Einstein College of Medicine



OURANIA TZARA
Research Scientist, H. Lundbeck A/S



NENA LOPEZ-LEE
Field Application Specialist, Gyros Protein Technologies



JAKE MICALLEF
Chief Scientific Officer, Volition



EMMA GHAFFARI
Field Application Scientist, Abcam



CHRISTINE FALK
Professor, Institut für Transplantationsimmunologie



SYLVAIN BERLEMONT
Chief Executive Officer & Founder, Keen Eye



ARIJIT MUKHOPADHYAY
Reader in Human Genetics, University of Salford



LINDSEY MARSH
Senior Field Application Scientist, Quanterix



ANGURAJ SADANANDAM
Founding Director, Centre for Global Oncology, The Institute of Cancer Research



JOELY IRLAM
Research Associate, University of Manchester



IRUNDIKA DIAS
Lecturer, Aston University



AMANDA HESLEGRAVE
Senior Research Fellow, University College London



STEPHEN HAGUE
Science and Technical Advisor, 10x Genomics



YANAIIKA HOK-A-HIN
Clinical Chemistry Department, VU University Medical Center



SHARON WILLIAMS
Director, Interactive Software Ltd.



PIETER MESTDAGH
Principal Scientist, Biogazelle



IAN PIKE
Chief Scientific Officer, Proteom Sciences



DANIEL MARTINEZ MOLINA
Chief Scientific Officer, Pelago Bioscience



LIVE AUDITORIUM



Oxford Global Welcome Address & Chairperson's Opening Address

Keynote Address: Enabling Precision Medicine In Respiratory Medicine

- New drug approvals for asthma, COPD and other common diseases remain low
- Taking a Precision Medicine approach to find the Right Patient is part of the solution
- By leveraging the worlds genomic data, exploiting large phenotyped cohorts and accessing target tissue non-invasively, we can change the target paradigm, linking the right target to right patient from the start

ADAM PLATT, Vice President and Head of Translational Science and Experimental Medicine, Respiratory & Immunology, AstraZeneca



LIVE AUDITORIUM

Navigating Precision Medicine Studies: Managing Biomarker, Regulatory and Drug Co-Development Priorities

- High attrition rates in drug development have become a critical issue and the low probability of success from first-in-human (FIH) to new drug application (NDA) has driven identification of biomarkers to enable earlier and more informed evaluation of drug candidates in clinical trials
- Biomarker development and application should keep in mind the intended use of the data and evolving regulatory requirements associated with that use, particularly if they may become a part of patient selection criteria or dosing decisions
- This presentation describes managing the analytical, clinical, regulatory and project coordination challenges when co-developing drugs and biomarkers in precision medicine collaborations particularly in small intended-to-treat populations or using complex lab developed diagnostic tests

TUC AHMAD, Director, Companion Diagnostics, Labcorp



BREAKOUT ROOM 1

Biomarkers: Biology vs Bioanalysis

In this presentation we will discuss the translation of the requirements for biomarkers are they progress through the drug development paradigm. We will look at the biologic requirements and expectations combined with variability and discuss the analytical aspects related to bioanalysis and the potential impacts and those implications to your investigations. The focus will be on clinical phases and ensuring that the assay development is appropriate for the intended use of the data

- Be able to assess the requirements for your biomarker assays
- Understand the limitations of Bioanalytical methodologies
- Understand the approaches to validating the Bioanalytical methodology
- How Celerion can assist you in your program

TIMOTHY SANGSTER, Executive Director, Bioanalytical Sciences, Celerion



BREAKOUT ROOM 2

Facilitating Tissue-Based Biomarker Research: Images To Insights

- Automatically quantify biomarker expression from single IHC biomarkers to multiplexed fluorescence using the HALO® platform
- Developing deep learning classifiers for cell phenotype detection and tissue morphology classification using HALO AI
- Assessing spatial relationships between numerous cell subtypes to better understand cellular phenotypes within the complex tissue microenvironment
- Collaborating and accessing images, annotations, and cell analysis results via cloud-based HALO Link
- Advanced data analysis and patient stratification

INES NEACHOU, Imaging Scientist, Indica Labs



BREAKOUT ROOM 3

Solution Provider Presentation

Breakout Room 3
will open at 8.55



LIVE AUDITORIUM

Developing And Applying Biomarker Assays For Use In The Clinic With Oncolytic Viral Immunotherapies

- How do we go about identifying biomarkers to be used in the clinic?
- What types of biomarker assays can be used to maximize biological information from our clinical studies?
- What are the challenges in developing and validating biomarker assays?
- How and when do we collect samples for biomarker assays to better understand viral and immune biological activity

JAREMA KOCHAN, Head Of Biomarkers, Diagnostics And Assay Development,
Turnstone Biologics

Translating Pharmacodynamic Immune Biomarkers To Clinic

- The value proposition: PD biomarkers demonstrate target engagement (proof of mechanism) and have a positive impact on project success
- Charles River's PD biomarker strategy: citing LPS-induced inflammation as an example
- Biomarker identification: determine potential PD biomarkers of inflammation using gene expression profile (NanoString nCounter system)
- Biomarker selection and confirmation: focus on promising biomarkers at the mRNA and protein level (qPCR and Luminex multiplex analysis)
- In vivo pharmacology model: analysis of selected biomarkers in in vivo pharmacology model of LPS peritonitis
- Translating biomarker assay to clinic: assay validation of whole blood ex vivo activation assay to GCLP standards
- Other case studies

RUSSELL GARLAND, Group Leader for Translational Biomarkers, **Charles River**



BREAKOUT ROOM 1

Where Is Biomarker Research Going So Wrong When 98% Fail?

- Millions are spent on Biomarker research in Academia and Industry but only a tiny fraction 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 succeed

CHRISTOPHER PETERS, Clinical Senior Lecturer & Consultant Upper GI Surgeon,
Imperial College London

Why Using ANGLE Liquid Biopsy Circulating Tumor Cell (CTC) Analysis Would Be Beneficial For Your Studies

- Why consider CTC Liquid biopsy for your studies
- ANGLE Parsortix CTC enrichment system
- Case study: CTC PD-L1 analysis in Metastatic Breast and NSCLC study
- ANGLE BioPharma Service

ANNE-SOPHIE PAILHES-JIMENEZ, Head R&D,
ANGLE



BREAKOUT ROOM 2

Artificial Intelligence In Digital Pathology: A Roadmap To Routine Use In Clinical Practice

- This talk takes you through a general workflow on how to use AI in digital pathology, specifically for efficient biomarker detection and patient prognostics
- It illustrates use cases and example applications proved to be successful

YASMINE MAKHLOUF, Lead Data Scientist,
Precision Medicine Centre of Excellence, **QUB**

Identification Of Immunosuppressive Cell Trios In TNBC With Implications For Immunotherapy

- Quantifying perivascular accretion of tumor immune cells by multiplexed immunofluorescence
- wDe novo discovery of a three-cell structure that may correlate with the efficacy of IO therapy

ANNA JUNCKER-JENSEN, Principal Scientist,
Associate Director, **NeoGenomics, Inc.**



BREAKOUT ROOM 3

The Impact Of The EU IVD Regulation On The Pharmaceutical Industry

- The In-Vitro Diagnostic Regulation (IVDR) replaces the IVD Directive (IVDD) on 26th May 2022
- The Precision Medicine Approach
- Routine Clinical Testing for Use with Precision Medicines
- Potential Shortages of Commercially Available Tests For Use With Precision Medicines
- Expected Reduction In Labs Able To Use LDTs For Use With Precision Medicines
- Interplay of IVDR & Clinical Trials Regulation (CTR)
- The diagnostic regulatory landscape in Europe is changing soon and we need to be ready

Joining Online: PATRICK FIVEY, Precision Medicine Policy, Global R&D,
AstraZeneca

SomaScan Proteomics As An Unparalleled Source Of Validated Health Assessments And New Mechanistic Discoveries

