FESTIVAL OF BIOLOGICS

Presents...

CLINICAL TRIALS EUROPE 2019

Basel Congress Center, 15th-17th October 2019

Confirmed speakers

Andy Lee, Head of Global Clinical Trial Operations, **MSD**
Benjamin Szilagyi, Global Head Medical Data & Information Solutions, **Roche**
Isabelle Naëije, Associate Global Trial Director, **Novartis**
Alain Bindels, Head of Innovation Facilitation, **Roche**
Kefeng (Kevin) Hua, Senior Manager, AI/Machine Learning Development, **Bayer**
Denise Steckel, Head, Clinical Collaborations Management, **Genentech**
Adama Ibrahim, Associate Director, Global Clinical Operations, **Biogen**
Raj Pallapothu, mHealth Global Lead - Business Operations, **Bayer**
Haider Alleg, Global Head of Digital, **Ferring Pharmaceuticals**
Mehdi Benchoufi, Assistant Professor Centre d'Epidémiologie Clinique, APHP**, Université Paris Descartes-Sorbonne Paris Cité**
Kaspar Rufibach, Principal Statistical Scientist, **Roche**
Mats Sundgren, Director Health Informatics, **AstraZeneca**
Mareile Hark, Director of Strategy and Operations, **Novartis**
Olivier Leconte, Head of Statistical Programming & Analysis, **Johnson & Johnson**
Kevin Bateman, Scientific Associate Vice President, **MSD**
Christophe Le Tourneau, Professor of Oncology, **Insitut Curie**
Faidra Van der Wal, Associate Director Global Clinical Development Operations Trial Lead, **Janssen**
Sharon Barton, Director, Biometrics Team Leader, Oncology R&D, **AstraZeneca**
Maud Kamal, Scientific Manager, **Insitut Curie**
Thomas Thoma, Head of Clinical Trials Supply, **Teva Europe**
Joerg Mahlich, Head Health Economics and Outcomes Research, **Janssen**
Janet Valentine, Director Clinical Practice Research Datalink, **MHRA**
Matt Cooper, Business Development and Research Director, **NIHR**
Brenda Hann, Director, Clinical Trials Operations, **Stanford Medicine**
Aji Barot, Co-Lead, **PhUSE Blockchain group**
Matthieu Schapranow, Group Leader & Scientific Manager Digital Health Innovations, **Hasso Plattner Institute**
Tanja Ouimet, Head of Clinical Operations**, Pharmaleads**
Kate O'Brien, Former Clinical Research Nurse
Amrit Takhar, GP Partner and Clinical Lead, **Wansford surgery – NHS**
Li-Sophie Rathje, Scientific Business Development Manager, **NextCell Pharma**
Sue Pavitt, Professor of Translational & Applied Health Research, **University of Leeds**
Christian Ohmann, Chair of the Network Committee, **European Clinical Research Infrastructure Network**
Tony Whetton, Professor of Cancer Cell Biology, **University of Manchester**
Emma Gray, Head of Clinical Trials, **MS Society**
Rana Musa al-ali "Malkawi", Head of Clinical Studies, **Jordan FDA**
Begoña Nafría Escalera, Patient Engagement Lead, **Hospital Sant Joan de Déu**
Céline Adessi, Senior Director, Group Head, Oncology, Clinical Safety Science, **Roche**
Simon Wandel, Associate Director Statistical Methodologist, **Novartis**
Miroslava Prades-Ogorelkova, Advisor at **FindMeCure Ltd**., Independent Expert – Evaluator**, European Commission**
Philip Pallmann, Deputy Director Research Design, **Cardiff University**
Mishal Patel, Senior Director & Head of Health Informatics, **AstraZeneca**
Sybille Eibert, Associate Director Transparency and Disclosure, **Teva**
Maya Zlatanova, Co-Founder and CEO, **FindMeCure**
Eamonn O'Brien, Former NHS Senior manager, Patient Involvement Advisor
Mary Lynne Van Poelgeest-Pomfret, Vice Chair, **European Forum for Good Clinical Practice (EFGCP)**

