

Partnerships in Clinical Trials Europe

27-29 November 2018

CCIB

Barcelona, Spain

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STREAM 1
Partnerships & Collaboration

STREAM 2
Patients as Partners

STREAM 3
Mobile Health & Wearables

STREAM 4
Governance, Quality, Oversight, Risk Management & RBM

STREAM 5
Investigator & Industry Partnerships

STREAM 6
Partnership Management & Emerging Trends

STREAM 7
Patient Recruitment, Retention & Engagement

STREAM 8
Real World Evidence, Paediatrics, Trial Design & Big Data

STREAM 9
Regulatory Updates

STREAM 10
Artificial Intelligence for Clinical Trials

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	Tuesday 27th November					
	OPENING PLENARY					
14:00	Opening remarks from the Chairperson Jeannett Dimsits, Senior Director, Trial Management Anchor, NovoNordisk, Denmark					
14:10	Examining the growing role of CROs as facilitators in the convergence of clinical research and clinical care Professor Kenneth Getz, Director and Associate Professor, CSDD, Tufts University School of Medicine, USA					
14:55	Business and Financial analysis and impact of mergers and acquisition of the CRO's on the Pharma Industry Neal McCarthy, Managing Director, Fairmount Partners, USA					
15:40	The future of Healthcare- Mobile Health, Digital, AI and Innovation with regards to clinical trials and healthcare- relate to other industries Inma Martinez, Venture Partner, Data Sciences & Product Innovation, Deep Science Ventures, UK					
16:25	PANEL: The Future of Clinical Trials - New partnerships, new innovations and new processes MODERATOR: Professor Kenneth Getz, Director and Associate Professor, CSDD, Tufts University School of Medicine, USA Almenia Garvey, Director of Site Alliances, ICON Clinical Research Services, France Laura Galuchie, TransCelerate Oversight Committee Member and Program Lead, MSD Amanda L. Goltz, Vice President, Digital, Biocompatibles Inc., a BTG International group company, USA Janis A. Little, Vice President, Global R&D Quality, Allergan, USA Alastair MacDonald, SVP Real World & Late Phase Client Engagement, Syneos Health, USA					
17:30	Welcome Drinks Reception in the Exhibition Hall sponsored by Covance					
	Wednesday 28th November					
	MORNING PLENARY					EARLY CLINICAL DEVELOPMENT
08:50	Opening remarks from the Chairperson Bruce Hellman, CEO, Co-Founder, UMotif, UK					(9:00) Chairpersons opening remarks Anna Matranga, Strategic Sourcing R&D, Consultant, AMC Alliances and Consulting, France
09:00	PATIENT'S AND DOCTORS JOINT STORY: Doctor and Patient working together to form OurBrainBank Jessica Morris, Founder and Chair, OurBrainBank, SVP and Partner, FleishmanHillard, USA Dr Alexis Demopoulos, Director, Neuro-oncology, Northwell Health System, Manhasset, USA					(9:10) Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products Dr Maria Beatrice Panico, Medical Assessor, Clinical Trials Unit, Medicines and Healthcare Products Regulatory Agency, UK
09:40	PANEL: How to manage different goals of Sponsor, CRO, Patients, Regulators and Investigators MODERATOR: Dr. David Bull, English Doctor, Television Host, Entrepreneur, David Bull, UK Lewis Cameron, Head of Global Clinical Development, Covance, UK Paul MacDonald, Director, Solutions Consulting EMEA, Medidata, USA Richard Stephens, Chairman, National Cancer Research Institute's Consumer Forum, UK Nicholas Brooke, Founder and Executive Director, PFMD (Patient Focused Medicines Development) and The Synergist, Belgium Jane Winter, SVP Strategic Alliance Management, Syneos Health, UK Dr Richard FitzGerald, Consultant Physician and Director, Clinical Research Unit, Royal Liverpool University Hospital, UK					(9:40) FiH Industry Perspective: First experiences with the new First in Human guideline Henrik Forsman, Director Scientific Project Management, AstraZeneca, Sweden
						(10:10) Role of PK/PD Modeling in supporting design of FIH-trials of high risk molecules Youssef Hijazi, Expert Clinical Pharmacokinetics, Sanofi-Aventis, Germany
10:40	Morning coffee and networking					
	STREAM 1 Partnerships & Collaboration	STREAM 2: Patients as Partners	STREAM 3: Mobile Health & Wearables	STREAM 4: Governance, Quality, Oversight, Risk Management & RBM	STREAM 5: Investigator & Industry Partnerships	EARLY CLINICAL DEVELOPMENT
11:25	Opening remarks from the Chairperson Estrella García, Director Global Clinical Operations, R&D, Almirall, Spain	Opening remarks from the Chairperson Nicholas Brooke, Chief Executive, PFMD (Patient Focused Medicines Development) and The Synergist, Belgium	Opening remarks from the Chairperson Nicole Powell, Director Business Development, SDC, USA	Opening remarks from the Chairperson Paul Bouten, Managing Director, PharmCMed, The Netherlands	Opening remarks from the Chairperson Dr Vivienne van de Walle, Director PT&R – Clinical Research Site, VivMedical - Life Science Consulting, The Netherlands	Opening remarks from the Chairperson Anna Matranga, Strategic Sourcing R&D, Consultant, AMC Alliances and Consulting, France
11:30	JOINT PRESENTATION: Vendor selection for sponsors – how to utilise the Request for Proposal (RFP) data to achieve the best partner Lara Silverstein, Operations Director, Avillion, UK Kieran Canisius, Co-founder, Seuss Consulting BV, The Netherlands	PATIENT'S STORY: 'Partners in research': Why patients should be part of the entire research process from bench to clinic - Insights from my personal journey through Parkinson's research Benjamin Stecher, Education Consultant, Writer and Parkinson's Disease Patient Advocate, Canada	CASE STUDIES: "Ready Participant One": The patient-centric Clinical Trial of the future Bruce Hellman, CEO, Co-Founder, UMotif, UK	CASE STUDY: Exploring the transformation in clinical trials using the Risk Based Monitoring Isabelle Naëije, Associate Global Trial Director, GDO Trial Management Oncology, Novartis Pharma AG, Switzerland	CASE STUDY: Best Practices for Site Identification and Selection Christian Milliet, Global Head Clinical Operations, Vifor Intl Ltd, Switzerland	A regulatory perspective on blood pressure assessments in phase I and II trials: Ambulatory blood pressure monitoring and other approaches Colette Strnadova, Senior Scientific Advisor, Health Canada, Canada
12:00	CASE STUDY: Discover – North West London data driving real world evidence through collaboration Amanda Lucas, Programme Director, Imperial College Health Partners, UK	CASE STUDY: The journey of Santhera Pharmaceuticals to effectively engage with patient groups in clinical trials Vanessa Dos Reis Ferreira, Head of Patient Advocacy Europe, Santhera, Switzerland	CASE STUDY: First of Its Kind Smart Trial and Engagement Program Implemented on a phase II clinical trial with Alzheimer Patients Dr Anna Bink, iSTEP study implementation lead, Janssen, Belgium	CASE STUDY: Operational risk management- A systematic approach to identifying risk in clinical trials upfront Dr. Diana Sims-Silbermann, Senior Trial Manager, Early Development and Clinical Pharmacology, Janssen-Cilag GmbH, Johnson & Johnson, Germany	CASE STUDY: Engagement with sites Jeannett Dimsits, Senior Director, Trial Management Anchor, NovoNordisk, Denmark Kate O'Brien, Senior Research Nurse, Freelance Site Consultant, UK	CV vital signs and safety – In addition to blood pressure do we need to consider the heart rate as well in drug development? Christer Gottfridsson, ECG Centre Cardiologist, AstraZeneca, Sweden