- How to precisely measure 7000 proteins at once and why it is important
- Why an expansive view of biology and resistance to reductionism can lead to better tests
- Why immutable factors (age, sex, medical history, polygenic risk scores) are left out in the cold
- How to plan and execute the world's largest cardiovascular surrogate endpoint qualification program
- Virtual holistic phenotyping of clinical trial participants – measuring changing health states during trials

STEPHEN WILLIAMS, Chief Medical Officer,
SomaLogic



09:10
-
09:35

09:35
-
10:05



LIVE AUDITORIUM



BREAKOUT
ROOM 1



BREAKOUT ROOM 2



BREAKOUT ROOM 3

Morning Break & 1-2-1 Meetings x4

Spatial Insights For An Optimal Biomarker Strategy

- Benefits of a pre-optimized flexible biomarker mIF assay for comprehensive tissue immunophenotyping analysis
- How advanced image analysis software can be applied to discover cell types, populations and morphological, spatial context
- How whole slide image analysis of the tumor microenvironment can provide insight into the immune environment of specific cancer types

CHRIS BAGNALL, Associate Principal Scientist,
Biomarker Strategy and Applications, **Ultivue Inc**



Fusion Type Dependent Biomarkers Impacting Overall Survival in Synovial Sarcoma, Revealed by HTG Transcriptome Profiling

- Synovial sarcomas are aggressive spindle cell sarcomas, showing a consistent translocation (X;18;p11;q11), either in the SYT-SSX1 or SYT-SSX2 transcriptional repressor gene
- Overall survival is significantly better for patients with SSX2 then with SSX1 translocation, so there is a need for prognostic biomarkers
- With broad extraction-free HTG Transcriptome profiling we identified biomarkers that are linked to the translocation type
- Differential expression profiles between synovial sarcoma and other spindle cell sarcoma types were in line with previous findings
- The identified biomarkers offer new opportunities for improved diagnostic for aggressive synovial sarcomas

Joining Online: HANS-ULRICH SCHILDHAUS,
Professor, **University Hospital Essen**



Circulatory Protein Biomarkers Improve Cancer Prevention, Intervention, Treatment Selection And Discovery Of New Druggable Targets

- The utility of the circulatory proteome in liquid biopsies across the continuum of cancer care from prevention to treatment selection
- Plasma protein biomarkers improve understanding of the molecular precursors of the earliest stages of cancer and premalignant disease
- Baseline predictive biomarkers of immunotherapy efficacy in cancer patients identified through the analysis of plasma proteomics
- A multiomics approach in cancer research, combining proteomics and genomics, to enable further understanding of biological mechanisms and empower discovery of biomarkers and new robust drug targets
- High throughput capability of Olink® Explore for protein biomarker discovery, interrogating thousands of proteins simultaneously with superior specificity, delivers high data quality from discovery to validation and implementation

MARIJANA RUCEVIC, Scientific Director, **Olink**



Enhanced Biomarker Discovery And Validation Using TMT® Proteomics

- Recent developments in proteomics are making it an essential tool supporting drug development. Broader profiling of disease mechanisms that go beyond relatively crude genetic drivers is opening up rafts of new targets, whilst deepening proteome coverage of peripheral fluids mean we can find disease-relevant biomarkers for monitoring treatment effect more readily
- Proteome Sciences has been at the forefront of driving the performance of proteomics through the introduction of Tandem Mass Tags®, invention of MS3 quantification and development of global profiling tools such as SysQuant® and TMTcalibrator™. Operating from 10,000 sq ft facility in Frankfurt, Germany, with ISO 9001:2015 and GCLP (for targeted assays) we provide our clients with a highly flexible and high-quality proteomics service that allows them to be more informed and efficient throughout the drug development process
- During this presentation I will describe our core technologies with examples of their application across a number of therapeutic areas. Applications include detailed analysis of underlying disease mechanisms to discover and contextualise therapeutic targets, monitoring of drug mechanism in experimental systems and the discovery and validation of circulating, disease-related biomarkers

IAN PIKE, Chief Scientific Officer, **Proteome Sciences**



Biomarkers UK: In-Person

DAY ONE: 08 NOVEMBER 2021

BIOMARKERS IN DISCOVERY
& DEVELOPMENT

BIOMARKERS FOR DIAGNOSTIC
DEVELOPMENT

DIGITAL PATHOLOGY & DIGITAL
BIOMARKERS

BIOMARKERS IN CLINICAL
DEVELOPMENT



LIVE AUDITORIUM

The Use Of Digital Pathology And Image Analysis In Tissue-Based Cancer Biomarker Validation

- This presentation shows an example of tissue-based validation of a set of breast cancer prognostic biomarker set
- Antibody validation and chromogenic IHC followed by digital pathology and image analysis of seven markers on two independent breast cancer tissue microarray sets (discovery cohort, validation cohort) was performed
- Data analysis identifies a smaller set of markers that are prognostic in both cohorts
- In one TMA cohort, this smaller subset was assessed using fluorescence multiplexed IHC and showed good prognostic value. Adding immune markers increases the prognostic ability of these markers

ARMAN RAHMAN, Head, Tissue Imaging Facility,
Precision Oncology Ireland,
University College Dublin

It's Not Human Error, It's A Design Challenge

- Decades of research tends to look at things in the same way
- New user focused approaches are needed and new insights in order to make progress

MARK MILTON-EDWARDS, Head of Product &
Health Solutions – Digital Health,
Teva



BREAKOUT ROOM 1

Roundtable Discussion: How Can Academia & Industry Work More Closely Together To Improve Biomarker Implementation In The Clinic?

Moderator: CHRISTOPHER PETERS, Clinical Senior
Lecturer & Consultant Upper GI Surgeon, Imperial
College London

Enabling Transformation In Clinical Trial Design With Patient Centric Sampling"

- This presentation will focus on patient centric sampling as an enabling technology for clinical trial design change. Decentralized clinical trials cannot occur without the collection of high quality samples to generate critical PK, PD and safety data
- New sampling technologies are making smaller sample collection, painless collection and remote collection a reality. The COVID-19 pandemic has caused a revolution in sample collection approaches and we must build upon this momentum to reduce patient burden in our trials
- The ability to collect samples remotely with new sampling devices can provide richer longitudinal data sets and may enhance our understanding of biological activity

Joining Online: MELANIE ANDERSON, Principal
Scientist, MSD



BREAKOUT ROOM 2

Attendees are welcome to attend co-located sessions

Attendees are welcome to attend co-located sessions



BREAKOUT ROOM 3

The Promise Of Minimal Residual Disease: Curing Cancer By Treating Earlier

- Early treatment is required to make cancer a curable disease
- Future vision where patients at high risk of relapse could be identified prior to recurrence, treated with the right drug and cured
- AZ is developing a highly sensitive personalized diagnostic assay to identify patients with Minimal Residual Disease (MRD) in partnership with a Dx partner
- MERMAID studies' aim is to transform clinical practice by identifying Non Small Cell Lung cancer patients who would benefit from additional treatment

Joining Online: NADIA GODIN-HEYMANN, Director,
Precision Medicine Lead,
AstraZeneca

Global Regulatory Considerations For The Use Of IVDs In Therapeutic Clinical Trials

- Innovative personalized medicine strategies are becoming more common within global therapeutic clinical development. In vitro diagnostic (IVD) assays used within clinical trials are an innovative approach that uses specific information about a person's own genes or proteins to prevent, diagnose or treat disease
- Alongside the implementation of these clinical trials, new frameworks for stronger collaboration between stakeholders in drug development including IVD partners, IRB's and regulatory agencies exists
- Clinical trial execution with IVDs varies in complexity from country to country and in the inclusion of In Vitro Diagnostic tests for clinical decision making present additional regulatory considerations for the use of IVDs for in global clinical trials
- This presentation is regional review of the global regulatory considerations for the use of IVDs in therapeutic clinical trials in key regions