Nicola Orlandi, Head of Data Privacy Business Policies, **Novartis**
Esteban Pombo-Villar, CEO, **TargImmune**
Susan Beatty, Clinical Operations Manager, **MHRA/CPRD**
Sophie Breeze, Clinical Trials Development Manager, **MHRA/CPRD**
Letizia Polito, Senior Data Scientist, Roche, Product Development, Personalized Health Care, **Roche**
Yvonne Brady, CEO & Founder of **EVB Sport** and Vice Chair of **Engineers Ireland Biomedical Division**
Anne Zuse, Head of Clinical Project Management**, SAKK**
Shantanu Karkare, Project Leader, **Teva**
Theophilos Tzaridis, Physician Scientist**, University Hospital Bonn**
Niels Grabe, Scientific Director, **National Center for Tumor Dsieases (NCT) Heidelberg**
Clare Relton, Senior Lecturer in Clinical Trials, **Queen Mary University of London**

<table>
<tr><th colspan="3">Day 1 - Tuesday 15th October</th></tr>
<tr><td>07:00</td><td colspan="2">Registration opens</td></tr>
<tr><td>08:30</td><td colspan="2">Conference doors open</td></tr>
<tr><td></td><td colspan="2">Clinical Trials keynotes – Operationalising Clinical Trials
ROOM: OSAKA/SAMARKAND</td></tr>
<tr><td>09:00</td><td colspan="2">Welcome from Terrapinn</td></tr>
<tr><td></td><td colspan="2">Chair’s opening remarks
Andy Lee, Head of Global Clinical Trial Operations, MSD</td></tr>
<tr><td>09:05</td><td colspan="2">Disruptive innovation for exquisite clinical trial performance and output
• Operational delivery for Keytruda in multiple indications
• Building quality into operational delivery
• Innovative ways to perform high quality site monitoring
Andy Lee, Head of Global Clinical Trial Operations, MSD (CONFIRMED)</td></tr>
<tr><td>09:25</td><td colspan="2">Case Study: working with collaborators in combination studies – CIT and beyond
• Looking at combination studies – CIT and beyond
• Working with collaborators in order to optimize performance
• Highlighting the key factors in making all collaborations successful
Denise Steckel, Head, Clinical Collaborations Management, Genentech (CONFIRMED)</td></tr>
<tr><td>09:45</td><td colspan="2">Panel discussion: the key challenges of biologics clinical trials
• Regulatory hurdles
• Working with different stakeholders
• Supply chain challenges
Moderator: Andy Lee, Head of Global Clinical Trial Operations, MSD
Brenda Hann, Director, Clinical Trials Operations, Stanford Medicine (CONFIRMED)
Rana Musa al-ali "Malkawi", Head of Clinical Studies, Jordan FDA (CONFIRMED)
Denise Steckel, Head, Clinical Collaborations Management, Genentech (CONFIRMED)</td></tr>
<tr><td>10:30</td><td colspan="2">Networking break</td></tr>
<tr><td>11:20</td><td colspan="2">Roundtable discussion session
ROOM: OSAKA/SAMARKAND</td></tr>
<tr><td></td><td>TABLE 1
End to end forecasting clinical trials supply chain

Thomas Thoma, Head of Clinical Trials Supply, Teva Europe (CONFIRMED)</td><td>TABLE 2
Patient engagement

Matt Cooper, Business Development and Research Director, NIHR (CONFIRMED)</td></tr>
<tr><td></td><td>TABLE 3
Remote clinical trials

Maya Zlatanova, Co-Founder and CEO, FindMeCure (CONFIRMED)</td><td>TABLE 4
Increasing research awareness to aid recruitment and retention

Kate O’Brien, Former Clinical Research Nurse (CONFIRMED)
Eamonn O’Brien, Former NHS Senior manager, Patient Involvement Advisor (CONFIRMED)</td></tr>
<tr><td>12:35</td><td colspan="2">Networking lunch</td></tr>
<tr><td>13:20</td><td colspan="2">ROOM: MEXICO
Workshop: What are the opportunities of undertaking commercial trials in primary care?
• How to tap into primary care populations at scale for commercial research?
• Current Opportunity as practices work together in Primary care networks
• Patient continuity and engagement – research nearer to home
• Access to detailed medical databases – searches undertaken by local team
• Challenges- Suitable staff and training at undertaking commercial trials
• Learn from successful existing practices undertaking commercial research with dedicated teams
Amrit Takhar, GP Partner and Clinical Lead, Wansford surgery – NHS (CONFIRMED)</td></tr>
<tr><td></td><td>Track 1
Precision and Molecular Profiling
Identifying Biomarkers
ROOM: HONG KONG</td><td>Track 2
Partnering with Sponsors, Sites and CROs
ROOM: MEXICO</td></tr>
</table>