	Wednesday 28th November					
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12:30	Title TBC David MacMurchy , Executive Vice President, Europe Asia Pacific & Africa, PRA Health Sciences, UK Elvira Klissourska , Senior Director, Head Clinical Operations, Clinical Development & Medical Affairs, Fresenius Kabi SwissBioSim GmbH, Switzerland	Direct engagements with Patients – where are the limits? Mike Jagielski , CEO, KCR, Germany	CASE STUDY: Use of technology to access isolated populations to improve lifelong health and education Véronique Inés Thouvenot , Co-Founder CCO & Scientific Director, Millennia2025 Women and Innovation Foundation, Switzerland	Beyond Risk-based Monitoring: Employing Risk-based Management Christopher Allan , Principal Solutions Consultant, Trial Oversight, ERT, USA	JOINT PRESENTATION: Clinical Trial Payment Software and success factors, lessons learned and results Greenphire; Joe Robbins , Director & Senior Manager, Global Clinical Pricing Head of Global Supplier Gov, Amgen	Current challenges in running early phase studies in patients rather than healthy volunteers Charlotte Chadwick , Head of Early Phase Unit and Pharmacy, MAC Clinical Research, UK
13:00	Lunch, Pain Clinic and Roundtable on Stress Management in the Patient Pavilion Zone in the Exhibition Hall					
14:30	CASE STUDY: Out-Tasking Lourdes López Bravo , Executive Director, Clinical Research Director Spain and Portugal, Global Clinical Trial Operations (GCTO), MSD, Spain	CASE STUDY: A rare disease in clinical trial: The Duchenne parent project Spain strategy Marisol Montolio del Olmo , Scientific Director, Duchenne Parent Project , adjunct Professor, University of Barcelona, Spain	CASE STUDY: Childhood Cancer Survivorship Passport: An integrated eHealth solution Professor Ruth Ladenstein , Senior Consultant in Paediatric Haematology–Oncology, OKIDS, Austria	CASE STUDY: RBM -key conditions in collaboration between Sponsor and CRO Marion Wolfs , Deputy Head Director Risk Management and Central Monitoring, TA lead oncology heme and ED/CP, Janssen, The Netherlands	CASE STUDY: What is it like to be an Investigator on a trial? Dr Richard FitzGerald , Consultant Physician and Director, Clinical Research Unit, Royal Liverpool University Hospital, UK	ECG-related cardiotoxicity in FIM/early phase studies Boaz Mendzelevski , President, Cardiac Safety Consultants
15:00	Partnership to Realize FDA Recent Guidance on Integration of EHR and EDC Data Gavin Nichols , Chief Information Officer & Executive Vice President, Technology, Bioclinica, UK	Making it easier for patients to learn about and participate in clinical trials: A practical approach to patient centricity Rosamund Round , Director, Patient Innovation Center, PAREXEL, UK	BYOD: A Game-Changer for Sponsors, Sites and Patients Chris Watson , Director of Product Strategy, ERT	Leveraging AI based platform and analytics for RBM, CM / RM, trial operations and improved outcomes Dr Krishnan Rajagopalan , Chief Growth Officer, Navitas Life Sciences, USA Dr Niranjana Rao , PhD FCP, Vice President, Clinical Development, Asana BioSciences, USA	Please go to Stream 1,2,3,4 or ECD	Using adaptive designs to streamline early clinical studies: case studies across a number of study designs Dr Graham Wood , Chief R&D Officer, Altasciences, Canada
15:30	Afternoon Break					
16:00	CASE STUDY: Managing Outsourcing Risk: The global and regional picture Edouard Masurel , Head of Third Party Resourcing (TPR) – Regions and LOCs, GlaxoSmithKline, UK	Delivering meaningful patient centricity in clinical trials: The patient organisation perspective Dr Chris Macdonald , Head of Research, Pancreatic Cancer UK, UK	CASE STUDY: Electronic eSource of data Jennifer Nielsen , Transcelerate eSource, Novo Nordisk A/S, Denmark (16:15) CASE STUDY: Digital Biomarkers – The Use of Digital Technology to Empower Clinical Trials Data Judith Kornfeld , Chief Business & Operations Officer, Oregon Health & Sciences University, USA	CASE STUDY: Quality Tolerance Limits – implementation in a large pharmaceutical company Morten Thorup Pedersen , Risk Based Monitoring Specialist, NovoNordisk, Denmark	The NCRI Consumer Forum - How patient partners can help Investigators and Industry Dr Richard Stephens , Chair of the National Cancer Research Institute's Consumer Forum, UK	The uses and abuses of Adaptive Clinical Trial Designs Martin Lunn , Clinical Pharmacologist, Specialist in Early Clinical Development and Visiting Senior Lecturer, King's College London, UK
16:30	PANEL: The evolution of outsourcing strategies: Managing change through M&A in stakeholders during outsourcing and strategic partnerships MODERATOR: Graham P Belgrave , Senior Vice President, European Operations, Advanced Clinica, UK Varun Grover , Clinical Contracts and Finance, Senior Associate, Gilead, UK Lan Bandara , Director, Clinical Outsourcing, Oncology Business Group, Eisai Limited Lidia Cappellina , Head of R&D Outsourcing Management, Chiesi Farmaceutici S.p.A, Italy	PANEL: Patient Engagement – discussing the value and has it actually made a difference to the Pharmaceutical companies? MODERATOR: Andrew Benson , Senior Director at Trial Trove, Citeline, UK Jennifer Preston , Patient and Public Involvement & Engagement Priority Lead, Dept. of Women's and Children's Health, Alder Hey Children's NHS Foundation Trust University of Liverpool, UK Russell Wheeler , Trustee, Leber's Hereditary Optic Neuropathy Society (LHON Society), UK Dr. Vanessa Spalding , Clinical Project Management Advisor, Neuroscience, Clinical Pharmacology, Eli Lilly and Company Limited, UK Mike Jagielski , CEO, KCR, Germany Almenia Garvey , Director of Site Alliances, ICON Clinical Research Services, France	PANEL: Wearables and sensors - Innovative ways to collect clinical data- what does it mean for patients and clinical trials? MODERATOR: Francesca Martinelli , Specialist in Quality of Life - Quality of Life Department, EORTC, Belgium Kai Langel , Director, Janssen Clinical Innovation (JCI), Janssen-Cilag GmbH, Johnson & Johnson, Belgium Melissa Menke , Founder and CEO, Access Afya., USA Pierre Peeters , Chief Operations Officer, Centre for Human Drug Research (CHDR), The Netherlands Emilio Vandelli , Managing Director, Arithmos (part of PM Holding), Italy	PANEL: Optimising the Sponsor-CRO partnership: Quality oversight in outsourced clinical trials MODERATOR: Paul Bouten , Managing Director, PharmCMed, The Netherlands Geoff Taylor , Director, Clinical Quality Assurance, Eisai Product Creation Systems, UK Dr Raphaela Mary , Director, Capability and Strategy, Central Clinical Planning & Solutions, Global Clinical Operations, Bristol-Myers Squibb, France Marion Wolfs , Deputy Head Director Risk Management and Central Monitoring, TA Lead Oncology Heme and ED/CP, Janssen, The Netherlands Jeana Nowick , Executive Director of Corporate Quality, Syneos Health Helen Whitelegg , Vice President, Clinical Project Management, IQVIA	PANEL DISCUSSION: Site budget in Clinical Trials – What is “fair market value”? Dr Diana Sims-Silbermann , Senior Trial Manager, Early Development and Clinical Pharmacology, Janssen-Cilag GmbH, Johnson & Johnson, Germany Philipp Badorrek , Head of Department, Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, Germany Dr Wolfgang Seibold , Clinical Operations, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany Dmitry Manuilov , Head of Clinical Development, MYR GmbH, Germany	PANEL DISCUSSION: Patient recruitment for special populations: paediatrics, geriatrics, and oncology MODERATOR: Javier Garcia-Corbacho , Head of Clinical Trials Unit of Clinic Institute of Haematological and Oncological Diseases (ICMHO), Early Phase Clinical Trials, Hospital Clinic, Spain Shaila Shabbir , Clinical Development Management, Respiratory Global Clinical Sciences & Delivery (GCSD), R&D Projects, GlaxoSmithKline, UK Dr Siru Virtanen , ECMC Programme Office, Research and Innovation Directorate, Cancer Research UK, UK
	CLOSING PLENARY					
17:30	Opening remarks from the Chairperson Dr Tamzin Blagbrough, Sourcing Consultant, Clinical Pharmacology Study Delivery Solutions, Eli Lilly and Company Limited, UK					
17:35	PCT Lifetime Achievement Award in					
17:40	Innovation and Technology – Exploring possibilities where humans and technology collide Mark Pollock, Explorer, Innovator and Collaboration Catalyst, Ireland					
18:30	Drinks Reception					

Thursday 29th November

	STREAM 6 Partnership Management & Emerging Trends	STREAM 7 Patient Recruitment, Retention & Engagement	STREAM 8 Real World Evidence, Paediatrics, Trial Design & Big Data	STREAM 9 Regulatory Updates	STREAM 10 Artificial Intelligence for Clinical Trials	EARLY CLINICAL DEVELOPMENT
08:50	Opening remarks from the Chairperson Julianne Hull , Chief Executive Officer, Wenstar, UK	Opening remarks from the Chairperson Andrew Benson , Senior Director at TrialTrove, Citeline, UK	Opening remarks from the Chairperson Anna Matranga , Strategic Sourcing R&D, Consultant, AMC Alliances and Consulting, France	Opening remarks from the Chairperson Nancy Meyerson Hess , Associate Partner, admedicum, Business for Patients GmbH & Co KG, Germany	Opening remarks from the Chairperson Aji Barot , Commercial Director, HealthUnlocked, UK	Opening remarks from the Chairperson Nigel Blackburn , Director of Drug Development, Cancer Research UK, UK
09:00	HEADLINE TALK: Trends in oncology and their implication for clinical research Thishi Surendranathan , Manager Health Advisory, KPMG Health and Life Sciences Advisory, UK	CASE STUDY: Paediatrics Trials – what are their experiences? Joana Claverol Torres , Coordinator of the Clinical Trials Unit, Sant Joan de Deu Hospital, Spain	CASE STUDY: Patient Reported Outcomes and beyond: A Self-Service setup Angelo Trotta , Connected Health Solutions & Operations, Janssen, Pharmaceutical Companies of Johnson & Johnson, Belgium	Stakeholder Feedback - Best practices to ensure you are ready for Clinical Trial Regulation Dr Carole Légaré MD , Director, Office of Clinical Trials, Health Canada	Crossing the Incurable Sea Jack Kreindler , Founder & Medical Director, CHHP - The Centre for Health & Human Performance Ltd., UK	Putting the patient first: Practically applying a patient centric approach to early phase study design Wolfgang Eglmeier , Head ZKS-UW/H, Centre for Clinical Studies, Witten/Herdecke University, Germany
09:30	CASE STUDY: Evolution and enhancement of a strategic partnership over 8 years Michael Carpenter , Strategic Partnering Lead, UCB, USA	Patient engagement – What is it and how do we make sure we are doing it right? Russell Wheeler , Trustee, Leber's Hereditary Optic Neuropathy Society (LHON Society), UK	The Role of Patient Reported Outcomes (PROs) and Quality of Life Measures in trials and clinical practice Professor Galina Velikova , Professor of Psycho-social and Medical Oncology, University of Leeds, UK	Strategies in preparation of the Clinical Trial Regulation Amer Alghabban , Vice President GxP Quality Assurance, Compliance Training, Karyopharm Therapeutics Inc., Switzerland	A Survey of Machine Learning Applications in Clinical Trials Faisal Khan , Executive Director, Advanced Analytics and Artificial Intelligence, AstraZeneca, USA	Facilitating collaboration between industry & academia in the discovery & development of new medicines: A Cancer Research UK Perspective Nigel Blackburn , Director of Drug Development, Cancer Research UK, UK
10:00	Explore how a patient-centric logistics approach can positively impact trial recruitment, retention and your clinical trial budget Sascha Sonnenberg , Vice President Cell & Gene Therapies and CTS Services, Marken, Germany	Jeff Lee , President eCOA and Patient Engagement, Bracket, UK	What can Big Data tell us about recent trends in Real World Study Design and post-marketing commitments in the EU and US? Dr. Alexandre Malouvier , Scientific Affairs Director, Real World Solutions, PRA Health Sciences, France	What Does Brexit Mitigation Look Like in Practice? Pete Young , Director, Quality Director, Catalent	Artificial Intelligence in Clinical Trials Automation Vitthal Gouri , Director, Clinical Solutions, ArisGlobal, UK	Increasing the value of your asset: Considerations for Phase I hybrid trials Amitava Ganguli , Medical Director, Medical & Scientific Affairs, Clinical Pharmacology Services, Covance
10:30	Morning coffee and networking					
11:20	The practical implementation of RBM by a Mid-Size Organization – What we have learned in 2 years Shunsuke Hagihara , Statistical Analysis Data Science, ONO Pharmaceutical Co.,Ltd, Japan	Laying the path for patient engagement Lorna Allen , PPI Co-ordinator, Cystic Fibrosis, UK	Engagement of young people across Europe to improve paediatric clinical trials Begonya Nafria Escalera , Patient Advocacy Manager in Research, Hospital Sant Joan de Déu, Spain Jennifer Preston , Patient and Public Involvement & Engagement Priority Lead, Dept. of Women's and Children's Health, Alder Hey Children's NHS Foundation Trust University of Liverpool, UK Sammy Ainsworth , Patient Research Ambassador	CASE STUDY: Sponsors responsibility for vendor oversight – impact from ICH E6R2 Guideline Geoff Taylor , Director, Clinical Quality Assurance, Eisai Product Creation Systems, UK	Using AI to generate and test novel hypotheses – increasing efficient and accuracy of clinical trial processes Kevin Hua , Senior Manager, AI Machine Learning, Bayer U.S., USA	CASE STUDY: NIMA – Advancing Science and Drug Development through Public – Private Collaborations Anja Hijzen , Associate Director, Clinical Scientist, Janssen, Pharmaceutical Companies of Johnson & Johnson, Belgium
11:50	The Eli Lilly and Covance clinical pharmacology partnership: 11 years and counting David Simpson , Executive Director, Clinical Pharmacology Services, Covance UK Dr Tamzin Blagbrough , Sourcing Consultant, Clinical Pharmacology Study Delivery Solutions, Eli Lilly and Company Limited, UK	CASE STUDY: Using primary care electronic medical records to identify study subjects in clinical trials of biomarkers Frank Sullivan , Director of Research, University of St Andrews, UK	Informed participation and patient empowerment: A patient-centred approach to give voice to the young patients and favour the paediatric research Mariangela Lupo , Networking Manager, TEDDY - European Network of Excellence for Paediatric Clinical Research, Italy	Emerging Markets in Global Clinical Trials MODERATOR: Nancy Meyerson-Hess , Associate Partner, admedicum Business for Patients GmbH & Co KG, Germany Adama Ibrahim , Senior Clinical Operations Lead, Biogen, UK Van Zyl Engelbrecht , Clinical Project Director, EU, UBC Michael Makanga , Executive Director, European & Developing Countries Clinical Trials Partnership (EDCTP)	Can we use machine learning to make clinical research more patient-centric? Jonathan Moshinsky , Head of Market Strategy, uMotif, UK	Challenges in early phase patient recruitment and ensuring representative populations Dr Javier García-Corbacho , Head of Clinical Trials Unit of Clinic Institute of Haematological and Oncological Diseases (ICMHO), Early Phase Clinical Trials, Hospital Clinic, Spain