ANDREA RENNINGER, Director, Global Regulatory
Lead, Precision Medicine, Bristol-Myers Squibb

Biomarkers UK: In-Person

DAY ONE: 08 NOVEMBER 2021

BIOMARKERS IN DISCOVERY
& DEVELOPMENT

BIOMARKERS FOR DIAGNOSTIC
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DIGITAL PATHOLOGY & DIGITAL
BIOMARKERS

BIOMARKERS IN CLINICAL
DEVELOPMENT



LIVE AUDITORIUM



BREAKOUT
ROOM 1



BREAKOUT ROOM 2



BREAKOUT ROOM 3

12:55

-

13:55

Lunch Break & 1-2-1 Meetings x3

Solution Provider Presentation

- Sengenics is a global leader in the detection and use of autoantibodies as biomarkers for disease and response to therapeutics
- Autoantibodies are an exceptional and underused route to novel biomarkers that can help profile diseases that are difficult to stratify. Sengenics technology produces data that is highly sensitive, with ultra-low background and exceptional reproducibility
- We present the use of Sengenics technology for discovering previously unknown patient groupings in systemic lupus erythematosus (SLE) based on autoantibody profiles
- Early detection of melanoma has also been shown through Sengenics autoantibody profiles
- Sengenics technology has been used for predicting responder/ non-responder groups in rheumatoid arthritis (RA) patients treated with Adelimumab (Humira) based on autoantibody profiles

GEOFF DANCE, Field Application Scientist, Europe, Sengenics



Supporting Biomarker Discovery With Bioinformatics

- Biomarker discovery and validation are key focus areas in medical research
- In this domain, vast amounts of 'omics data are being generated, which provides computational challenges to analyse and interpret the data
- Careful use of appropriate computational tools are essential to identifying relevant biological output
- This presentation outlines Fios Genomics' role in this area illustrated with an oncology biomarker case study

Joining Online: MAX BYLESJO, Technical Director, Fios Genomics



Multiplex Phenotyping – Enabling Tissue Microenvironment Insights

- Discover how the Visiopharm platform can be used for multiplex analysis
- Review an example analysis of an mIF 8plex image
- See an example analysis of a Fluidigm Hyperion
- CyTOF image covering the below topics
- Tissue segmentation using AI deep learning
- Cell segmentation using AI deep learning
- Phenotyping
- An example tumor microenvironment region analysis
- Learn how the new Visiopharm Data Insights tool can be used for exploring image objects

FABIAN SCHEIDER, Service Project Lead, R&D, Visiopharm



Clinical Trial Assay Development & Validation – Strategies For Success

- Key considerations in the development & validation of CTAs for clinical stratification
- The importance of adequate specimen collection & stabilisation
- Major factors influencing platform selection
- The requirement of bridging studies and lessons learned
- Challenges of demonstrating adequate analytical performance of panels
- Considerations for data analysis pipelines

CHERYL MCFARLANE, Assay Development & Validation Manager, Almac





LIVE AUDITORIUM

Developing A Clinical Biomarker Strategy For The T-SiGN Tumour Re-Engineering Pipeline

- The T-SiGN vector NG-350A encodes a fully human IgG monoclonal antibody that is a potent & selective CD40 agonist
- In the FORTITUDE first-in-human dose-escalation study of NG-350A we have seen dose dependent serum cytokine elevations that are consistent with the mechanism of action of an anti-CD40 antibody
- The cytokine biomarker signature provides platform proof of concept of tumour selective transgene protein expression

DAVID KRIGE, Vice President, Translational Medicine,
PsiOxus Therapeutics

Clinically Meaningful & Feasibility Of Some Selected Biomarkers In ANCA-Associated Vasculitis (MPA & GPA) For Clinical Development Of Future Therapies

- GPA and MPA: Disease characteristics and diagnosis
- Patient identification and profiling (GPA and MPA)
- How can some biomarkers be used more meaningfully?
- What is the value of literature research in ANCA-Associated Vasculitis for biomarker clinical development?

DOMENICO MERANTE, Global Clinical Development TA Lead, **Vifor Pharma**



BREAKOUT ROOM 1

Sensitive Detection Of Novel Clonal Neoantigen Reactive T Cells (cNeTs) For Cell Reactivity & Expansion Postdosing

- Achilles Therapeutics has developed ATL001, a patient-specific TIL-based product manufactured using the VELOS™ process. The active component of this process, cNeT (Clonal Neoantigen-reactive T cells), are expected to target multiple clonal neoantigens present in all tumour cells within a patient
- Two Phase I/IIa clinical trials of ATL001 are ongoing in patients with advanced Non-Small Cell Lung Cancer, CHIRON (NCT04032847), and metastatic or recurrent Melanoma, THETIS (NCT03997474)
- Extensive cNeT product characterisation and immune-monitoring through Achilles' Translational Science Programme allows precise characterisation of the active component of this therapy during manufacture and accurate quantification of cNeT in peripheral circulation post-dosing

EMMA LEIRE, Team Leader, Translational Science Immune Monitoring,
Achilles Therapeutics

Targeting Tumor Neo-epitopes With Therapeutic Monoclonal Antibodies

- Antibody/target identification
- Mechanisms of action (MOA): ADCC and others
- Clinical Trial Development based on MOA

Joining Online: PHILIP ARLEN, President and Chief Executive Officer, **Precision Biologics**



BREAKOUT ROOM 2

Harnessing Spatial Transcriptomics To Understand Cellular Diversity

Joining Online: OMER BAYRAKTAR, Team Leader,
Wellcome Sanger Institute

Roundtable Discussion: Digital Pathology & Spatial Biology

Moderator: MATT HUMPHRIES, NPIC Research Operations Manager,
Leeds Teaching Hospitals NHS Trust



BREAKOUT ROOM 3

Panel Discussion: The Next Disruption In Diagnostic Development

- What novel technologies are impacting molecular diagnostics?
- Data management for diagnostic devices, including ML and AI
- What's on the horizon for diagnostics regulation?
- What does the future hold for diagnostics and precision medicine?

Moderator: ANDREAS VOSS, Medical Director,
Apis Assay Technologies

Panellists:
BENJAMIN DIZIER, Head of In Vitro Diagnostics,
UCB
GRAHAM BALL, Professor of Bioinformatics,
Nottingham Trent University

14:25
-
14:50

14:50
-
15:15



LIVE AUDITORIUM

Precision Medicine In Practice For NSCLC

- Over the past decade, the treatment of patients with advanced non-small-cell lung cancer (NSCLC) has become reliant on tissue specimens and biomarkers to help guide targeted treatment options
- By testing a tumor sample for biomarkers, investigators can learn if a cancer has one of these defects, which may point to a specific treatment choice
- There are now many biomarker-defined patient subgroups, with evidence showing that treatment with targeted therapies has superior clinical outcomes when compared with cytotoxic agents. However, rapid change in the field of precision medicine brings with it the challenge of translating biomarker recommendations into clinical practice and clinical development
- Herein, we will discuss the application of practice guidelines to patients with NSCLC. We will also review novel diagnostic assays, such as Next Generation Sequencing (NGS) and simplex / multiplex immunohistochemistry (IHC) in lung tissue specimens within Cerba Research offerings

Joining Online: RANIA GASPO, Therapeutic Area Expert, Oncology, **Cerba Research**



BREAKOUT ROOM 1

Whole Transcriptome Digital Spatial Profiling Of Organ Tissues With Spatial Context

- GeoMx® Digital Spatial Profiler – discussing the benefits of a phenotypic driven selection of spatial data
- Highlighting spatial research from more than 70 pre-reviewed publications
- Spatial Organ Atlas – A new resource for enabling spatial research

MICHAEL RHODES, Senior Director, Advanced Applications, **NanoString Technologies**



BREAKOUT ROOM 2

A Spatial Biology Approach In Immuno-Oncology: From Biomarker Discovery To Clinical Research