	Chair: Andy Lee, Head of Global Clinical Trial Operations, **MSD** (CONFIRMED)	**Chair: Faidra van der Wal,** Associate Director Global Clinical Development Operations Trial Lead, **Janssen Pharmaceutical**
14:10	**Precision medicine & bio-markers** • Adaptation of biomarkers in clinical trials • How precision medicine blended in clinical trials • Decentralized trials | vrtual clinical trials growth • User engagement & growing expectations **Raj Pallapothu,** mHealth Global Lead - Business Operations, **Bayer** (CONFIRMED)	**Strategic partnering with CROs** • Reasons why we outsource • Modes of outsourcing • Strategic Partnership- ground rules **Faidra van der Wal,** Associate Director Global Clinical Development Operations Trial Lead, **Janssen Pharmaceutical** (CONFIRMED)
14:30	**Precision Medicine (PM) challenges and opportunities** • Molecular profiling programs establish the molecular profile of patients' tumors with the aim to guide therapy based on identified molecular alterations • PM trials use treatment algorithms to assign patients to specific targeted therapies based on tumor molecular alterations. • Clinical evidence-based criteria to prioritise genomic alterations to select patients for targeted therapies are key **Maud Kamal,** Scientific Manager**, Insitut Curie** (CONFIRMED)	**Building relationships with clinical research sites** • Working together during all phases of the study • Identify the key stakeholders • Streamline communication to meet study goals **Brenda Hann,** Director, Clinical Trials Operations, **Stanford Medicine** (CONFIRMED)
14:50	**Protein biomarkers for precision medicine: Development of a large-scale integrated platform for clinical proteomics and drug target discovery** • Precision Medicine • Biomarkers for precision medicine: the issues and requirement • Proteomic Biomarkers and their development: industrialising proteomics • Ovarian cancer risk biomarkers and other examples **Tony Whetton,** Professor of Cancer Cell Biology, **University of Manchester** (CONFIRMED)	**Panel discussion: Site selection and feasibility challenges** • Communication and relationships between Sites, CROs, and Sponsors • Looking at countries and patient populations • Feasibility methodologies • Future possibilities **Moderator: Eamonn O'Brien,** Former NHS Senior manager, Patient Involvement Advisor(CONFIRMED) **Kate O'Brien,** Former Clinical Research Nurse (CONFIRMED) **Amrit Takhar,** GP Partner and Clinical Lead, **Wansford surgery – NHS** (CONFIRMED) **Brenda Hann,** Director, Clinical Trials Operations, **Stanford Medicine** (CONFIRMED) **Shantanu Karkare,** Project Leader, **Teva** (CONFIRMED)
15:10	**Biomarker search for glioblastoma progression analysis** • EVs from GB cells show a distinct profile of surface proteins and RNA signature. • A combination of EV-associated biomarkers and cell-free RNA can be utilised for detection of tumour progression in GB patients **Theophilos Tzaridis,** Physician Scientist, **University Hospital Bonn** (CONFIRMED)	
15:30	**Afternoon refreshments**	
	Complex Clinical Trial Designs **ROOM: RIO**	
	Chair: Andy Lee, Head of Global Clinical Trial Operations, **MSD**	
16:30	**Adaptive trial designs: Delivering the unicorn of clinical trials in the UK** • Translate insight, experience and best practice gained from analysing the delivery of trials using an adaptive model in the UK into practical solutions for implementation locally • Recognise the challenges in the delivery of trials using an adaptive model • Identify where the best opportunities lie for introducing or broadening the use of clinical trials using an adaptive model **Matt Cooper,** Business Development and Research Director, **NIHR** (CONFIRMED)	
16:50	**Clinical trial designs aiming at evaluating precision medicine in oncology**	