Thursday 29th November

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12:20	FUTURE DEBATE: What single activity will change our industry the most by 2030? MODERATOR: Julianne Hull, Chief Executive Officer, Wenstar, UK Amanda Lucas , Programme Director, Imperial College Health Partners, UK Nancy C Caralla , Founding President, Executive Director, C Diff Foundation Chris Watson , Director of Product Strategy, ERT Srinivas Karri , Director Product Strategy, Oracle Health Sciences, UK	PANEL: What are the reasons and motivations for persons to participate in trials and how to achieve patient engagement? MODERATOR: Eamonn O'Brien, Independent Consultant, UK Ben Cromarty , North Yorkshire AIDS Action (NYAA), Medical Research Council Clinical Trials Unit, University College London Patient and Public Involvement Group, UK Kate O'Brien , Senior Research Nurse, Freelance Site Consultant, UK Dr Richard Stephens , Chair of the National Cancer Research Institute's Consumer Forum, UK Sammy Ainsworth , Patient Research Ambassador, UK Mathias Praus , World Courier, USA	PANEL: Now, next and future for clinical trial design? MODERATOR: Roland Rich, Operations Expert, CQA, Novartis, France Margi Sheth , Clinical Information Sharing Programme Manager, AstraZeneca UK Dmitry Manuilov , Head of Clinical Development, MYR GmbH, Germany Ursula Garczarek , Associate Director of Strategic Consulting, Cytel Matt Cooper , Business Development & Marketing Director, NIHR, UK	CTR: A catalyst for change Sebastian Payne , Director, Deloitte	PANEL: Achieving improved patient centricity and engagement with the use of AI – Opportunities and Limitations Xia Wang , Informatics Science Director, Advanced Analytics Centre, AstraZeneca, USA Faisal Khan , Executive Director, Advanced Analytics and Artificial Intelligence, AstraZeneca, USA Kevin Hua , Senior Manager AI/Machine Learning Development, Bayer Life Sciences iHub, USA	PANEL DISCUSSION: Outsourcing early clinical trials Nigel Blackburn , Director of Drug Development, Cancer Research UK, UK Anja Hijzen , Associate Director, Clinical Scientist, Janssen, Pharmaceutical Companies of Johnson & Johnson, Belgium Jaclyn Patterson , Senior Director, Early Dev. Clinical Trial Management, Regeneron, USA Shaila Shabbir , Clinical Development Manager, Respiratory Global Clinical Sciences & Delivery (GCSD), R&D Projects, GlaxoSmithKline, UK
13:00	Using technology to transform clinical trial performance Richard Young , VP Vault EDC, Veeva Systems, UK	Please go to Stream 6,8,9, 10 or ECD	Real World Data: Improving clinical trial design and patient recruitment Michelle Jones , Senior Director, Clinical Informatics, and Feasibility, Recruitment & Engagement (FRE), Covance Ben Quartley , Head of Feasibility, Recruitment, Engagement and m-Health, Covance	The Clinical Trial Regulation No 536/2014 in the context of Paediatric Research Dr Martine Dehlinger-Kremer , Vice President, Pediatric Development, Synteract		Preclinical development, Research Infrastructures and CRO partnership. Giovanni Migliaccio , Scientific Director, Consorzio per Valutazioni Biologiche e Farmacologiche
13:30	Lunch and Pain Clinic in the Patient Pavilion Zone in the Exhibition Hall					
15:00	Please go to Stream 8, 9 or 10	Please go to Stream 8, 9 or 10	CASE STUDY: Collaborative studies and platform studies – changing the scope of clinical research Katrin Haeveers , Clinical Scientist and External Affairs Director, Deputy Head Director Risk Management and Central Monitoring, TA lead oncology heme and ED/C	The impact on patient data under GDPR Charlotte Ryckman , Senior Associate, Covington & Burling	JOINT CASE STUDY: Cross-Industry Collaboration evaluating how Blockchain can Transform the Pharmaceutical and Healthcare Industry, part of Emerging Trends & Technology PhUSE Workgroup Adama Ibrahim , Senior Clinical Operations Lead, Biogen, UK Aji Barot , Commercial Director, HealthUnlocked, UK	(14:50) Chairpersons opening remarks Julianne Hull , Chief Executive Officer, Wenstar, UK (15:00) Early clinical development in neuromuscular rare disease Wojciech Smoron , Assoc. Global Trial, Director, Novartis, Switzerland
15:30			Big Health Data –Insights you can generate from routine data sources.. if you still “haven’t found what you are looking for” Professor Daniel Prieto-Alhambra , NIHR Clinician Scientist, Oxford University, UK	Panel discussions: Interaction with Industry and Member states on the landscape of regulatory compliance Kristof Van Quathem , Special counsel – advocaat, Covington & Burling LLP	Making all data machine learnable Mishal Patel , Head of Health Informatics, AstraZeneca, UK	Early phase clinical trials for rare diseases and oncology Gianluca Laus , Indication Lead Director Role, AstraZeneca
16:00			Technology enablement and wealth of data Roland Rich , Operations Expert, CQA, Novartis, France		Please move to Stream 8 Technology enablement and wealth of data Roland Rich , Operations Expert, CQA, Novartis, France	Please go to Stream 8 or 10
16:30	End of Conference					

CONFIRMED PCT 2018 SPEAKERS SO FAR...

Lorna Allen, PPI Co-ordinator, **Cystic Fibrosis, UK**

Philipp Badorrek, Head of Department, **Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, Germany**

Lan Bandara, Director, Clinical Outsourcing, Oncology Business Group, **Eisai Limited, UK**

Aji Barot, Commercial Director, **HealthUnlocked, UK**

Riccardo Belli, Director, **Novartis Oncology, Switzerland**

Dr Tamzin Blagbrough, Sourcing Consultant, Clinical Pharmacology Study Delivery Solutions, **Eli Lilly and Company Limited, UK**

Andrew Bottomley, Assistant Director, Head, Quality of Life Department, **EORTC, Belgium**

Paul Bouten, Managing Director, **PharmCMed, The Netherlands**

Lourdes López Bravo, Executive Director, Clinical Research Director Spain and Portugal, Global Clinical Trial Operations (GCTO), **MSD, Spain**

Nicholas Brooke, Chief Executive, **PFMD (Patient Focused Medicines Development) and The Synergist, Belgium**

Kieran Canisius, Co-founder, **Seuss Consulting BV, The Netherlands**

Lidia Cappellina, Head of R&D Outsourcing Management, **Chiesi Farmaceutici S.p.A, Italy**

Nancy C Caralla, Founding President, Executive Director, **C Diff Foundation, USA**

Michael Carpenter, Strategic Partnering Lead, **UCB, USA**

Ben Cromarty, North Yorkshire AIDS Action (NYAA), Medical Research Council Clinical Trials Unit, **University College London Patient and Public Involvement Group, UK**
Marisol Montolio del Olmo, Scientific Director, **Duchenne Parent Project, Spain** and Adjunct Professor, **University of Barcelona, Spain**

Dr Martine Dehlinger-Kremer, Vice President, Pediatric Development, **Syneract**

Dr Alexis Demopoulos, Neurology, Medical Oncology, **New York Hospital, USA**

Jeannett Dimsits, Senior Director, Trial Management Anchor, **NovoNordisk, Denmark**

Vanessa Dos Reis Ferreira, Head of Patient Advocacy Europe, **Santhera, Switzerland**

Diane Driver, Global Head Outsourcing Contracts & Strategic Partnering, **UCB, UK**

Henrik Forsman, Director Scientific Project Management, **AstraZeneca, Sweden**

Wolfgang Eglmeier, Head ZKS-UW/H, Centre for Clinical Studies, **Witten/Herdecke University, Germany**

Van Zyl Engelbrecht, Clinical Project Director, EU, **UBC**

Dr Richard FitzGerald, Consultant Physician and Director, Clinical Research Unit, **Royal Liverpool University Hospital, UK**

Jill Gallagher, Clinical Development and Regulatory Manager, **Parkinson UK, UK**

Laura Galuchie, TransCelerate Oversight Committee

Member and Program Lead for MSD, USA

Dr Javier García-Corbacho, Head of Clinical Trials Unit of Clinic Institute of Haematological and Oncological Diseases (ICMHO), Early Phase Clinical Trials, **Hospital Clinic, Spain**

Estrella García, Director Global Clinical Operations, Global Clinical Operations – R&D, **Almirall, Spain**

Almenia Garvey, Director of Site Alliances, **ICON Clinical Research Services, France**

Ken Getz, Senior Research Fellow, Tufts Center for the Study of Drug Development, **Tufts University, USA**

Amanda L. Goltz, Vice President, Digital, **Biocompatibles Inc., a BTG International group company, USA**

Christer Gottfridsson, ECG Centre Cardiologist, **Astrazeneca, Sweden**

Varun Grover, Clinical Contracts and Finance, Senior Associate, **Gilead, UK**

Dr. Med Uwe Gudat, Head of Clinical Safety & Pharmacovigilance, **Fresenius Kabi SwissBioSim GmbH, Switzerland**

Katrin Haeverans, Clinical Scientist and External Affairs Director, **Janssen Research and Development, Belgium**

Shunsuke Hagihara, Statistical Analysis Data Science, **ONO Pharmaceutical Co.,Ltd, Japan**

Kai Langel, Director R&D, Operation Innovations, **Janssen-Cilag GmbH, Johnson & Johnson, Belgium**

Shunsuke Hagihara, Statistical Analysis Data Science, **ONO Pharmaceutical Co.,Ltd, Japan**

Bruce Hellman, CEO, Co-Founder, **UMotif, UK**

Anja Hijzen, Associate Director Clinical Scientist, **Janssen, Pharmaceutical Companies of Johnson & Johnson, Belgium**

Youssef Hijazi, Expert Clinical Pharmacokinetics, **Sanofi-Aventis, Germany**

Kevin Hua, Senior Manager, AI Machine Learning, **Bayer U.S., USA**

Adama Ibrahim, Senior Clinical Operations Lead, **Biogen, UK**

Mike Jagielski, CEO, **KCR**

Michelle Jones, Senior Director, Clinical Informatics, and Feasibility, Recruitment & Engagement (FRE), **Covance**

Faisal Khan, Executive Director, Advanced Analytics and Artificial Intelligence, **AstraZeneca, USA**

Disa Lee Choun, Head of Data Acquisition, **UCB PHUSE Blockchain Working Group**

Dr. Carole Légaré MD, Director, Office of Clinical Trials at Health Products and Food Branch, **Health Canada**

Elvira Klissourska, Senior Director, Head Clinical Operations, Clinical Development & Medical Affairs, **Fresenius Kabi SwissBioSim GmbH, Switzerland**

Svilen Konov, Director, **SEVT Ltd, UK**

Judith Kornfeld, Chief Business & Operations Officer, **Oregon Health & Sciences University, USA**

Professor Ruth Ladenstein, Senior Consultant in Paediatric

Haematology–Oncology, **OKIDS, Austria**

Gianluca Laus, Indication Lead Director Role, Tagrisso Team, **AstraZeneca UK Ltd**

Jeff Lee, President eCOA and Patient Engagement, **Bracket, UK**

Janis A. Little, Vice President, Global R&D Quality, **Allergan, USA**

Amanda Lucas, Programme Director, **Imperial College Health Partners, UK**

Mariangela Lupo, Networking Manager, **TEDDY - European Network of Excellence for Paediatric Clinical Research, Italy**

Dr Chris Macdonald, Head of Research, **Pancreatic Cancer UK, UK**

Paul MacDonald, Director, Solutions Consulting EMEA, **Medidata, USA**

Dmitry Manuilov, Head of Clinical Development, **MYR GmbH, Germany**

Dr Raphaele Mary, Director, Capability and Strategy, Central Clinical Planning & Solutions, Global Clinical Operations, **Bristol-Myers Squibb, France**

Anna Matranga, Strategic Sourcing R&D, Consultant, **AMC Alliances and Consulting, France**

David MacMurchy, Executive Vice President, Europe Asia Pacific & Africa, **PRA Health Sciences, UK**

Boaz Mendzelevski, President, **Cardiosafety Consultants Melissa Menke**, Founder and CEO, **Access Afya., USA**

Nancy Meyerson-Hess, Associate Partner at admedicum Business for Patients, **GmbH & Co KG, Germany**

Giovanni Migliaccio, Scientific Director, **Consorzio per Valutazioni Biologiche e Farmacologiche, Italy**