- Ultra-high plex platform for revealing 40+ protein markers within a single tissue section
- High-throughput multiplex solution for visualising and quantifying whole slide sections
- Application of these solutions to uncover novel insights in tissue biology at a single cell resolution

AMELIE VIRATHAM, Field Application Specialist, **Akoya Biosciences**



BREAKOUT ROOM 3

Advantages Of A Holistic Approach For Novel Autoantibody Discovery

- Autoantibodies as Biomarkers
- Technological Approaches
- Holistic Biomarker Case Study
- Relevance of the right biospecimen

JÖRG-M. HOLLIDT, General Manager & Chief Executive Officer, **engine the biomarker company**



Afternoon Break & 1-2-1 Meetings x3

Biomarkers UK: In-Person

DAY ONE: 08 NOVEMBER 2021

BIOMARKERS IN DISCOVERY
& DEVELOPMENT

BIOMARKERS FOR DIAGNOSTIC
DEVELOPMENT

DIGITAL PATHOLOGY & DIGITAL
BIOMARKERS

BIOMARKERS IN CLINICAL
DEVELOPMENT



LIVE AUDITORIUM

Panel Discussion: Revolutionising Tissue Imaging & Analysis Through Digital Pathology and Spatial Biology

- How can spatial technologies help researchers answer critical biological questions, understand disease processes and drive advances in patient diagnostics and prognostics
- What impact can digital pathology have in tumour biology and immuno-oncology

Moderator: TBA

Panellists:
ELTON REXHEPAJ, Principal Scientist, **Sanofi**



BREAKOUT ROOM 1

Panel Discussion: Integrated Approaches To Immuno-Oncology Biomarkers & Companion Diagnostics

- New predictive biomarkers and companion diagnostics platforms that are currently being developed in immuno-oncology
- Multi-diagnostic approaches in immuno-oncology
- Challenges of developing and validating companion diagnostics

Moderator: TBA

Panellists:
PHILIP ARLEN, President and Chief Executive Officer, **Precision Biologics**



BREAKOUT ROOM 2

Uniting World-Leading Researchers To Tackle The Biggest Challenges In Early Detection Of Cancer: The International Alliance For Cancer Early Detection

- The International Alliance for Cancer Early Detection (ACED) is a partnership between Cancer Research UK, the Canary Center at Stanford University, the University of Cambridge, the Knight Cancer Institute at Oregon Health and Sciences University (OHSU), University College London and the University of Manchester
- ACED aims to accelerate research in the early detection of cancer by harnessing some of the best science across the UK and US. Together, ACED researchers will compare different methodologies and integrate multiple approaches where appropriate to identify the most suitable biomarkers for clinical implementation.
- In this talk, we will illustrate the Alliance's scientific remit by highlighting three cross Centre collaborations using different technologies to discover novel biomarkers for early detection of hereditary kidney cancer, lung and prostate cancers

WENDY ALDERTON, Early Detection Programme Manager, CRUK Cambridge Centre, w
University of Cambridge

MARTIN BONE, International Alliance for Cancer Early Detection Programme Manager,
Cancer Research UK Manchester Institute

Roundtable Discussion: Strategies For Accelerating Early Cancer Detection

Moderator: WENDY ALDERTON, Early Detection ACED Programme Manager, CRUK Cambridge Centre,
University of Cambridge



BREAKOUT ROOM 3

Patient Enrichment Strategies: An Opportunity To Accelerate Early Clinical Trials In Oncology & Immuno-Oncology

- What does patient enrichment mean? What are the options for clinical development in Oncology?
- How to design patient enrichment strategies
- Examples and use cases for patient enrichment in Oncology

Joining Online: BRUNO GOMES, Head of Biomarkers Oncology,
Roche

Delegates are welcome to attend co-located presentations

Networking Drinks & End of Day One



LIVE AUDITORIUM

Keynote Address: Ultrasound Imaging For Intestinal Damage

- Brief overview of Sosei Heptares and their interest in targets GPCRs in the GI tract
- Outline some of the challenges facing biomarker development for GI conditions
- Summarise the potential application of ultrasound as an imaging biomarker
- Describe the pre-clinical development of a high resolution contrast enhanced ultrasound intestinal imaging platform

ALASTAIR BROWN, Vice President, Translational Sciences,
Sosei Heptares



LIVE AUDITORIUM

Human Stem Cell Models Of Neurodegeneration: Exploitation Of In Vitro Phenotypes To Support Drug Discovery

- Where do you see human stem cell models fitting into the drug discovery process?
- Do we still need to use animal models to support drug discovery?

CLARE JONES, Chief Scientific Officer,
Talisman Therapeutics



BREAKOUT ROOM 1

Implementing A Strategy To Consider Biomarker Data Context Of Use & Improve Biomarker Translation Through Pre-Clinical And Clinical Developments

- Biomarkers are invaluable during the drug development process, from early pre-clinical stages through to clinical trials. While the biomarker being measured may remain the same at different stages, the context of use for that biomarker data may change as a project moves through the development pipeline, and it is important to discuss, agree and document these uses at key points
- F-star have developed a Biomarker Strategy that facilitates constructive discussions and strategic planning to ultimately improve efficiencies, reduce costs and unnecessary time
- The strategy links to planning and developing assays that can be validated appropriately for the context of use for the biomarker data
- Conclusion: the biomarker strategy developed by F-star encourages cross-functional communication and ensure plans and discussions are recorded, with a positive impact on project progression

CLAIRE SEAL, Principal Scientist,
F-Star Biotechnology



BREAKOUT ROOM 2

Liquid Biopsies For Nucleic Acids Based Biomarker Analysis: A Complete Workflow

- We have developing a clinical workflow for liquid biopsy analysis, from sampling to data analysis
- We are using ultrasensitive sequencing to analyse nucleic acids in plasma and immune cells
- We will present data from several ongoing projects, focusing on monitoring treatment efficacy
- Clinical and technical considerations using nucleic acids based biomarkers in liquid biopsies will be discussed

Joining Online: ANDERS STAHLBERG, Associate Professor, **University of Gothenburg**



BREAKOUT ROOM 3

Developing Machine Learning Pathway Models From Transcriptomic Data For Biomarker And Drug Target Discovery – A TP53 Breast Cancer Case Study

- Introduction to Machine learning methods for pathway mining
- Challenges in Omics Data
- Mining breast cancer omics data using the TP53 pathway as a target framework – Result an amended TP53 marker list (TP53+)
- Network inference methods for the identification of pathway molecular drivers and generation of a TP53+ pathway model
- Taking the targets forward for drug discovery

GRAHAM BALL, Professor of Bioinformatics,
Nottingham Trent University



LIVE AUDITORIUM

Development Of A Fast, Sensitive, And Accurate Amyloid Beta 1-40 Biomarker Assay Using A High-Sensitivity Gyrolab CD

- There is a need for more robust ligand-binding assays for CSF biomarkers in biotherapeutic development
- Cytokine assay sensitivity has recently been increased 2- to 6-fold to low pg/mL sensitivity on the Gyrolab microfluidic immunoassay platform with the Gyrolab Bioaffy™ 4000 CD
- We present a customer case study demonstrating the use of this CD for the development of a robust abeta 1-40 assay in various preclinical matrices

NENA LOPEZ-LEE, Field Application Specialist, **Gyros Protein Technologies**
OURANIA TZARA, Research Scientist, **H. Lundbeck A/S**

GYROS PROTEIN
Technologies



BREAKOUT ROOM 1

Using Image Analysis To Enhance Prevalence Studies

- Prevalence studies are a vital part of translational medicine as this allows strategic targeting of a candidate molecule in indications where it has the most chance to work
- Image analysis can provide a more robust analysis of prevalence study samples by reducing intra- and inter-observer variability that happens in manual scoring
- However, image analysis does face some challenges and is more time consuming for a de novo analysis than a pathologist manually scoring slides
- To make the most out of image analysis we need to go beyond an H-score and course binning of data to provide continuous scoring metrics and spatial statistics