	• Some targeted therapies and immunotherapies have been demonstrated to be very active in molecularly-selected subgroups of patients with the same cancer type • Some recent drugs have been shown to be active all cancer patients independent of tumor type, provided the molecular aberration is present • New clinical trial designs have been developed in order to evaluate the value of precision medicine in oncology **Christophe Le Tourneau**, Professor of Oncology, **Insitut Curie** (CONFIRMED)
17:10	**Platform studies in early clinical development** • Master Protocols - Basket, Umbrella & Platform Trials • Key considerations/recommendations • Examples Within Early-Phase Oncology **Sharon Barton,** Director, Biometrics Team Leader, Oncology R&D, **AstraZeneca** (CONFIRMED)
17:30	**Adaptive clinical trials in MS** • MS community initiative to establish adaptive trial • Practicalities of setting up platform trials • Methodological challenges in MS trial design • Patient and ethical perspective **Sue Pavitt,** Professor of Translational & Applied Health Research, **University of Leeds** (CONFIRMED) **Emma Gray,** Head of Clinical Trials, **MS Society** (CONFIRMED)
18:00	Chair's end of day 1 remarks
18:10	**Offsite drinks reception**

Day 2 – Wednesday 16th October		
08:00	Registration opens	
09:00	Conference doors open	
	Track 1 **Innovation in Clinical Trials – Disruptive Technologies** **ROOM: OSAKA/SAMARKAND**	
09:00	**Day 2 opening remarks** **Chair: Maya Zlatanova,** Co-Founder and CEO, **FindMeCure**	
09:05	**The future of clinical trials – how to make it work?** • Exemplifying of how an agile approach is being used in pharma to support digital transformation • Analysing this customer-centric approach, which can have real impact on the way we address clinical research • Presenting concrete examples on how we apply design thinking to (digital) innovation in pharma • How to set yourself up for innovation **Alain Bindels,** Head of Innovation Facilitation, **Roche** (CONFIRMED)	
09:30	**Panel discussion: what's slowing down uptake of technology in clinical trials?** • Understanding the necessity for pharma to adopt AI • The challenges of implementing new technologies • Which pharma companies are ahead? **Moderator: Maya Zlatanova,** Co-Founder and CEO, **FindMeCure** **Alain Bindels,** Head of Innovation Facilitation, **Roche** (CONFIRMED) **Matthieu Schapranow,** Group Leader & Scientific Manager Digital Health Innovations, **Hasso Plattner Institute** (CONFIRMED) **Raj Pallapothu,** mHealth Global Lead - Business Operations, **Bayer** (CONFIRMED)	
10:20	**Networking break**	
	Track 1 **Data and Analytics** **ROOM: HONG KONG**	**Track 2** **Innovation in Clinical Trials** **ROOM: MEXICO**
	Chair: Simon Wandel, Associate Director Statistical Methodologist, **Novartis**	**Chair: Maya Zlatanova,** Co-Founder and CEO, **FindMeCure**
11:25	**Implications of the ICH E9 estimand addendum on how we develop, run, and analyse clinical trials** • How will the addendum change clinical trials? • Experience from real pharmaceutical clinical trial examples incl. health authority feedback. • Are we pushing boundaries thanks to the addendum? **Kaspar Rufibach,** Principal Statistical Scientist, **Roche** (CONFIRMED)	**Risk-adjusted planning for clinical trial process optimization** • Clinical trials are expensive and risky business expenditures • Accurate planning of clinical trials is difficult given the number and variety of uncertainties and the undeterministic nature of the trials • Mining data from historical clinical trials to identify the risk factors and their impact on the variances of durations and costs can be used to define risk-adjusted planning for future trials • Actionable measures can also be identified and simulated on reduction of time and costs for more efficient planning and execution of clinical trials **Kefeng (Kevin) Hua,** Senior Manager, AI/Machine Learning Development, **Bayer** (CONFIRMED)
11:50	**Leveraging adult data for clinical trials in children: concept and application** • When is it appropriate to leverage adult data for trials in children • How does the regulatory landscape look like? • Application: statistical and operation aspects **Simon Wandel,** Associate Director Statistical Methodologist, **Novartis** (CONFIRMED)	**Leverage SOPHiA's expertise to streamline drug development** • SOPHiA for Clinical Trials accelerates the development of new therapies by leveraging our expertise acquired throughout the years in both Genomics and Radiomics and the knowledge of our growing global community • SOPHiA Trial Detect™ offers innovative genomics and radiomics applications to stratify patients and identify good and poor responders