Christian Milliet, Global Head Clinical Operations, **Vifor Intl Ltd, Switzerland**

Neal McCarthy, Managing Director, **Fairmount Partners, USA**

Begonya Nafria Escalera, Patient Advocacy Manager in Research, **Hospital Sant Joan de Déu, Spain**

Isabelle Naëije, Associate Global Trial Director, GDO Trial Management Oncology, **Novartis Pharma AG, Switzerland**

Jennifer Nielsen, Transcelerate eSource, **Novo Nordisk A/S, Denmark**

Kate O'Brien, Senior Research Nurse, **Freelance Site Consultant, UK**

Dr Maria Beatrice Panico, Medical Assessor, Clinical Trials Unit, **Medicines and Healthcare Products Regulatory Agency, UK**

Mishal Patel, Head of Health Informatics, **AstraZeneca, UK**

Jacyln Patterson, Senior Director, Early Dev. Clinical Trial Management, **Regeneron, USA**

Sebastian Payne, Director, **Deloitte**

Jennifer Preston, Patient and Public Involvement & Engagement Priority Lead, Dept. of Women's and Children's Health, **Alder Hey Children's NHS Foundation Trust University of Liverpool, UK**

Joe Robbins, Director & Senior Manager, Global Clinical Pricing Head of Global Supplier Gov, **Amgen**

Morten Thorup Pedersen, Risk Based Monitoring Specialist, **NovoNordisk, Denmark**

Daniel Prieto- Alhambra, Associate Professor & NIHR Clinician Scientist, **Oxford University, UK**

Mark Pollock, Explorer, Innovator & Collaboration, **Catalyst**

Ben Quartley, Head of Feasibility, Recruitment, Engagement and m-Health, **Covance**

Roland Rich, Operations Expert, CQA, **Novartis, France**

Dr Wolfgang Seibold, Clinical Operations, **Boehringer Ingelheim Pharma GmbH & Co. KG, Germany**

Shaila Shabbir, Clinical Development Manager, Respiratory Global Clinical Sciences & Delivery (GCSD), R&D Projects, **GlaxoSmithKline, UK**

Margi Sheth, Clinical Information Sharing Programme Manager, **AstraZeneca UK**

Dr Diana Sims-Silbermann, Senior Trial Manager, Early Development and Clinical Pharmacology, **Janssen-Cilag GmbH, Johnson & Johnson, Germany**

Lara Silverstein, Operations Director, **Avillion, UK**

Sascha Sonnenberg, Vice President Cell & Gene Therapies and CTS Services, **Marken, Germany**

Dr Vanessa Spaldin, Clinical Project Management Advisor, Neuroscience, Clinical Pharmacology, **Eli Lilly and Company Limited, UK**

Benjamin Stecher, Education Consultant, Writer and Parkinson's disease patient advocate

Colette Strnadova, Senior Scientific Advisor, **Health Canada, Canada**

Frank Sullivan, Director of Research, **University of St Andrews, UK**

Thishi Surendranathan, Manager Health Advisory, **KPMG Health and Life Sciences Advisory, UK**

Geoff Taylor, Director, Clinical Quality Assurance, **Eisai Product Creation Systems, UK**

Joana Claverol Torres, Coordinator of the Clinical Trials Unit, **Sant Joan de Deu Hospital, Spain**

Angelo Trotta, Connected Health Solutions & Operations, **Janssen, Pharmaceutical Companies of Johnson & Johnson, Belgium**

Kristof Van Quathem, Special Counsel, **Covington & Burling LLP, Belgium**

Professor Galina Velikova, Professor of Psycho-social and Medical Oncology, **University of Leeds, UK**

Dr Siru Virtanen, ECMC Programme Office, Research and Innovation Directorate, **Cancer Research UK, UK**

Vivienne van de Walle, Director PT&R – clinical research site, **VivMedical - Life Science Consulting, The Netherlands**

Russell Wheeler, Trustee, **Leber's Hereditary Optic Neuropathy Society (LHON Society), UK**

Marion Wolfs, Deputy Head| Director Risk Management and Central Monitoring, TA lead oncology heme and ED/CP, **Janssen, The Netherlands**

Richard Young, VP Vault EDC, **Veeva Systems, UK**

Vijay Zala, Clinical Project Manager, **Imperial College London, UK**

DAY ONE: Tuesday 27th November

PartneringONE meetings and networking

OPENING PLENARY

14:00 Opening remarks from the Chairperson

Jeannett Dimsits, Senior Director, Trial Management Anchor, **NovoNordisk**, *Denmark*

14:10 Examining the role of CROs as facilitators in the convergence of clinical research and clinical care

The level of inefficiency associated with finding and engaging investigative sites and study volunteers combined with the growing value of rich data and analytics are driving the convergence of clinical research into large clinical care settings. Recent transactions indicate that leading CROs are anticipating this convergence and leveraging new approaches to differentiate their service offerings. This session characterizes the operating conditions leading to the eventual convergence of clinical research and clinical care environments, discusses the critical role of CROs as facilitators of this convergence, and provides insight into a new and disruptive clinical trial paradigm punctuated by flexibility, customization and integration.

Professor Kenneth Getz, Director and Associate Professor, CSDD, **Tufts University School of Medicine**, *USA*

14:55 Business and Financial analysis and impact of mergers and acquisition of the CRO's on the Pharma Industry

- Building a better CRO – services, geography and therapeutic expertise
- CRO Models - One stop shop to FSP to staffing
- More pharma than pharma
- Unique merger models – tea and biscuits or chalk and cheese
- Private Equity driving CROs mergers
- The Billion 7, the Second Line, the Asia Pack, the Early Birds and Non-CROs
- The good and bad of larger versus specialist/regional CROs
- Bolt-ons versus merger of equals
- What to do when your CRO gets gobbled
- Merger cycles and new growth
- Evolution – what just happened, and what will happen soon
- Long term prognosis and the likely effects of research sites mergers and virtual trials

Neal McCarthy, Managing Director, **Fairmount Partners**, *USA*

15:40 The future of Healthcare- Mobile Health, Digital, AI and Innovation with regards to clinical trials and healthcare- relate to other industries ACCELERATED DIGITALISATION AND DATIFICATION OF LIFE

- The forces of digitalisation are data and computational power
- Technology growth is exponential hence the need to respond quickly to its disruptive forces and embrace its transformational opportunities
- Big Data and the Liquidity of Information
- A.I. is the evolutionary result of data analysis and machine learning
- Deep Learning:
- Force Brute Computation vs Self-Learning machines
- Demystifying DL: when Reward Functions cannot deliver unbiased results

MAN + MACHINE COLLABORATIONS

- The Future of Human Cognition: the New Super Humans
- Unveiling collaborative approaches to Human + Machine Cognition
- Revealing Human Creativity and all other cognitive skills where humans deliver with better results and precision
- How A.I. and HPC are advancing other sectors: case studies in Automotive, Energy, Food and Agriculture, Asset Management.
- What A.I. and Data can offer by way of Computational Drug Discovery
- The 3Ds Powering AI in Drug Discovery: Domain Expertise, Deep Learning and Data

Inma Martinez, Venture Partner, Data Sciences & Product Innovation, **Deep Science Ventures**, *UK*

16:25 PANEL: The Future of Clinical Trials - New partnerships, new innovations and new processes

- News flash over the 12 months: significant changes and news from the panel's perspective
- Overview of compelling new mergers and acquisition, partnerships and collaborations
- Greatest challenges anticipated as we move closer to this new future vision
- The role of new technologies in supporting this new future vision

MODERATOR:

Professor Kenneth Getz, Director and Associate Professor, CSDD, **Tufts University School of Medicine**, *USA*

Amanda L. Goltz, Vice President, Digital, **Biocompatibles Inc.**, a **BTG International** group company, *USA*

Janis A. Little, Vice President, Global R&D Quality, **Allergan**, *USA*

Laura Galuchie, TransCelerate Oversight Committee Member and Program Lead, **MSD**

Alastair MacDonald, SVP Real World & Late Phase Client Engagement, **Syneos Health**, *USA*

Almenia Garvey, Director of Site Alliances, **ICON Clinical Research Services**, *France*

17:30 Welcome Drinks Reception in the Exhibition Hall

Sponsored by:



MORNING PLENARY

08:50 Opening remarks from the Chairperson

Bruce Hellman, CEO, Co-Founder, UMotif, UK

09:00 PATIENT'S AND DOCTORS JOINT STORY: Doctor and Patient working together to form OurBrainBank

Jessica Morris, Founder and Chair, OurBrainBank, SVP and Partner, FleishmanHillard, USA

Dr Alexis Demopoulos, Director, Neuro-oncology, Northwell Health System, Manhasset, USA

09:40 PANEL: How to manage different goals of sponsor, CRO, Patients, Regulators and Investigators

- Optimizing the future of clinical trials
- How can we achieve this goal for everyone?
- Representing the patient in study design, planning and conduct
- What are the tensions?
- How to overcome the challenges?
- What do patients (and the public) want from trials generally
- What do participants want from their own trials and how can patients (or the public) help themselves and those running the trials

MODERATOR:

Dr. David Bull, English Doctor, Television Host, Entrepreneur, David Bull, UK

Panelists:

Lewis Cameron, Head of Global Clinical Development, Covance, UK

Richard Stephens, Chair, National Cancer Research Institute's Consumer Forum, UK

Nicholas Brooke, Chief Executive, PFMD (Patient Focused Medicines Development) and The Synergist, Belgium

Dr Richard FitzGerald, Consultant Physician and Director, Clinical Research Unit, Royal Liverpool University Hospital, UK

Jane Winter, SVP Strategic Alliance Management, Syneos Health, UK

Paul MacDonald, Director, Solutions Consulting EMEA, Medidata, USA

10:40 Morning coffee and networking



STREAM 1: Partnerships and Collaboration

OUTSOURCING PARTNERSHIP

11:25 Opening remarks from the Chairperson

Estrella García, Director Global Clinical Operations, R&D, **Almirall**, *Spain*

11:30 JOINT PRESENTATION: Vendor selection for sponsors – How to utilise the Request for Proposal (RFP) data to achieve the best partner

Lara Silverstein, Operations Director, **Avillion**, *UK*

Kieran Canisius, Co-founder, **Seuss Consulting BV**, *The Netherlands*

12:00 CASE STUDY: Discover – North West London data driving real world evidence through collaboration

- Role of Imperial College Health Partners in facilitating research collaborations
- Introduction to an exciting new new product launched earlier this year – Discover, which provides North West London data for driving real work evidence through collaboration
- Explain how Discover acts as a partner for realising potential of new products and can add value throughout the drug development cycle through effective and efficient study design and delivery and generation of a robust evidence base. It is cost effective and you can feel confident that you are investing back into the NHS by choosing us.
- Unique position enables us to bring together researchers, patients, industry and the NHS - working relationships with NHS Trusts and universities, co-production and insights gained through engagement with patients and charities.