JACK ROBERTSON - Translational Pathology Image Analysis Lead, Oncology R&D, **Indica Labs**

indica labs
informed pathology



BREAKOUT ROOM 2

Exploiting Tumor RNA Sequencing For Prediction Of Immune Checkpoint Inhibition Response

- Only a subset of patients respond to immune checkpoint inhibition therapy
- Several predictive biomarkers, including TMB, MSI, TILs and expression signatures, have been proposed
- All of these markers can be extracted from tumor RNA-sequencing data

PIETER MESTDAGH, Principal Scientist, **Biogazelle**

biogazelle



BREAKOUT ROOM 3

Enabling Multiplex Biomarker Discovery And Screening With FirePlex® Assays

- Developing reproducible multi-biomarker signatures for drug development with limited sample volumes is a key challenge
- FirePlex is a particle-based multiplexed assay technology for profiling multiple proteins or miRNA that can help overcome this issue in biomarker analysis and discovery studies
- Utilising your existing instrumentation, FirePlex offers up to 70-plex discovery panels to identify unknown biomarkers in disease pathways, as well as pre-designed and customisable mix and match panels Available in 96-well and automation friendly, high-throughput no-wash 384-well formats, FirePlex offers a flexible solution for the quantitation of a range of targets
- With high quality recombinant rabbit monoclonal antibodies available, FirePlex assays are robust and highly specific. Our Case study demonstrates how FirePlex is already being utilised by leaders in the field

EMMA GHAFARI, Field Application Scientist, **Abcam**

abcam

Morning Break & 1-2-1 Meetings x3

Biomarkers UK: In-Person

DAY TWO: 09 NOVEMBER 2021

BIOMARKERS IN DISCOVERY
& DEVELOPMENT: NEUROSCIENCE
& NASH

NEW BIOMARKER DATA &
TECHNOLOGIES

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TO CLINICAL DEVELOPMENT



LIVE AUDITORIUM

Multiplex-Protein Technologies For Covid-19 Research: Beyond Antibodies And Cytokines

- Cytokine "storm" in COVID-19
- SARS-CoV-2 S and N-specific antibodies in COVID-19
- Autoantibodies in COVID-19

Joining Online: CHRISTINE FALK, Professor, **Institut für Transplantationsimmunologie**

MERCK



BREAKOUT ROOM 1

Deep Learning Image Analysis: A Guide To Optimize Your Biomarker Strategy From Early Stage Research To Clinical Trials

- Presentation of Keen Eye
- How deep learning can empower biomarker analysis
- Onboard deep learning technology into your GCP process
- Conclusion

SYLVAIN BERLEMONT, Chief Executive Officer & Founder, **Keen Eye**

Keen Eye



BREAKOUT ROOM 2

The Integrated Genomics Universe: From Biomarker Discovery To Biomarker Validation

- Introduction on genomic biomarker discovery and validation
- Technologies for whole genome biomarker discovery
- Focused methods for DNA marker discovery
- Overview on RNA marker discovery strategies
- DNA biomarker validation / Best practices and technologies for research and clinical trials

TOBIAS PAPROTKA, Director of Research and Development, **Eurofins Genomics**

eurofins | Genomics



BREAKOUT ROOM 3

Simoa Technologies For Ultrasensitive Biomarker Detection, Futureproofing Your Bioanalysis

Quanterix brings ultrasensitive biomarker detection to transform the future of healthcare. We empower researchers to bring new discoveries in disease and treatment to the forefront with our Simoa precision instruments, wide-ranging menu of assay kits and custom assay development services

- Understanding on the 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
- A deep-dive on some of Quanterix' top technology including the SP-X, SR-X and HD-X
- How critical biomarker detection is applicable to a wide range of therapeutic areas
- Assay development and custom services

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

Quanterix
The Science of Precision Health

10:50
-
11:20

Biomarkers UK: In-Person

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LIVE AUDITORIUM

Autoantibody profiling of Sjögren's syndrome sera as clinical biomarker tool

- In our study autoantibody profiling was a robust and reproducible biomarker method
- Autoantibody profiling provides a promising tool for identification of patient subpopulations and tools for clinical biomarker analysis or precision medicine

Joining Online: GERBEN BOUMA, Head of Translational Science – C3 DPU, **GlaxoSmithKline**

Panel Discussion: Developing Non-Invasive Biomarkers – Challenges & Opportunities

- Advances in identifying novel non-invasive biomarkers
- Utility of non-invasive biomarker panels for diagnosis
- What challenges remain when integrating non-invasive biomarkers, such as imaging tools, in biomarker research

Moderator: XUEMEI ZHAO, Principal Scientist, MSD
Panellists:
ALASTAIR BROWN, Vice President, Translational Sciences, **Sosei Heptares**
JOELY IRLAM, Research Associate, **University of Manchester**
IRUNDIKA DIAS, Lecturer, **Aston University**
CHRISTOPHER PETERS, Clinical Senior Lecturer & Consultant Upper GI Surgeon, **Imperial College London**



BREAKOUT ROOM 1

Translating A Lead Candidate From Bench To Clinic: How Preclinical Biomarkers Inform Clinical Development

MARSILIO ADRIANI, Principal Scientist, Lead Translational Science, **4D Pharma**

Turning Immune Cold Tumours Hot - Treating Pancreatic Tumours With Bioengineered Immunotherapy

- We demonstrate a novel bioengineering strategy that potentiates response to anti-PD1 therapy in immune cold tumours in preclinical models of pancreatic cancer
- We use stromal characteristics in our bioengineering approach to heat up cold tumours
- We have developed a combined therapeutic approach for potential personalised therapy

ANGURAJ SADANANDAM, Founding Director, Centre for Global Oncology, **The Institute of Cancer Research**



BREAKOUT ROOM 2

Panel Discussion: Delivering The Next Generation Of Precision Therapies

- Strategies for encouraging the widespread adoption of routine genomic testing in oncology
- What is required to achieve precision medicine in oncology
- Optimizing clinical trial designs and the road to precision oncology
- Technology improvements impacting precision medicine

Moderator: TUC AHMAD, Director, Companion Diagnostics, **Labcorp**

Panellists:
THOMAS HACH, Executive Director Patient Engagement, **Novartis**
RACHID BOUZID, Scientist, **Merus** nl
XIAOFENG ZHAO, Senior Scientist, **Simcere**



BREAKOUT ROOM 3

Use Of Plasma Extracellular Vesicles / Exosomes For The Discovery Of Non-Invasive Biomarkers For Neurodegenerative Disease

- Purification method validation.
- Strategies for the assessment of CNS-specific biomarkers from plasma EVs.
- Discussion on potential pitfalls and misleading results.