		• SOPHiACDx™empowers pharma and biotech companies to develop and deploy precise companion diagnostics solutions **Sarah Berger**, Sales and Business Development Manager, **Sophia Genetics** (CONFIRMED)
12:15	**Federated EHR platforms - innovation in improving clinical trials: overview, results and outlook** • Setting the scene - RWD the awakening giant • Deployment towards a scalable and sustainable eco system of EHR driven services • The new federated EHR technology approach – the case of the InSite hospital network in Europe **Mats Sundgren,** Director Health Informatics, **AstraZeneca** (CONFIRMED)	**How will AI affect the patient journey of the future?** • Learn together how we will be affected by latest technology trends, such as digital health and artificial intelligence • How will we prevent, diagnose, and treat complex diseases, such as cancer, in the future? • Oncology case study: the patient journey and benefits and limitations of digital health solutions • Learn about innovative digital health tools for participation of citizens as an informed partner in the healthcare system **Matthieu Schapranow,** Group Leader & Scientific Manager Digital Health Innovations, **Hasso Plattner Institute** (CONFIRMED)
12:40	**Patients data in clinical trials. Data Privacy implications for the future of research** • Legal Grounds for data collection and implications for the organizations • Sustainability for further use of data • Need for a governance **Nicola Orlandi,** Head of Data Privacy Business Policies, **Novartis** (CONFIRMED)	**How blockchain can help design and control development of health-oriented AI algorithms** • Core functionalities of blockchain applied to clinical trials • Impacts and implications **Mehdi Benchoufi,** Assistant Professor Centre d'Epidémiologie Clinique, APHP**, Université Paris Descartes-Sorbonne Paris Cité** (CONFIRMED)
13:05	**Networking lunch**	
13:15	**ROOM: MEXICO** **WORKSHOP: How can I use real world data in clinical research? – A beginner's guide** • Are you interested in using real world data but are not sure how you can apply this in delivering your clinical research? • The workshop offers a practical guide, tips and examples of how electronic patient records can be used in different ways to answer clinical research needs **Janet Valentine,** Director Clinical Practice Research Datalink, **MHRA** **Susan Beatty,** Clinical Operations Manager, **MHRA/CPRD** **Sophie Breeze,** Clinical Trials Development Manager, **MHRA/CPRD**	
	Data and Analytics **ROOM: HONG KONG**	**Patient Recruitment and Retention** **ROOM: MEXICO**
	Chair: Simon Wandel, Associate Director Statistical Methodologist, **Novartis**	**Chair: Miroslava Prades-Ogorelkova,** Advisor at **FindMeCure Ltd**., Independent Expert – Evaluator**, European Commission**
14:35	**Game of Data Thrones - is winter coming?** • We have been witnessing over the last decade the emergence of new data types and trends, each of them bringing claims of revolutionizing how we use clinical data, report it and leverage it • Despite that, the way we submit data to health authorities has only marginally changed. But we keep hearing that change is coming • So, Biometrics, Real Word Evidence, Big Data, Data Science, which one will seat on the Data Throne? **Olivier Leconte,** Head of Statistical Programming & Analysis, **Johnson & Johnson** (CONFIRMED)	**Using routine electronic patient records to recruit patients and manage the execution of more cost-effective clinical trials** • The potential for real world data (RWD) to transform the efficiency of clinical studies is much talked about, but yet to be fully realised • Electronic Health Records (EHR) are an under-used resource to support clinical studies and evaluate clinical effectiveness in real world populations • EHR can be used in novel ways from optimising study design, determining protocol feasibility, identifying investigator sites, pre-screening eligible patients, managing a study based on real-time data capture from EHR, to long-term follow up

<table>
<tr><td>14:55</td><td>Data driven decision making using AI and machine learning
How can we use data speed up trials and better understand diseases?
Deep learning and AI images – analysing biomarkers to identify patients earlier
Mats Sundgren, Director Health Informatics, AstraZeneca on behalf of Mishal Patel, Senior Director & Head of Health Informatics, AstraZeneca</td><td rowspan="3">Hear how these techniques can be applied to reduce protocol amendments, achieve more targeted patient recruitment, avoid duplication of effort in study execution, streamline site monitoring and reduce bias through patient-independent follow-up
Janet Valentine, Director Clinical Practice Research Datalink, MHRA (CONFIRMED)