Amanda Lucas, Programme Director, **Imperial College Health Partners**, *UK*

12:30 Getting it right from the outset – Relationships before Partnerships

- Early engagement between parties – consultative approach
- Cultural alignment – values, priorities, “chemistry”
- Commitments – managing expectations, building trust
- Executive engagement – building foundation for “making bad times better”

David MacMurchy, Executive Vice President, Europe Asia Pacific & Africa, **PRA Health Sciences**, *UK*

Elvira Klissourska, Senior Director, Head Clinical Operations, Clinical Development & Medical Affairs, **Fresenius Kabi SwissBioSim GmbH**, *Switzerland*

13:00 Lunch, Pain Clinic and Roundtable on Stress Management in the Patient Pavilion Zone in the Exhibition Hall

14:30 CASE STUDY: Out-Tasking

Lourdes López Bravo, Executive Director, Clinical Research Director Spain and Portugal, Global Clinical Trial Operations, **MSD**, *Spain*

15:00 Partnership to Realize FDA Recent Guidance on Integration of EHR and EDC Data

Gain insight into the recently updated guidance from the FDA as part of their drive to modernize clinical trials to increase access to drugs and treatments. Understand how collaboration between sponsors, EHR vendors and EDC systems, leveraging Blockchain can greatly improve the collection and quality of EDC data. Such collaboration will enable sponsors to become better aligned with this new guidance and provides an environment which improves research for patients, sites and point of care clinicians. Some of the key benefits to sponsors are:

- Reduced site burden and overall costs
- Greater transparency into operational activity
- More control without additional overheads
- Improved time management for all
- Consistent, real-time and higher quality data

Gavin Nichols, Chief Information Officer & Executive Vice President, Technology, **Bioclinica**, *UK*

15:30 Afternoon Break

16:00 CASE STUDY: Managing Outsourcing Risk: The global and regional picture

- How can we better mitigate, control or reduce risk associated with outsourcing?
- How to do it? Getting control of all outsourcing that is happening in the regions
- How to achieve smarter resourcing in a global context

Edouard Masurel, Head of Third Party Resourcing (TPR) – Regions and LOCs, **GlaxoSmithKline**, *UK*

IMPACT OF MERGERS & ACQUISITION OF CROs

16:30 PANEL: The evolution of outsourcing strategies: Managing change through M&A in stakeholders during outsourcing and strategic partnerships

- Impact of mergers and acquisition of the CRO's on the Pharma Industry, risks and opportunities from M&A, a sponsor's perspective? CROs should maintain a high level of performance, CRO staff turnover as result of M&A?
- Mergers and Acquisition of CRO- how do you still take forward the partnership? How does this impact the trial? How to keep fresh and on-track when this happens? How well is the integration managed? Business continuity and risk management during M&A period
- Real-life experience of what can go wrong in a partnership and how can this be avoided? CROs to be aware of the new sponsors culture, how to remain versatile, preferred provider for Sponsor?
- Quality oversight during a fully outsourced study, including pitfalls and solutions
- Is this the death of small specialist CROs?
- How to manage change after M&A, the impact on contracts and budgets with CRO/Sponsors, exploring other types of contracting models best suited to adapt to change, what constitutes a change in scope?
- Monitoring supplier performance, introducing KPI's

MODERATOR: Graham P Belgrave, Senior Vice President, European Operations, **Advanced Clinica**, *UK*

Varun Grover, Clinical Contracts and Finance, Senior Associate, **Gilead Sciences**, *UK*

Lan Bandara, Global Head of Outsourcing, **Eisai Limited**

Lidia Cappellina, Head of Outsourcing Management, **Chiesi Pharmaceuticals**, *Italy*

STREAM 2: Patients as Partners

PATIENT CENTRICITY & ENGAGEMENT

11:25 Opening remarks from the Chairperson

Nicholas Brooke, Chief Executive, PFMD (Patient Focused Medicines Development) and The Synergist, *Belgium*

11:30 PATIENTS STORY: 'Partners in research': Why patients should be part of the entire research process from bench to clinic - Insights from my personal journey through Parkinson's research

- The pace of novel advances seems to be slowed down by a system that cannot move fast enough to keep up with our own neurodegeneration
- The "average PD patient" is a statistical construct rather than a physical entity
- Too often, these clinical trials seem to be conducted to support new patents rather than patients
- As a first step towards ameliorating these problems, patients should become part of the clinical trial design process. Rather than just being told which hoops to jump through they should be recognized as partners in research
- We need patient-scientist teams to work together to maximize the likelihood that studies are designed in a way that will ultimately best inform patient and clinician treatment decisions

Benjamin Stecher, Education Consultant, Writer and Parkinson's Disease Patient Advocate, **Parkinson's Research Advocacy Group**, *Canada*

12:00 CASE STUDY: The journey of Santhera Pharmaceuticals to effectively engage with patient groups in clinical trials

- Preparation for and encouragement of feedback from patient groups
- Challenges, obstacles and getting through them
- Impact on company decisions after patient groups feedback
- Recommendations

Vanessa Dos Reis Ferreira, Head of Patient Advocacy Europe, **Santhera**, *Switzerland*

12:30 Direct engagements with Patients – where are the limits?

- View of different aspects on direct patient engagement in clinical trials
- What is the potential impact and where are possible limitations?

Mike Jagielski, CEO, **KCR**, *Germany*

13:00 Lunch, Pain Clinic and Roundtable on Stress Management in the Patient Pavilion Zone in the Exhibition Hall

14:30 CASE STUDY: A rare disease in clinical trial: The Duchenne parent project Spain strategy

- Clinical Trial Support: Save drugs from Valley of death
- Patients' Registry
- Collaboration with Pharma
- Input to EMA

Marisol Montolio del Olmo, Scientific Director, **Duchenne Parent Project**, *Spain*
and Adjunct Professor, **University of Barcelona**, *Spain*

15:00 Making it easier for patients to learn about and participate in clinical trials: A practical approach to patient centricity

- Benefits of the patient centricity phenomenon
- Addressing literacy and health literacy to enhance clinical trial understanding
- How to incorporate the patient perspective into the protocol design process
- What can be done to reduce financial, geographical and practical challenges to trial participation
- Through case studies and examples, understand the practical application of a patient centric approach to planning and implementing clinical trials

Rosamund Round, Director, Patient Innovation Center, **PAREXEL**, *UK*

15:30 Afternoon Break

PATIENT ADVOCACY GROUPS

16:00 Delivering meaningful patient centricity in clinical trials: The patient organisation perspective

- Hear how UK medical research charities have been successfully integrating patient insight in to their activities for over 10 years
- Find out how they strike a practical balance of delivering effective research outcomes whilst ensuring relevance through principled and meaningful patient involvement
- Through case studies and examples, explore how industry and medical research charities can learn from one another and collaborate for mutual benefit in clinical trials
- Discuss the body of evidence and moral imperative that is quickly making patient centricity a key focus of those delivering clinical trials and regulators

Chris Macdonald, Research Involvement Manager, **Pancreatic Cancer UK**, *UK*

16:30 PANEL: Patient Engagement – Discussing the value and has it actually made a difference to the Pharmaceutical companies?

- Has the focus on Patient Centricity really sped up the development of molecules?
- What cost implications are there in being patient centric?
- Is it really changing protocols? Is it delaying start-up times?
- Have they recruited faster? Is it actually delivering on recruitment and better retention?
- What are companies doing? What's the value in it?
- Involving patients from start to finish - Engage for protocol development through to end
- Engaging patients to talk to regulators?
- Have they got better data? Have they got faster approval? What is the feedback from the regulators?
- Holistic made people feel good, helping with pharma industry profile
- What is the Regulators viewpoint on this? Engaging with patients - how will they respond to that? FDA has done patient engagement... how do they view patient engagement? Study design or end points have been requested by patients? How do they react to that?
- Experience of patients may be better but is it speeding up clinical research?

MODERATOR: Andrew Benson, Senior Director at Trial Trove, **Citeline**, *UK*

Jennifer Preston, Patient and Public Involvement & Engagement Priority Lead, Dept. of Women's and Children's Health, **Alder Hey Children's NHS Foundation Trust University of Liverpool**, *UK*

Russell Wheeler, Trustee, **Leber's Hereditary Optic Neuropathy Society (LHON Society)**, *UK*

Almenia Garvey, Director of Site Alliances, **ICON Clinical Research Services**, *France*

Dr. Vanessa Spalding, Clinical Project Management Advisor, Neuroscience, Clinical Pharmacology, **Eli Lilly and Company Limited**, *UK*

Mike Jagielski, CEO, **KCR**, *USA*

CLOSING PLENARY See Page 14

STREAM 3: Mobile Health and Wearables

11:25 Opening remarks from the Chairperson

Nicole Powell, Director Business Development, **SDC**, *USA*

11:30 CASE STUDIES: “Ready Participant One”: The patient-centric Clinical Trial of the future

- Informed consent: Patients need to know what's expected
- Data ownership: Trust and balance across all partners
- Data capture: Combination of a range of sources
- And this future is now - case studies from across the industry

Bruce Hellman, CEO, Co-Founder, **UMotif**, *UK*

12:00 CASE STUDY: First of Its Kind Smart Trial and Engagement Program Implemented on a phase II clinical trial with Alzheimer Patients

- Impact of personalized patient engagement and automated real-time data collection on patients, sites and company via smart phones, smart blisters and scanning devices
- Ensuring the “right” kit and “right” pill is given to the “right” patient at all times
- Improving patient's understanding of drug information and all-in-one digital drug labels.
- Value of engaging patients, sites, health authorities and ethics committees directly during the development of smart technologies
- Transforming clinical trials by disruptive partnerships with technology, software, mobile and package vendors.

Dr Anna Bink, iSTEP study implementation lead, **Janssen**, *Belgium*

12:30 CASE STUDY: Use of technology to access isolated populations to improve lifelong health and education

- How isolated populations have access and use technologies for their health and education – case studies in Peru, Brazil, Nigeria, Nepal and Mongolia.
- How technologies are used from birth to elderly
- How local knowledge is collected and shared with technologies
- What challenges have still to be overcome to enhance security in the communities
- What can we learn from these examples to benefit clinical trial design and the promotion of longterm healthcare solutions

Dr Véronique Inès Thouvenot, Co-Founder CCO, & Scientific Director, **Millennia2025 Women and Innovation Foundation**, *Switzerland*

13:00 Lunch

14:30 CASE STUDY: Childhood Cancer Survivorship Passport: An integrated eHealth solution

- Continuity of Care and Advice
- Survivorship Passport
- Interoperable electronic Health Records
- Patient Empowerment
- Long Term Follow Up Research

Ruth Ladenstein, Senior Consultant in Paediatric haematology–Oncology, **OKIDS**, *Austria*

15:00 BYOD: A Game-Changer for Sponsors, Sites and Patients

Electronic clinical outcomes assessments (eCOA) are no longer just about how the patients feel or function pre-approval. With recent technological advancements, eCOA has become a valuable tool that helps sponsors gain greater insight into patient experiences post-approval – especially in site-less trials. A bring-your-own-device (BYOD) approach, coupled with wireless integration with mobile medical devices, opens up a whole new world of data collection options for trial sponsors, sites and patients. In this discussion, we'll share BYOD and flexible provisioning success stories, as well as demonstrate why sponsors need to incorporate this approach into study protocols and post- marketing evidence programs:

- Know what's really meant by 'BYOD' and 'flexible provisioning'
- Understand how FDA, EMA and regional regulators view BYOD data
- See how BYOD has moved beyond patient smartphones to include site tablets and workstations
- Preview how exploratory endpoints and real world evidence may include wearables and even voice-assisted technology such as Amazon Alexa

Chris Watson, Director of Product Strategy, **ERT**

15:30 Afternoon Break

16:00 CASE STUDY: Electronic eSource of data

- What is source data, what isn't?
- Multi Esource data- how to tackle that?
- What are the emerging methodologies?
- How do you prove the electronic source is the data you are reporting for your clinical trial?
- How to go from eSource to reporting?
- Validation of the data from eSource

Jennifer Nielsen, Transcelerate eSource, **Novo Nordisk A/S**, *Denmark*

16:15 CASE STUDY: Digital Biomarkers – The Use of Digital Technology to Empower Clinical Trials Data

Unobtrusive, continuously collected in-home data using sensors and sensor embedded devices are increasingly becoming useful in detecting gradual health changes that are often not noticeable or cannot be accurately collected during periodic in-clinic visits due to self-reporting and or validity limitations and the missing data between in-clinic visits. But challenges remain: How are these devices to be regulated and how will the regulatory bodies accept these uniquely collected clinical trial data as part of the approval process? An example of an in-home sensor based digital technology and the data collected using this platform will be demonstrated.

Judith Kornfeld, Chief Business & Operations Officer, **Oregon Health & Sciences University**, *USA*

16:30 PANEL: Wearables and sensors - Innovative ways to collect clinical data- what does it mean for patients and clinical trials?