Joining Online: HUBERT AVIOLAT, Senior Scientist, **AbbVie**

A High-Performance Analytical Platform For Fluid Biomarker Development, Validation And Measurement At The UK Dementia Research Institute

- Who we are
- What we do
- Technologies used
- Why are super sensitive platforms so important
- Collaboration

AMANDA HESLEGRAVE, Senior Research Fellow, **University College London**

Lunch Break & 1-2-1 Meetings x3



LIVE AUDITORIUM

Transforming Drug Discovery Through Precision Research

- Discover how single cell genomics provides resolution to enable enhanced biomarker discovery, translational and clinical research
- Demonstration of relevant approaches to biomarker discovery in immuno oncology, oncology and Neurology and multiome approaches to further enhance biomarker characterization

STEPHEN HAGUE, Science and Technical Advisor,
10x Genomics



BREAKOUT ROOM 1

Breast Cancer Recurrence Risk Classification And Molecular Subtyping Using HTG EdgeSeq Technology

- Determine the risk of relapse in early-stage HR+/HER2- breast cancer and the molecular subtype, based on one single 5µm thin-section of a FFPE tissue block
- Oncotype (OT) and Mammaprint (MP) matching accuracy of 80.5%, specificity of 80.7%; and NPV, 91.4%
- This IVO MPD test identifies HR+/HER2- early-stage BC patients with high-risk of distant relapse improving the prognostic value of those studies that compare MP and OT, suggesting a more precise risk classification

JOSE ANTONIO LÓPEZ GUERRERO, Head of the
Molecular Biology Laboratory Service.
Instituto Valenciano de Oncología (IVO)



BREAKOUT ROOM 2

CETSA Based Biomarker Discovery – Focus On The Proteins

- Proteins carry out the work in the cell
- CETSA monitors cellular protein states
- Correlating proteome wide CETSA profiles with treatment outcome – a new tool for biomarker discovery

DANIEL MARTINEZ MOLINA, Chief Scientific Officer,
Pelago Bioscience



BREAKOUT ROOM 3

Thimet Oligopeptidase Is A Potential CSF Biomarker For Alzheimer's Disease - A Cross-Platform Validation Study

Using antibody-based proteomics, the neuropetidase Thimet Oligopeptidase (THOP1) was identified as a potential cerebrospinal fluid (CSF) biomarker to discriminate Alzheimer's Disease (AD) from Lewy body dementia (DLB) and controls. We aimed to develop specific THOP1 immunoassays to facilitate the translation of our biomarker discovery findings into commutable immunoassays for further large scale validation and potential clinical implementation. Our data suggests that the strategy followed, using antibodies in both discovery and validation studies, may facilitate translation of proteomic findings and accelerate the development of body-fluid-based biomarkers.

Joining Online: YANAICA HOK-A-HIN, Clinical Chemistry Department, **VU University Medical Center**



13:20
-
13:50



LIVE AUDITORIUM

Circulating Tumour DNA in Oncology Drug Development

- ctDNA provides multiple opportunities for new approaches to clinical trials
- New and earlier points of intervention
- Potential new clinical trial endpoints

DARREN HODGSON, Global Project Leader & Executive Director Translational Medical Strategy, AstraZeneca

Liquid Biopsy for Easy and Difficult Cancers

- My talk will first describe the present state of the art in liquid biopsy whereby cancers that release much DNA into the circulation have yielded advances in patient management that are now adopted into routine clinical practice
- I will describe our work on head and neck cancer as an exemplar of this
- However, for cancers that are low-secretors of cfDNA or where very high sensitivity is required such as in definition of minimal residual disease, I will describe a totally new approach, apheresis-based capture of cfDNA, as a way to increase markedly assay sensitivity.

TIM AITMAN, Professor of Molecular Pathology and Genetics, The University of Edinburgh



BREAKOUT ROOM 1

Predictive Molecular Marker For Clostridium Difficile Infection Recurrence

Joining Online: XUEMEI ZHAO, Principal Scientist, MSD

Roundtable Discussion: Developing A Collaborative Biomarker Strategy

- What makes a good biomarker strategy?
- How can we make strategies more collaborative?
- What are the evolving technologies that can support a good collaborative strategy?

Moderator: GAYLE MARSHALL, Lead Biomarker Scientist, Medicines Discovery Catapult



BREAKOUT ROOM 2

Workshop: Data Management & Bioinformatic Strategies For Biomarker Research

Presentation 1:

- What data is available for biomarker research
- From data types to analytics
- How we can use this data
- What new data we need

IGOR RUDYCHEV, Vice President, Enterprise Analytics, Horizon Therapeutics

Panel Discussion: Bioinformatics Strategies For Biomarker Research

Moderator:

IGOR RUDYCHEV, Vice President, Enterprise Analytics, Horizon Therapeutics

Panellists:

GRAHAM BALL, Professor of Bioinformatics, Nottingham Trent University

SHARON WILLIAMS, Director, Interactive Software Ltd.



BREAKOUT ROOM 3

Possible Use Of Mir-379/656 MicroRNA Cluster As Non-Invasive Biomarker For Neurodegenerative Diseases

- We have shown the possible utility of this microRNA cluster as biomarkers in neurooncological tumours (GBM) and other cancers [PMIDs: 34575183, 23618224, 29769662, 29931616]
- We have reported the utility of exosomal microRNA as biomarker in respiratory diseases [PMID: 23683467]
- We have reported the enhanced tissue specific microRNA editing in members of this cluster in human brain [PMIDs: 32498345, 28550310]
- We have preliminary evidence (unpublished) that members of this microRNA cluster are preferentially secreted via exosomes and thus can be powerful non-invasive biomarkers

ARIJIT MUKHOPADHYAY, Reader in Human Genetics, University of Salford

Spatial & Temporal Transcriptomics For Neuroscience

New transcriptomic methods can provide information about the spatial and temporal context of gene expression. These methods will ultimately enable the discovery of new biomarkers reflecting cell-cell interactions or aspects of cell physiology

SAM RODRIQUES, Team Leader, Francis Crick Institute

13:50
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14:15

14:15
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14:40

Biomarkers UK: In-Person

DAY TWO: 09 NOVEMBER 2021

BIOMARKERS IN DISCOVERY
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LIVE AUDITORIUM

Two Sides Of The Same Coin - ImmunoID NeXTTM And NeXT LiquidTM Biopsy: Comprehensive Solutions For Tumor Immunogenomics

- ImmunoID NeXT is a comprehensive solution to characterize the tumor and its immune related components in the microenvironment
- Whole exome and whole transcriptome sequencing of >20,000 genes consolidate multiple biomarker assays into one
- Various analytical modules generate informative immuno-oncology insights
- NeXT Liquid Biopsy complements ImmunoID NeXT by analyzing cfDNA molecules shed into the blood
- Monitoring clonal & subclonal variants to view cancer evolution for therapy response, and exploring critical areas of tumor biology often missed in targeted gene panels

MAIK PRUESS, Senior Field Application Scientist,
Personalis



BREAKOUT ROOM 1

Solution Provider Presentation

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



BREAKOUT ROOM 2

Nu.Q Discover - Epigenetic Profiling Of Circulating Nucleosomes

- Volition provides rapid epigenetic profiling in disease models, preclinical testing and clinical trials - a complete solution to profiling nucleosomes
- Determine levels of circulating cell free nucleosomes and profile nucleosome epitopes including global levels of histone modifications and variants
- Applications include biomarker discovery in oncology, inflammatory conditions, diabetes and more. • Assays are analytically validated on K2-EDTA samples but other types of samples like cell culture supernatant, chromatin extract or other plasma matrix could be used
- Submit your samples for processing using up to 13 nucleosome biomarkers to our "state-of-the-art" service facility
- Low input volume required helping to preserve valuable samples. Available to researchers, pharmaceutical development researchers, diagnostic development researchers and other interested parties. The benefits of using Nu.Q® Discover Measure treatment efficacy, on-target and off-target effects in drug development pipelines, and expand your understanding of epigenetics

JAKE MICALLEF, Chief Scientific Officer, **Volition**



BREAKOUT ROOM 3

Enhancing Biomarker Discovery In Neurodegenerative Diseases With Advances In Mass Spectrometry-Based Proteomics Technologies

- Quantitative profiling of CSF samples for biomarker discovery and subject stratification
- Next-generation platform to explore CSF beyond protein expression
- Outlook: deploying protein structural features in neurodegenerative diseases

YUEHAN FENG, Scientific Director, R&D
Applications, **Biognosys**



Afternoon Break

Biomarkers UK: In-Person

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LIVE AUDITORIUM

Understanding The Applicability Of Clinical Biomarkers For NASH And Fibrosis To Understanding Disease Progression And Therapeutic Efficacy In Preclinical Models

- Biomarkers such as the ELF score are used to stratify fibrosis progression in subjects with NASH
- The preclinical biology group at Gilead is evaluating whether these biomarkers also indicate disease progression in preclinical models and are assessing the correlation of changes in biomarkers to histological endpoints