15:00 Effective patient recruitment strategies using internet and social media
Unlocking social media platforms as pre-screening tool to save time during patient recruitment
Saving money on lengthy recruitment processes through cost effective digital advertising strategies
Engaging the extensive network of patient advocacy groups based online by using their social media platforms to advertise your trial
Tanja Ouimet, Head of Clinical Operations, Pharmaleads (CONFIRMED)

15:25 How to assess whether your clinical trial is attractive to patients
Maya Zlatanova, Co-Founder and CEO, FindMeCure (CONFIRMED)</td></tr>
<tr><td>15:15</td><td>Towards objective clinical trials: decentralizing cancer pathology
Building a global decentralised resource for efficient pathology analysis
Blockchain as the solution for the challenge of large-scale diagnostic consensus making
Building a portfolio of image-based data and machine-learning algorithms using decentralised experts
Niels Grabe, Scientist, National Center for Tumor Diseases & University Hospital (CONFIRMED)</td></tr>
<tr><td>15:35</td><td>Enabling PHC at Roche through F.A.I.R. and shared medical data
Culture and mindset challenges
Processes, decision making, adherence to principles across R&D
Technology, infrastructural consequences
Benjamin Szilagyi, Global Head Medical Data & Information Solutions, Roche (CONFIRMED)</td></tr>
<tr><td>15:55</td><td colspan="2">Afternoon refreshments</td></tr>
<tr><td>16:00</td><td colspan="2">ROOM: MEXICO
WORKSHOP: Cross-industry collaboration evaluating how Blockchain can transform the pharmaceutical and healthcare industry, part of emerging trends & technology PhUSE workgroup
Describing the landscape in the pharma and healthcare settings
Exploring the areas where Blockchain could be used
Presenting two detailed use cases (a. Drug Supply Chain using Smart Contracts; b. Patient Data Access/Transparency)
Demo several functionalities around Patient ID, eConsent and Data Sharing
Adama Ibrahim, Associate Director, Global Clinical Operations, Biogen (CONFIRMED)
Aji Barot, VP Pharma, Medsafe (CONFIRMED)</td></tr>
<tr><td></td><td colspan="2">Track 1
Patient Engagement
ROOM: RIO</td></tr>
<tr><td></td><td colspan="2">Chair: Miroslava Prades-Ogorelkova, Advisor, FindMeCure, Independent Expert – Evaluator, European Commission</td></tr>
<tr><td>17:00</td><td colspan="2">Enabling patient centricity and remote trials in clinical development through at home sample collection
Traditional approaches for measurement of drug exposure in clinical trials involves having the patient travel to a clinical site for collection of venous blood
This puts a burden on the patient while also limiting the opportunities for assessment of drug exposure or other measurements to these clinical visits.
The ability to collect samples at home would provide a more patient centric approach, enabling remote trials
At home collection would provide benefit for 1) disease areas associated with episodic events (e.g. asthma, migraine, etc.), 2) long half-life compounds, 3) assessment of adherence, 4) developing understanding of adherence patterns for new dosing regimens (i.e. QWeekly, QMonthly), and 5) more frequent assessment of biomarkers of efficacy and toxicity
This talk will share results from recent clinical pilot studies employing at home sampling technologies</td></tr>
</table>

	Kevin Bateman, Scientific Associate Vice President, **MSD** (CONFIRMED)
17:20	**Informing decision-making in R&D with patient experience data** **Mareile Hark**, Director of Strategy and Operations, **Novartis** (CONFIRMED
17:40	**Shared decision making and patient satisfaction** • How is patient involvement in the treatment decision related to patient satisfaction? • What is the role of biologics in achieving patient satisfaction? • Do patients from different cultures have different views on patient involvement? **Jörg Mahlich,** Head of Health Economics and Outcomes Research**, Janssen** (CONFIRMED)
18:00	**Chair's closing remarks**
18:05	**On site drinks reception**