- Mobile Health - Taking clinical trial to the patient - Shifting clinical research from hospital to home – when will this happen?
- What do you do with all the data? How much do you use? How will companies analyse that data? How will agencies accept the data?
- Choosing the right device for your trial - what are the requirements?
- How to look at it in a risk-based manner?
- What extent are people, using them? What results have been submitted?
- Experiences – who has done it? What did they found out? What are the difficulties?
- What evidence is there with regulated trials?
- How do you generate more value for your clinical programme by using wearables? How to translate into the real world?
- Can I trust the technology?
- Making trials accessible for many more people – allow people to participate who can't get to hospitals
- What is the opportunity for mobile/ wearables in emerging markets?

MODERATOR: Francesca Martinelli, Specialist in Quality of Life - Quality of Life Department, **EORTC**, *Belgium*

Kai Langel, Director, Janssen Clinical Innovation (JCI), **Janssen-Cilag GmbH, Johnson & Johnson**, *Belgium*

Pierre Peeters, Chief Operations Officer, **Centre for Human Drug Research (CHDR)**, *The Netherlands*

Melissa Menke, Founder and CEO, **Access Afya.**, *Africa*

Emilio Vandelli, Managing Director, **Arithmos (part of PM Holding)**, *Italy*

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STREAM 4: Governance, Quality, Oversight, Risk Management & RBM

11:25 Opening remarks from the Chairperson

Paul Bouten, Managing Director, PharmCMed, The Netherlands

RISK MANAGEMENT

11:30 CASE STUDY: How Novartis governs risk Management in clinical trials

- What are the recommendations from the regulators?
- What can we put in place in our trials?
- Which monitoring model for the future?

Isabelle Naëije, Associate Global Trial Director, GDO Trial Management Oncology, Novartis Pharma AG, Switzerland

12:00 CASE STUDY: Operational risk management- A systematic approach to identifying risk in clinical trials upfront

Protocol risks:

- Complicated IP preparation
- IP with potential side effects (e.g. biologicals)
- Extensive PK days
- Complicated Trial specific activities
- Timelines on processes that affect trial conduct (e.g. long TAT for certain lab assessments, timelines for entering data into IWRS to receive medication)

Site risks:

- Adequate site staff
- Adequate site staff experience
- PI oversight
- Adequate equipment

What can sponsor /CRA do?

- Risk management assessment of protocol taking site capabilities into account before trial starts
- Identify and mitigate possible "danger points" upfront
- Discuss these points with site staff at SIV
- During trial
- Close contact with sites to monitor identified risks in real time

Dr. Diana Sims-Silbermann, Senior Trial Manager, Early Development and Clinical Pharmacology, Janssen-Cilag GmbH, Johnson & Johnson, Germany

12:30 Beyond Risk-based Monitoring: Employing Risk-based Management

The volume and variety of data required in today's clinical trials create significant challenges for trial sponsors and CROs alike — many of whom are still using spreadsheets and manual processes to understand performance, track status and manage risks. But these outdated approaches are time consuming, costly and increase the potential for human error. In this discussion, we'll share practical guidance on how trial leaders can proactively manage performance at the study, site and trial portfolio levels. Highlights include:

- Exploring process, resource, and technology challenges in implementing risk-based management (RBM)
- Overcoming challenges in data source variability, data latency and data aggregation
- Moving beyond RBM: Incorporating study start-up metrics, milestone tracking and other KPIs
- Complying with ICH E6 guidance: Sponsor / CRO roles in risk-based management and oversight
- Finding the best model and solution for your organization: The value of pilots and proofs of concept (POCs)

Christopher Allan, Principal Solutions Consultant, Trial Oversight, ERT, USA

13:00 Lunch, Pain Clinic and Roundtable on Stress Management in the Patient Pavilion Zone in the Exhibition Hall

RISK BASED MONITORING (RBM)

14:30 CASE STUDY: RBM -key conditions in collaboration between Sponsor and CRO

Although Risk Based Monitoring (RBM) high level definitions and processes are similar across the pharmaceutical industry, the practical implementation, organizational structures, naming of documents and processes, system capabilities, etc., can be different from company to company. Through an Alliance Level Relationship with our preferred CROs, we have gained experience and developed best practices with RBM operational deployment and assessing CRO RBM capabilities and competencies. Clarity around roles and responsibilities as well as a good understanding of system capabilities and data flows, especially where there are shared systems between the Sponsor and CRO, are found to be key success factors. Besides possible organizational changes and the development of mutual processes and system capabilities, the human element is not to be underestimated. Managing the changes in processes and change in mind set within both the Sponsor and CRO organization is crucial to successful implementation of RBM.

Marion Wolfs, Director Risk Management and Central Monitoring, Janssen, The Netherlands

15:00 Leveraging AI based platform and analytics for RBM, CM / RM, trial operations and improved outcomes

Several new models for transforming Clinical Trial operations are being pursued by the industry. While process, people / roles and standards are being refined to continue to be more efficient, the core requirement of "near real-time" data availability for decisions on quality, risk, compliance, cycle time, "go / no-go" on studies and cost of trials continues to remain critical.

We will cover some of the key topics below as part of the discussion:

- An Overview of the Challenges in the Clinical Trials Landscape and the Drivers towards Innovations
- Leveraging Operating Models - Risk Based Monitoring (RBM), Quality by Design (QdD) and CM/RM
- Technology developments and considerations – AI, automation, Digital approaches etc.,
- Case study on implementing innovative technology, OneClinical Integrated Clinical Enterprise Platform from Navitas Life Sciences and how it is leveraged to optimize data integration, analytics and data visualization and some pivotal decisions on the study

Dr Krishnan Rajagopalan, Chief Growth Officer, Navitas Life Sciences, USA

Dr Niranjana Rao, PhD FCP, Vice President, Clinical Development, Asana BioSciences, USA

15:30 Afternoon tea and coffee

16:00 CASE STUDY: Quality Tolerance Limits – implementation in a large pharmaceutical company

- Introduction to Quality Tolerance Limits (QTLs)
- What does ICH-GCP require the industry to do
- What is TransCelerate's approach to QTLs
- How to establish a framework for implementing QTLs
- How to define QTLs and for which parameters
- How to monitor QTLs

Morten Thorup Pedersen, Risk Based Monitoring Specialist, NovoNordisk, Denmark

16:30 PANEL: Optimising the Sponsor-CRO partnership: Quality oversight in outsourced clinical trials

- What is meant by oversight - Do we mean the same if using oversight?
- Balance between micromanagement and oversight
- Developing and implementing the right tools parties involved in oversight (sponsor and CRO/third party) - How to label it as quality oversight?
- Makes RBM oversight easier
- What is the effect from RBM on Quality, Risk Management and how captured during oversight
- How much oversight is overkill?
- Governance and Oversight – the difference if any?

MODERATOR: Paul Bouten, Managing Director, PharmCMed, The Netherlands

Geoff Taylor, Director, Clinical Quality Assurance, Eisai Product Creation Systems, UK

Dr Raphaela Mary, former Director, Capability and Strategy, Central Clinical Planning & Solutions, Global Clinical Operations, Bristol-Myers Squibb, France

Marion Wolfs, Deputy Head Director Risk Management and Central Monitoring, TA lead oncology heme and ED/CP, Janssen, The Netherlands

Jeana Nowick, Executive Director of Corporate Quality, Syneos Health

Helen Whitelegg, Vice President, Clinical Project Management, IQVIA

CLOSING PLENARY See Page 14

STREAM 5: Investigator & Industry Partnerships

11:25 Opening remarks from the Chairperson

Dr Vivienne van de Walle, Director PT&R – Clinical Research Site, **VivMedical - Life Science Consulting**, *The Netherlands*

SITE SELECTION

11:30 CASE STUDY: Best Practices for Site Identification and Selection

- Major challenges in a competitive landscape
- Available tools and sources for site identification
- The Feasibility Study 2.0
- Benefits of direct site contact

Christian Milliet, Global Head Clinical Operations, **Vifor Pharma**, *Switzerland*

12:00 CASE STUDY: Engagement with sites

Jeannett Dimsits, Senior Director, Trial Management Anchor, **NovoNordisk**, *Denmark*

Kate O'Brien, Senior Research Nurse, **Freelance Site Consultant**, *UK*

12:30 JOINT PRESENTATION: Global Site Payment Transformation

Attend this joint presentation to learn how Amgen chose Greenphire's eClinicalGPS to automate its site payments for a more transparent, reliable process that eliminated as many manual points of intervention as possible.

- How the holistic approach included standardization of global budget processes, creating an internal clinical payments database and implementing key integrations (ERP, EDC) to distribute payments to sites
- Automating configuration improves controls, reduces errors and keeps the sponsor in the ownership role
- Site payment automation allows the sponsor to eliminate holdback, pay more frequently, accurately with full transparency
- Key findings from the pilot program, global implementation and worldwide payment transformation

Jim Murphy, CEO, **Greenphire**

Joe Robbins, Senior Manager, Global Clinical Pricing Head of Global Supplier Gov, **Amgen**

13:00 Lunch, Pain Clinic and Roundtable on Stress Management in the Patient Pavilion Zone in the Exhibition Hall

INVESTIGATOR

14:30 CASE STUDY: What it's like to be an Investigator on a trial?

Dr Richard FitzGerald, Consultant Physician and Director, Clinical Research Unit, **Royal Liverpool University Hospital**, *UK*

15:00 Please go to Stream1,2,3,4 or ECD

15:30 Afternoon Break

16:00 The NCRI Consumer Forum - How patient partners can help Investigators and Industry

Dr Richard Stephens, Chair of the **National Cancer Research Institute's Consumer Forum**, *UK*

SITE BUDGET & PAYMENT

16:30 PANEL DISCUSSION: Site budget in Clinical Trials – What is “fair market value”?

- Offered budget for set up is often far too low, especially in multi-centre trials. (ever increasing training requirements and document reviews (lab manual, procedure manual, protocol, CRF)
- Why is there so often a marked difference in budgets between early phase and late phase trials? The need for training and the level of quality is the same.
- Activities outside the mere procedure costs are often not recognised, like time to enter CRFs, communication time with sponsor/CRO, internal team meetings, etc.

Dr Diana Sims-Silbermann, Senior Trial Manager, Early Development and Clinical Pharmacology, **Janssen-Cilag GmbH, Johnson & Johnson**, *Germany*

Philipp Badorrek, Head of Department, **Fraunhofer Institute for Toxicology and Experimental Medicine ITEM**, *Germany*

Dr Wolfgang Seibold, Clinical Operations, **Boehringer Ingelheim Pharma GmbH & Co. KG**, *Germany*

Dmitry Manuilov, Head of Clinical Development, **MYR GmbH**, *Germany*

CLOSING PLENARY See Page 14

CLOSING PLENARY

17:30 Opening remarks from the Chairperson

Dr Tamzin Blagbrough, Sourcing Consultant, Clinical Pharmacology Study Delivery Solutions, **Eli Lilly and Company Limited**, *UK*

17:35 PCT Lifetime Achievement Award in association with mdgroup

17:40 Innovation and Technology - Exploring possibilities where humans and technology collide

- Adversity and challenges - Resilience and attitude under pressure
- Leadership and motivation - Goal setting and leading through a crisis
- Collaboration and teamwork - Creating and motivating dispersed teams across disciplines and geographies

Mark Pollock, Explorer, Innovator and Collaboration Catalyst, *Ireland*

Unbroken by blindness in 1998, Mark went on to compete in ultra-endurance races across deserts, mountains, and the polar ice caps including being the first blind person to race to the South Pole. In 2010 Mark was left paralysed after falling from a second story window. He is now exploring the frontiers of spinal cord injury recovery combining an innovative electrical stimulator over his spinal cord and a drug super-charging his nervous system, whilst walking hundreds of thousands of steps in his Ekso Bionics robotic legs.