Joining Online: ARCHANA VIJAYAKUMAR, Research Scientist, Fibrosis, Gilead

Novel Serum Biomarkers For Non-Alcoholic Fatty Liver Disease

- Non-alcoholic fatty liver disease (NAFLD) encompasses a spectrum of progressive liver disease ranging from non-alcoholic fatty liver (NAFL) to non-alcoholic steatohepatitis (NASH)
- Approximately 1 in 3 people in the UK and 25% of adults worldwide are expected to have some degree of NAFLD and most affected individuals are unaware they have the disease
- We have shown that our fibrosis biomarkers are promising compared to the biomarkers used in current tests such as FibroTest, ELF test, Hepascore, and FIBROSpect
- The novel Oxford biomarkers would allow clinicians to identify NAFLD patients so they could be advised about lifestyle changes, such as diet and exercise, which could help to reverse the disease and thus save money for healthcare providers

BEVIN GANGADHARAN, Research Scientist, University of Oxford



BREAKOUT ROOM 1

Evolving Precision Medicine - Humanizing Biosignatures

- Currently we are in a world of imprecision medicine
- We have a lot of data that we can use to identify biosignatures for precision medicine
- Often, we look too much at the data alone and don't use common sense or accept an inconvenient truth (example: the dog that is the solution and not insulin injections)
- The "totality of data" will guide the way
- With all the digital possibilities, let's not lose the human touch

Joining Online: THOMAS HACH, Executive Director, Patient Engagement, Novartis

The Genetics Of Longevity

Joining Online: NIR BARZILAI, Director of the Institute for Aging Research, Albert Einstein College of Medicine



BREAKOUT ROOM 2

Breakout Room 2 is now closed for the day

Breakout Room 2 is now closed for the day



BREAKOUT ROOM 3

Breakout Room 3 is now closed for the day

Breakout Room 3 is now closed for the day

End of Conference

All Times Shown
are GMT (UTC+0)



VIRTUAL EVENT PLATFORM

Clinical Proteomics Enters Clinical Trials: Biomarker Discovery And Qualification By Quantitative Mass Spectrometry

BIOMARKER
TECHNOLOGIES

11:00

-

11:20

- Promising pre-clinical protein biomarker are not followed up in the clinic
- Unbiased and targeted protein biomarker may contribute to a better PK/PD relationship and disease understanding
- Quantitative Mass Spectrometry represents a time- and cost-effective method to build and conduct assays for testing hypotheses in multiple settings, including in the clinics

AXEL DUCRET, Senior Principal Scientist,
F. Hoffmann-La Roche Ltd

EATRIS-Plus: The Development Of A Multi-Omic Tool Box For Performing High-Quality Research In Personalised Medicine

BIOMARKER
TECHNOLOGIES

11:20

-

11:45

- Efficient advancement of Personalised Medicine depends on the availability of validated patient-targeted biomarkers
- In order to turn the multi-omic promises into a reality, systemic bottlenecks impacting the biomarker field needs to be overcome
- EATRIS-Plus project aims to develop a Multi-omics toolbox to support cross-omics analysis and data integration in clinical samples with a quality and reproducibility perspective
- The multi-omics toolbox is the engine to enable high-quality and reproducible research in the context of patient stratification and accelerate the implementation of personalised medicine

EMANUELA OLDONI, Scientific Programme Manager,
EATRIS, the European Infrastructure for Translational Medicine

Exosomal dsDNA As New Potential Biomarker In Adult Acute Myeloid Leukemias

GENOMIC
MARKERS

11:45

-

12:05

- Liquid biopsy is a very hot topic in both Oncology and Hematology and extracellular vesicles are one of the most important carriers of the information searched by liquid biopsy analysis. The isolation of extracellular vesicles, and of exosomes in particular, released by a particular cellular population is of great interest since it may increase the sensitivity and the efficacy of liquid biopsy approaches
- Acute Myeloid leukemia (AML) is still a big challenge for hematologists. An improvement in prognostication and in early detection/prediction of relapse are one of the most important goals, at present. New biomarkers are needed in order to achieve these goals
- The synergy of leukemia-derived exosome enrichment techniques and of NGS in the detection of molecular biomarkers in peripheral blood of AML patients may allow the identification of active leukemic cells resident in the bone marrow of patients and may predict disease relapse

SIMONA BERNARDI, Research Fellow, Chair of Hematology,
University of Brescia

Clinical Application Of Single Cell Analysis And Liquid Biopsy

GENOMIC
MARKERS

12:05

-

12:25

Currently, one in four deaths is caused by cancer, mainly as a result of systemic spread and metastatic disease. Despite new drugs, the currently available therapies are effective only in one in four cancer patients. Monitoring of genetic alterations in the course of systemic cancer disease at close intervals could thus help in recognizing the development of resistance at an early stage and in selecting the most appropriate therapy for each patient. For this, we developed a platform using single cell technologies to follow the genetic evolution of systemic cancer and generate patient-derived models for therapy prediction. Moreover, we focus on pushing the liquid biopsy concept beyond blood samples to other body fluids and even tissues to develop tailored strategies for defined clinical questions.

BERNHARD MICHAEL POLZER, Head of Cellular and Molecular Diagnostics,
Fraunhofer-Institute for Toxicology and Experimental Medicine

Lunch Break

Evolution Of Tumor Mutation Burden As A Tumor Agnostic Biomarker For Pembrolizumab

GENOMIC
MARKERS

13:25

-

13:45

- Association of TMB and MSI
- TMB as a pan tumor biomarker
- Measuring TMB
- Role of TMB beyond PDL1 and MSI as biomarkers

DEEPTI AURORA-GARG, Executive Director, Companion Diagnostics,
MSD

FNHI Biomarkers Consortium Development Of Quality Control Materials For ctDNA Assays

GENOMIC
MARKERS

13:45

-

14:05

- ctDNA shows great promise for cancer patient management, but there is a need for standardization in its use
- The FNHI Biomarkers Consortium initiated a public private partnership (PPP) to develop recognized quality control materials (QCM) for widespread use in ctDNA testing
- Designed for use across multiple assays, the QCMs will provide confidence in interpretation of ctDNA biomarker assay results, paving the way for more effective clinical research and therapeutic decision-making
- This presentation describes the need and acceptable performance characteristics of QCMs and establishment of the PPP and provides an update on current status of the FNHI ctDNA QCM project
- The project is a member of the International Liquid Biopsy Standardization Alliance (ILSA) and the development and objectives of this new, recognized Collaborative Community will also be discussed

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



VIRTUAL EVENT PLATFORM

Clinical Validation Of A ctDNA Panel

GENOMIC
MARKERS

- Pre-analytic considerations for analytic validation
- Validation design and sample selection
- Clonal hematopoiesis and its role in specificity assessment
- Assay performance

ROBIN HARRINGTON, Research Associate, Molecular Characterization Laboratory,
Frederick National Laboratory for Cancer Research

Tissue And Circulating Microbiomes – The New Frontier

GENOMIC
MARKERS

- When it comes to cancer, we need to think beyond stool, oral and skin microbiomes
- Tissue and circulating microbiomes are very promising sources of oncology innovation
- These can be analysed to improve early stage cancer detection and monitoring of the disease progression or even improving drug trials with new sets of biomarkers

SANDRINE MILLER-MONTGOMERY, President & Chief Executive Officer,
Micronoma

Afternoon Break

Genetically Engineering CAR Macrophages For The Treatment Of Solid Tumors

DISCOVERY

- Challenges cell therapies face in the TME
- Overview of the CAR-M platform
- Understanding of CAR-M biology using syngeneic mouse model
- Ongoing First in human clinical study