Day 3 – Thursday 17th October	
08:45	Conference doors open
	Track 1 **Data Sharing and Industry Collaboration** **ROOM: HONG KONG**
09:05	**Day 3 opening remarks** **Chair: Olivier Leconte,** Head of Statistical Programming & Analysis, **Johnson & Johnson**
09:10	**Introduction to new channels of clinical trial transparency** • Overview of established channels, e.g., registries, EMA Policy 0070, sharing of patient-level data • Health Canada regulations on public release of clinical information • Disclosure and layperson summaries according to EU Clinical Trials Regulation (No 536/2014) **Sybille Eibert,** Associate Director Transparency and Disclosure, **Teva** (CNFIRMED)
09:35	**Panel Discussion: the value of sharing clinical trial data and challenges** • Maximising the value of clinical data through data sharing • The role of clinical trial registries for trial registration, results posting, sharing of individual participant data and lay summaries • Findability, accessibility, transparency, privacy and risk • The responsibilities of regulators, sponsors, researchers, IECs/IRBs, authors, editors, and publishers Moderator: **Olivier Leconte,** Head of Statistical Programming & Analysis, **Johnson & Johnson** (CONFIRMED) **Christian Ohmann,** Chair of the Network Committee, **European Clinical Research Infrastructure Network** (CONFIRMED) **Benjamin Szilagyi,** Global Head Medical Data & Information Solutions, **Roche** (CONFIRMED) **Nicola Orlandi,** Head of Data Privacy Business Policies, **Novartis** (CONFIRMED)
10:25	**Networking break**
	Real World Evidence **ROOM: HONG KONG**
	Chair: Yvonne Brady, CEO & Founder of **EVB Sport** and Vice Chair of **Engineers Ireland Biomedical Division** (CONFIRMED)
11:30	**Generating Real World Evidence to advance scientific and medical knowledge** • Using Electronic Health Record (EHR) to describe real world treatment pattern • How clinical practice keep pace with the rapidly changing treatment landscape • How RWD can help addressing evidence gap **Letizia Polito,** Senior Data Scientist, Roche, Product Development, Personalized Health Care, **Roche** (CONFIRMED)
11:55	**Innovation in trial designs - the efficient production of real-world evidence** • Innovative randomised controlled trials designs use cohorts and routine health data sources to recruit and obtain outcomes • How innovative designs help provide real world evidence efficiently • CONSORT Reporting guidelines for these designs soon to be published **Clare Relton,** Senior Lecturer in Clinical Trials, **Queen Mary University of London** (CONFIRMED)
12:20	**Real world evidence and the patient perspective** **Mary Lynne Van Poelgeest-Pomfret,** Vice Chair, **European Forum for Good Clinical Practice (EFGCP)** (CONFIRMED)
12:45	**Networking lunch**
	Early Clinical Development **ROOM: HONG KONG**
	Chair: Esteban Pombo-Villar, CEO, **TargImmune (**CONFIRMED)
13:45	**Conducting clinical trials as a small biotech company, an example from Sweden** • Importance of having University and hospital with support functions to attract companies • Understanding the challenges of a small company and sticking to the time plan **Li-Sophie Rathje**, Scientific Business Development Manager, **NextCell Pharma** (CONFIRMED)
14:05	**Adaptive designs in early development - why use them, how to run them and how to report them** • When are adaptive designs applicable • What adaptive designs can (and cannot) accomplish • What the practical implications of using an adaptive design • How should the results from an adaptive design be interpreted and reported **Philip Pallmann,** Deputy Director Research Design, **Cardiff University** (CONFIRMED)

14:25	**Benefit-risk evaluation of immunotherapies today: a discussion of EMA/FDA Guidance for Industry** • Modernizing the reporting, collection, assessment of adverse events • Patient reporting outcome • Benefit-risk balance evaluation **Céline Adessi,** Senior Director, Group Head, Oncology, Clinical Safety Science, **Roche** (CONFIRMED)
14:45	**Development of phase-1 oncology trials** • Oncology Studies conducted within the network of SAKK (Swiss Group for Clinical Cancer Research) • SAKK in the role as sponsor for academic, clinical patient-oriented cancer research • Benefits and challenges of a non-profit organization **Anne Zuse,** Head of Clinical Project Management**, SAKK** (CONFIRMED)
15:05	**Chair's closing remarks**
15:10	**End of conference – see you next year!**