18:30 Drinks Reception



STREAM 6: Partnership Management & Emerging Trends

08:50 Opening remarks from the Chairperson

Julianne Hull, Chief Executive Officer, **Wenstar, UK**

09:00 HEADLINE TALK: Trends in oncology and their implication for clinical research

Thishi Surendranathan, Manager Health Advisory, **KPMG Health and Life Sciences Advisory, UK**

OUTSOURCING PARTNERSHIPS

09:30 CASE STUDY: Evolution and enhancement of a strategic partnership over 8 years

8 years since we made the decision to change our outsourcing strategy, our Strategic Partnerships are continuing to grow and develop. In 2015 we shared how we worked with our Strategic Partners to develop an Oversight model that allowed us to help evolve our Partnerships. This case study will provide a further update on how we have continued to evolve and enhance our Partnerships - lessons we've learned, and how we've addressed them together to take our Partnerships to the next level.

Michael Carpenter, Strategic Partnering Lead, **UCB, USA**

10:00 Explore how a patient-centric logistics approach can positively impact trial recruitment, retention and your clinical trial budget

Sascha Sonnenberg, Vice President Cell & Gene Therapies and CTS Services, **Marken, Germany**

10:30 Morning Break

EMERGING TRENDS

11:20 The practical implementation of RBM by a Mid-Size Organization – What we have learned in 2 years

Over the past 2 years ONO Pharmaceutical has researched, planned and implemented their Risk Based Monitoring strategy. Most recently they implemented their chosen technology to support central statistical monitoring to complement the RBM approach. This presentation shares ONO experiences, decisions, and challenges as it continues to benefit from an improved approach to managing risk and increasing clinical data quality and oversight.

Shunsuke Hagihara, Statistical Analysis Data Science, **ONO Pharmaceutical Co.,Ltd, Japan**

11:50 The Eli Lilly and Covance clinical pharmacology partnership: 11 years and counting

David Simpson, Executive Director, Clinical Pharmacology Services, **Covance UK**

Dr Tamzin Blagbrough, Sourcing Consultant, Clinical Pharmacology Study Delivery Solutions, **Eli Lilly and Company Limited, UK**

12:20 FUTURE DEBATE: What single activity will change our industry the most by 2030?

10mins to cover a topic and at the end of it the audience vote. Who told you something that you didn't know? Was it worth knowing? Was it factually correct?

MODERATED BY: Julianne Hull, Chief Executive Officer, **Wenstar, UK**

Working collaboratively

Amanda Lucas, Programme Director, **Imperial College Health Partners, UK**

Patient Centric Approaches

Nancy C Caralla, Founding President, Executive Director, **C Diff Foundation, USA**

Voice assistant technology discussion include:

- Using voice assistant technology in clinical trials, e.g., data capture, patient engagement/support
- Reviewing examples from proof of concept work ERT has completed
- Navigating regulatory requirements

Chris Watson, Director of Product Strategy, **ERT**

Clinical 2030: The intersection of Data, AI and Patient Centricity

Srinivas Karri, Director Product Strategy, **Oracle Health Sciences, UK**

13:00 Using technology to transform clinical trial performance

Richard Young, VP Vault EDC, **Veeva Systems, UK**

13:30 Lunch and Pain Clinic in the Patient Pavilion Zone in the Exhibition Hall

15:00 Please go to Stream 8, 9 or 10

STREAM 7: Patient Recruitment, Retention & Engagement

08:50 **Opening remarks from the Chairperson**

Andrew Benson, Senior Director at TrialTrove, **Citeline**, *UK*

PATIENT ENGAGEMENT

09:00 **CASE STUDY: Paediatrics Trials – what are their experiences?**

Joana Claverol Torres, Coordinator of the Clinical Trials Unit, **Sant Joan de Deu Hospital**, *Spain*

09:30 **Patient engagement - what is it and how do we make sure we are doing it right?"**

- Patient engagement - defining the undefinable
- Best practice in implementation of patient engagement
- Early evidence and reasons to be optimistic

Russell Wheeler, Trustee, **Leber's Hereditary Optic Neuropathy Society (LHON Society)**, *UK*

10:00 **Jeff Lee**, President eCOA and Patient Engagement, **Bracket**, *UK*

10:30 Morning Break

PATIENT RECRUITMENT & RETENTION

11:20 **Laying the path for patient engagement**

- Exploring clinical trial opportunities (the patient's perspective)
- Laying the path – addressing the barriers
- The Clinical Trials Accelerator Platform
- When to start the conversation

Lorna Allen, PPI Co-ordinator, **Cystic Fibrosis**, *UK*

11:50 **CASE STUDY: Using primary care electronic medical records to identify study subjects in clinical trials of biomarkers**

- Recruitment to trials often fails
- Studies within a trial (SWATs) are needed – but difficult
- EMRs enable more Precision recruitment- e.g. 12K patients recruited to ECLS
- Feasibility platforms e.g. SHARE and Patient Reported data (Tablet study)
- Use tools to see what sites are applicable
- Using epidemiological data- computer science and stats to optimise inclusion/exclusion criteria

Frank Sullivan, Director of Research, **University of St Andrews**, *UK*

PATIENT ENGAGEMENT

12:20 **PANEL: What are the reasons and motivations for persons to participate in trials and how to achieve patient engagement?**

- Increased involvement of patients in clinical trials for the trial design - How do we innovate clinical trials to include input from patients?
- How to reach patient groups? Different aspects?
- Improve the trial design – e.g. provide childcare for trial participants, compensation, travel costs, global differences, should patients receive financial compensation? A controversial area
- Patient receives good clinical care already, why would they want to undertake a new medication trial? Why enter a clinical trial with a new substance if already have a good standard of care- how to attract? What would be a the motivation?
- How to make trials more attractive to patients?
- Flexibility have home care visits- nurses to send to home
- Better understanding of the gap between what patients expect and what drs are delivering when it comes into information of clinical trials
- What can patients contribute to the trial design / development of trial protocols?
- How can they be actively involved in all levels of the trial (including steering committees etc)

MODERATOR: Eamonn O'Brien, Independent Consultant, *UK*

Ben Cromarty, North Yorkshire AIDS Action (NYAA), **Medical Research Council**

Clinical Trials Unit, University College London Patient and Public Involvement Group, *UK*

Kate O'Brien, Senior Research Nurse, **Freelance Site Consultant**, *UK*

Sammy Ainsworth, Patient Research, **Ambassador**, *UK*

Richard Stephens, Chair of the National Cancer Research Institute's Consumer Forum, **NCRI**, *UK*

Mathias Praus, **World Courier**, *USA*

13:00 Please go to Stream 6,8,9, 10 or EC

13:30 Lunch and Pain Clinic in the Patient Pavilion Zone in the Exhibition Hall

15:00 Please go to Stream 8, 9 or 10

STREAM 8: Real World Evidence, Paediatrics, Trial Design & Big Data

08:50 Opening remarks from the Chairperson

Anna Matranga, Strategic Sourcing R&D, Consultant, **AMC Alliances and Consulting**, *France*

REAL WORLD EVIDENCE

09:00 CASE STUDY: Patient Reported Outcomes and beyond: A Self-service setup

- How we currently deploy ePRO and mobile apps within clinical trials
- Challenges we're facing with ePRO and mobile apps
- Self-Service model for ePRO and beyond: pilot setup
- How can we effectively scale up
- Unified support model

Angelo Trotta, Connected Health Solutions & Operations, **Janssen, Pharmaceutical Companies of Johnson & Johnson**, *Belgium*

09:30 The role of Patient Reported Outcomes (PROs) and Quality of Life Measures in trials and clinical practice

- Monitoring of patients' physical and psychological problems during and after cancer treatment is essential in modern oncology practice. Traditional clinical methods can be supplemented by Patient-Reported Outcome (PROs) measures. The potential role of PROs is recognized and endorsed by national and international practice guidelines.
- This presentation will first provide a brief historical overview and define the terms used in the field, such as health status, health-related quality of life, patient-reported outcomes, clinical outcomes.
- The second part will give examples of cancer clinical trials where QOL data provided important extra information for patients and oncologists.
- The third part will focus on using PROs in clinical practice to monitor symptoms and side-effects during cancer treatment. There is increasing research evidence that using PROs in individual patient care in oncology is beneficial to patients, supporting communication, achieving better symptom control, and possibly better survival. A brief overview of this evidence will be provided, followed by an example of our experience in Leeds, UK of online monitoring of toxicity during cancer chemotherapy using patient self-reported side-effects integrated with the electronic patient records (electronic patient self-Reporting of Adverse-events: Patient Information and Advice- eRAPID research program funded by the National Institute for Health Research). The values and challenges of PROs integration in routine oncology practice will be discussed.

Professor Galina Velikova, Professor of Medical Oncology, **University of Leeds and Leeds Cancer Centre**, *Leeds, United Kingdom*

10:00 What can Big Data tell us about recent trends in Real World Study Design and post-marketing commitments in the EU and US?

- Compare and contrast EU versus US post-market commitments for marketed products overall and by therapeutic area
- Examine trends over time in the types of study designs employed for marketed products, and whether studies were mandated versus voluntary
- Profile the research burden associated with 1st in class products versus entrants into established classes
- Determine if mandated post-market safety commitments have changed over time for products with the same mechanism of action

Dr. Alexandre Malouvier, Scientific Affairs Director, Real World Solutions, **PRA Health Sciences**, *France*

10:30 Morning Break

PAEDIATRIC TRIALS

11:20 Engagement of young people across Europe to improve paediatric clinical trials

- Paediatric clinical trials landscape for the upcoming years
- Young advocates can have a voice and involvement along the lifecycle of medicines
- Standardization of the young advocates participation in clinical trials needs to be a gold standard
- Good practices about the involvement of young people along the lifecycle of medicines
- European Young Persons' Advisory Groups Network

Begonya Nafria Escalera, Patient Advocacy Manager in Research, **Hospital Sant Joan de Déu**, *Spain*

Jennifer Preston, Patient and Public Involvement & Engagement Priority Lead, Dept. of Women's and Children's Health, **Alder Hey Children's NHS Foundation Trust University of Liverpool**, *UK*

Sammy Ainsworth, Patient Research Ambassador

11:50 Informed participation and patient empowerment: A patient-centred approach to give voice to the young patients and favour the paediatric research

- Patient Empowerment and Patient Advocacy to draw on patient own knowledge and experience
- Rarely these attempts to increase awareness for the patient involvement in clinical research pay attention to the paediatric population needs
- The regulatory framework at European level to promote the children's active participation in the decision-making process and to increase awareness for the patient involvement in clinical research: EU Clinical Trials Regulation, Summaries of Clinical Trial Results for Laypersons; Ethical Considerations for Clinical Trials on Medicinal products conducted with Minors
- The Challenges to be faced for the engagement of children requiring appropriate means and language
- The need of a patients age-tailored approach to design Informed consent in paediatrics: the experience of TEDDY
- Specifically tailored methods should be applied to the training and empowerment process of paediatric patients
- The role for paediatric patients and the relevance of clinical and translational research (including patients' engagement in clinical trials, the consent issue, the patient - reported outcomes in the context of paediatric rare diseases)
- The role of Young Persons Advisory Groups (YPAGs) to overcome this gap: the Italian and Albanian experience

Mariangela Lupo, Networking Manager, **TEDDY - European Network of Excellence for Paediatric Clinical Research**, *Italy*

STREAM 8: Real World Evidence, Paediatrics, Trial Design & Big Data (continued)

CLINICAL TRIAL DESIGN

12:20 **PANEL: Now, next and future for clinical trial design?**

- How virtual can we go?
- Looking at all the different trial options- advantages and disadvantages
- Why we do it and the benefits of platform studies?
- How can we make trials more cost-effective without losing the quality of data?
- What is really important for the data quality?