THOMAS CONDAMINE, Senior Director, Translational Sciences,
Carisma Therapeutics

Network-Based Proteomics For Biomarker Discovery In Alzheimer's Disease

DISCOVERY

- Increasing evidence indicates that Alzheimer's disease (AD) develops from an intricate web of biochemical and cellular processes that extend beyond amyloid and tau accumulation
- Growing recognition surrounding the diversity of AD pathophysiology underscores the need for holistic systems-based approaches to explore AD pathogenesis
- Network-based proteomics of human brain has provided a framework for the complex protein pathophysiology underlying AD, which can be leveraged to advance translational efforts for the novel protein biomarkers in cerebrospinal fluid (CSF)

NICHOLAS SEYFRIED, Associate Professor of Biochemistry and Neurology,
Emory University

Novel Digital Diagnostics & Biomarkers Within Neuroscience

DIAGNOSTICS

ELEFThERIA PISSADAKI, Manager, Systems Neuroscientist,
Biogen

Diagnostic Development and Commercialization: Establishing Effective Therapeutic-Diagnostic Partnerships

DIAGNOSTICS

- Development and Commercialization of Diagnostics
- Factors for Consideration in the Evaluation of Commercial Partnerships
- Key areas to evaluate and align corporate capabilities when developing partnering strategy

ELIZABETH SOMERS, Diagnostic Pathway Lead,
Eisai

End Of Digital Day

A NEW CONFERENCE EXPERIENCE

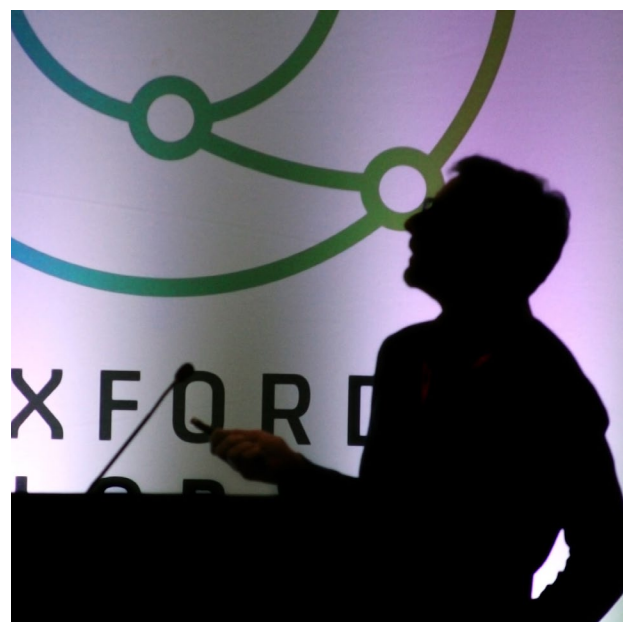
The digital revolution has hit conference organisation

...and just because we're returning to In-Person events doesn't mean a return to the traditional set-ups. It's why we're excited to welcome you to our new and improved In-Person conferences: maintaining the high-quality presentations and networking that you expect from an Oxford Global event but harmonised with digital elements and new formats to optimise attendee experience.

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Biomarkers UK: In-Person can be attended in-person or via our virtual events platform.

MORE INFORMATION



You now have more chances than ever to shape your daily agenda around the exact types of sessions you enjoy. Our **AUDITORIUM** is the place to be for our keynote talks, where you can hear high-level strategy and aspirational case studies from the biggest names impacting the industry, from pharma giants and academic innovators through to technology providers ready to help you achieve your research goals.



To delve more deeply into recent updates and novel work done in a specific field, our **BREAKOUT ROOMS** provide themed talks around a particular area of interest. Ideal for gaining insights into the new technologies, modalities and techniques about to impact your workflow, they also allow you to advance your understanding of multiple different topics that cross-over with your expertise.



Prefer to join the conversation via interactive discussions, and keen to benefit from the high levels of networking enabled at in-person events? Our **DISCUSSION ROOM** is jam-packed with panels, roundtables and workshops to encourage as much knowledge-sharing as possible. Join for a specific theme or stay for a full day of debate – who knows where the conversations may lead.



Our agendas are now fully **COLOUR-CODED** so that you can see which room you need to be in for the tracks of interest to you – and don't worry, the room themes only ever change at a breaktime, so you'll be able to grab a coffee, re-charge, and then follow your sessions of interests into the next room.







That's not all... Reflecting the move to a more online conference world, our In-Person events now include an increased amount of digital content and experience: from live streaming of certain auditorium talks, allowing you to catch them digitally, through to a host of online-only content on our **DIGITAL DAY**, bringing you closer to your global peers from the comfort of one location and with instant content accessibility. We've also introduced a variety of industry-leading new event technologies, including an intuitive digital system for question-asking, so that no matter where you are, you're able to submit your questions on the app to benefit as much as possible from the speakers' expertise.

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-  **Oligonucleotides: Chemistry & Therapeutics Symposium**
28 April 2021 | BST (UTC+1)
-  **Biologics UK: In-Person**
06 - 07 September 2021 | London, UK
-  **Biotherapeutics US: Online**
17 - 18 November 2021 | EST (UTC-5)

Biomarkers Series

www.oxfordglobal.co.uk/biomarkers/

-  **Biomarkers Week: Online**
17 - 21 May 2021 | BST (UTC+1)
-  **Advancing Biomarker Analysis Europe: Online**
14 - 16 September 2021 | BST (UTC+1)
-  **Biomarkers UK: In-Person**
08 - 09 November 2021 | Manchester, UK
-  **Digital Biomarkers & Pathology Symposium**
07 December 2021 | EDT (UTC-4)
-  **Biomarkers US: In-Person**
07 - 08 February 2022 | San Diego, USA

Cell Series

www.oxfordglobal.co.uk/cell/

-  **Gene Therapy Europe: Online**
05 - 06 May 2021 | BST (UTC+1)
-  **Cell UK: In-Person**
28 - 29 October 2021 | London, UK
-  **3D Cell Culture Symposium**
02 December 2021 | GMT (UTC+0)

Discovery Series

www.oxfordglobal.co.uk/discovery/

-  **Virtual Symposium: Targeted Protein Degradation & PROTAC**
16 - 17 February 2021 | GMT (UTC+0)
-  **Organoid Discovery Symposium**
13 April 2021 | BST (UTC+1)
-  **Discovery Week: Online**
01 - 04 June 2021 | BST (UTC+1)
-  **Discovery UK: In-Person**
26 - 27 October 2021 | London, UK
-  **Discovery Chemistry US: Online**
15 - 17 November 2021 | EST (UTC-5)





Formulation & Delivery Series

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-  **Formulation & Delivery Europe: Online**
20 - 21 April 2021 | BST (UTC+1)
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29 - 30 June 2021 | EDT (UTC-4)
-  **Formulation & Delivery UK: In-Person**
21 - 22 September 2021 | London, UK
-  **Formulation & Delivery US: In-Person**
01 - 02 February 2022 | San Diego, USA





Immuno Series

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-  **Oncolytic Viruses Symposium**
25 May 2021 | BST (UTC+1)
-  **Immuno Week: Online**
06 - 09 July 2021 | BST (UTC+1)
-  **Immuno UK: In-Person**
13 - 14 October 2021 | London, UK
-  **Immuno US: In-Person**
07 - 08 February 2022 | San Diego, USA





NextGen Omics Series




www.oxfordglobal.co.uk/omics/

-  **Spatial Biology Europe: Online**
14 - 16 April 2021 | BST (UTC+1)
-  **Spatial Biology US: Online**
27 - 30 September 2021 | EST (UTC-5)
-  **NextGen Omics UK: In-Person**
04 - 05 November 2021 | London, UK
-  **NextGen Omics US: In-Person**
29 - 30 March 2022 | Boston, USA

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www.oxfordglobal.co.uk/pharmatec/

-  **Pharma Data Congress: In-Person**
02 - 03 September 2021 | London, UK
-  **SmartLabs Congress: In-Person**
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-  **Pharma Manufacturing Europe: Online**
01 - 02 December 2021 | GMT (UTC+0)
-  **PharmaTec Networking Dinners**
October / November / December 2021

 In-Person Event  Online Event  Online Symposium

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