MODERATOR: Roland Rich, Operations Expert, DevQA, **Novartis, France**

Dmitry Manuilov, Head of Clinical Development, **MYR GmbH, Germany**

Margi Sheth, Clinical Information Sharing Programme Manager, **AstraZeneca UK**

Ursula Garczarek, Associate Director, Strategic Consulting, **Cytel**

Matt Cooper, Business Development & Marketing Director, **NIHR, UK**



REAL WORLD EVIDENCE

13:00 **Real World Data: Improving clinical trial design and patient recruitment**

Michelle Jones, Senior Director, Clinical Informatics, and Feasibility, Recruitment & Engagement (FRE), **Covance**

Ben Quartley, Head of Feasibility, Recruitment, Engagement and m-Health, **Covance**

13:30 **Lunch and Pain Clinic in the Patient Pavilion Zone in the Exhibition Hall**

15:00 **CASE STUDY: Collaborative studies and platform studies – Changing the scope of clinical research**

- The sad truth about Alzheimer's Dementia
- EPAD (Early Prevention of Alzheimer's Disease) – A New Era for Performing Prevention studies using a platform approach
- EPAD Consortium joining forces - Framework and Scene setting
- Building a Platform
- What are the operational challenges?
- What is the added value for pharma companies?

Katrin Haeveryans, Clinical Scientist and External Affairs Director, **Janssen (EMEA), Belgium**

BIG DATA

15:30 **Big Health Data – Insights you can generate from routine data sources... If you still "haven't found what you are looking for"**

- Start here: Data discovery, what is out there? Their Pros and Cons
- First steps: Big health data to inform patient recruitment
- Letting go for a while: Routine data linkage for long-term follow-up in trials
- The aftermath: Big healthcare data for post-marketing drug and device surveillance

Professor Daniel Prieto-Alhambra, Associate Professor & NIHR Clinician Scientist, **Oxford University, UK**

16:00 **Technology enablement and wealth of data**

Roland Rich, Operations Expert, DevQA, **Novartis, France**

16:30 **End of Conference**

STREAM 9: Regulatory Updates

08:50 Opening remarks from the Chairperson

Nancy Meyerson Hess, Associate Partner, **admedicum, Business for Patients GmbH & Co KG**, *Germany*

09:00 Clinical Trial Regulations in Canada

- Update on Clinical Trial Regulation Portal
- Providing timelines and the status of the CTR Portal
- The requirements of industry to use the regulation portal
- Expectations of the CTR portal by the 2019 deadline

Dr Carole Légaré MD, Director, Office of Clinical Trials, Health Products and Food Branch, **Health Canada**

9:30 Strategies to prepare of Clinical Trial Regulation

- The impact of the CTR on industry
- Preparation required by industry to be ready for implementation in 2019
- Changes needed to clinical trial studies and strategies to implement these requirements

Amer Alghabban, Vice President, GxP Quality Assurance, Compliance Training, **Karyopharm Therapeutics Inc.**, *Switzerland*

10:00 What Does Brexit Mitigation Look Like in Practice?

Pete Young, Quality Director, **Catalent**

10:30 Networking Break

11:20 CASE STUDY: Sponsors responsibility for vendor oversight – impact from ICH E6R2 Guideline

- Need for new processes for vendor selection and oversight, including delegated activities.
- Who has overall responsibility, who needs to be involved and how does this work from a QA perspective?
- Introducing risk management into vendor oversight, what is the best mechanism for doing this?
- What might regulators expect under ICH GCP R2?
- How to effectively implement and document vendor oversight

Geoff Taylor, Director, Clinical Quality Assurance, **Eisai Product Creation Systems**, *UK*

11:50 Emerging Markets in Global Clinical Trials

- We will address the following aspects:
- Why is it important to include emerging markets and diversity in global clinical development and clinical trials?
- What needs to be considered in order to be successful: for the sponsor, the sites, the patients?
- What are the regulatory drivers?

Nancy Meyerson-Hess, Associate Partner, **admedicum Business for Patients GmbH & Co KG**, *Germany*

Adama Ibrahim, Senior Clinical Operations Lead, **Biogen**, *UK*

Michael Makanga, Executive Director at European & Developing Countries, **Clinical Trials Partnership (EDCTP)**

12:20 Spotlight From Deloitte

13:00 The Clinical Trials Regulation in the context of Paediatric Research

Dr Martine Dehlinger-Kremer, Vice President, Pediatric Development, **Synteract**

13:30 Lunch and Pain Clinic in the Patient Pavilion Zone in the Exhibition Hall

15:00 Patient data under GDPR

- How we protect patient data?
- Strategies to get GDPR compliance
- Understanding the requirements of collected images such as chest X-Rays. Do we need to remove their name?
- What does it mean for clinical research consent? Will people able to consent to certain parts of the trial?

Charlotte Ryckman, Senior Associate, **Covington & Burling**

15:30 Panel discussions: Interaction with Industry and Member states on the landscape of regulatory compliance

- The impact of Brexit on the regulatory landscape
- The long-term effect of the GDPR and ICH
- Preparations needed for the CTR

Charlotte Ryckman, Senior Associate, **Covington & Burling**

16:00 End of Conference

STREAM 10: Artificial Intelligence for Clinical Trials

08.50 **Chairpersons opening remarks**

Aji Barot, Commercial Director, **HealthUnlocked**, UK

ROBOTICS & PROCESS AUTOMATION IN CLINICAL DEVELOPMENT

09.00 **Crossing the Incurable Sea - How Data, AI and a the world's first National-scale SMART Grid for trialling Adaptive Combination Therapies are dead set to find the cures for currently untreatable cancers**

Dr Jack Kreindler, Founder & Medical Director CHHP, **The Centre for Health & Human Performance Ltd**, UK

09.30 **A Survey of Machine Learning Applications in Clinical Trials**

Operational: Running clinical trials better, faster and more efficiently

- Site Selection
- Patient Recruitment and Enrolment Modelling
- Investigator Performance Analytics
- Supply Chain Analytics

Scientific

- Integrating wearables
- Removing manual steps (cardiovascular event adjudication)
- Integrating companion diagnostics
- Integrating Medical Image screening

Faisal Khan, Executive Director, **AstraZeneca**, USA

10.00 **Sponsored Speaking Slot - Artificial Intelligence in Clinical Trials Automation**

- | | |
|---|---|
| • What automation? | • Approach to automation in clinical trials |
| • Technology(AI) adoption for clinical trials automation | • Automation planning and implementation |
| • Regulatory prospective of automation in clinical trials | • Conclusion |

Vitthal Gouri, Director, Clinical Solutions, **ArisGlobal**, UK

10.30 Morning Coffee and Networking

MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE FOR PATIENT RECRUITMENT

11.20 **Using AI to generate and test novel hypotheses – increasing efficient and accuracy of clinical trial processes**

- How machine learning can be used to analyse complex data sets
- The use of programs to generate and test novel hypotheses more efficiently than traditional processes – thus enabling much faster and more accurate clinical trial periods

Kevin Hua, Senior Manager AI/Machine Learning Development, **Bayer Life Sciences iHub**, USA

11.50 **Can we use machine learning to make clinical research more patient-centric?**

Jonathan Moshinsky, Head of Market Strategy, **uMotif**, UK

NATURAL LANGUAGE PROCESSING (NLP) AND PATIENT VOICE ANALYSIS TO IMPROVE THE TRIAL EXPERIENCE

12.20 **PANEL: Achieving improved patient centricity and engagement with the use of AI – Opportunities and Limitations**

- Is there an opportunity to effectively and efficiently use ambient listening devices?
- How can AI and machine learning be leveraged
- Detection of adverse events?
- The use of NLP and other strategies for analysis?

Kevin Hua, Senior Manager, AI Machine Learning, **Bayer U.S.**, USA

Faisal Khan, Executive Director, Advanced Analytics and Artificial Intelligence, **AstraZeneca**, USA

Xia Wang, Informatics Science Director, Advanced Analytics Centre, **AstraZeneca**, USA

13.00 **INNOVATION DEN (10 mins x 3)**

13.30 Lunch and Pain Clinic in the Patient Pavilion Zone in the Exhibition Hall

AI, BLOCKCHAIN AND BIG DATA – WHERE DO WE BEGIN?

15.00 **JOINT CASE STUDY: Cross-Industry Collaboration evaluating how Blockchain can Transform the Pharmaceutical and Healthcare Industry, part of Emerging Trends & Technology PhUSE Workgroup**

- Understanding 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)
- Share details of the next phase in developing the proof of concept
- Lessons learnt for collaborative groups

Adama Ibrahim, Senior Clinical Operations Lead, **Biogen**, UK

Disa Lee Choun, Head of Data Acquisition, **UCB**

PhUSE Blockchain Working Group

15.30 **Making all data machine learnable**

- Leveraging data for machine learning projects
- Implementing robust data standards
- Analysing big data using machine learning algorithms

Xia Wang, Director, **AstraZeneca**, USA

16.00 **Technology enablement and wealth of data**

Roland Rich, Operations Expert, CQA, **Novartis**, France

16.30 End of Conference

REGULATORY & SCIENCE

09:00 Chairpersons opening remarks

Anna Matranga, Strategic Sourcing R&D, Consultant, **AMC Alliances and Consulting**, *France*

09:10 Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products

- Scope and background of the guidance
- Main aspects
- Dosing selection
- Planning and conducting first-in-human and early clinical phase trials

Dr Maria Beatrice Panico, Medical Assessor, Clinical Trials Unit, **Medicines and Healthcare Products Regulatory Agency**, *UK*

09:40 FiH Industry Perspective: First experiences with the new First in Human guideline

- Experiences on the impact on progression speed of early phase studies
- Case examples of managing risk in FiH studies
- Discussion of operational challenges related to the FiH guideline and how to overcome
- Does the guideline have a positive effect on early phase clinical trials?

Henrik Forsman, Director Scientific Project Management, **AstraZeneca**, *Sweden*

10:10 Role of PK/PD Modeling in supporting design of FIH-trials of high risk molecules

- Recently, two tragic events in FIH trials have occurred: with TGN1412 in March 2006 and with BIA-10-2474 in January 2016, which have triggered enormous discussions and reform in the approaches used for FIH
- Integration of all available in vitro and in vivo pharmacology findings and data on drug-target binding through PK/PD modelling can be used for starting dose selection.
- The MABEL approach can support FIH design for high risk biologics e.g. agonist antibodies or bispecifics
- PK/PD modelling can be useful to predict duration of drug action for drugs with covalent binding to target, where a disconnect between PK and PD exists, which could mitigate safety risks that might occur with molecules of similar nature to BIA-10-2474
- The utility of two PK/PD modelling approaches will be presented

Youssef Hijazi, Expert Clinical Pharmacokinetics, **Sanofi-Aventis**, *Germany*

10:40 Morning coffee and networking

11:30 A regulatory perspective on blood pressure assessments in phase I and II trials: Ambulatory blood pressure monitoring and other approaches

Colette Strnadova, Senior Scientific Advisor, **Health Canada**, *Canada*

12:00 CV vital signs and safety – In addition to blood pressure do we need to consider the heart rate as well in drug development?

Christer Gottfridsson, ECG Centre Cardiologist, **AstraZeneca**, *Sweden*

12:30 Current challenges in running early phase studies in patients rather than healthy volunteers

- The changing landscape of early phase trials
- Advantages and disadvantages of including patients in trials earlier
- The use of integrated protocols
- Ethical and regulatory challenges
- Operational and recruitment challenges.

Charlotte Chadwick, Head of Early Phase Unit and Pharmacy, **MAC Clinical Research**, *UK*

13:00 Lunch, Pain Clinic and Roundtable on Stress Management in the Patient Pavilion Zone in the Exhibition Hall

14:30 ECG-related cardiotoxicity in FIM/early phase studies

Boaz Mendzelevski, President, **Cardiosafety Consultants**

15:00 Using adaptive designs to streamline early clinical studies: case studies across a number of study designs

Adaptive study designs, across all stages of drug development, are helping to increase study efficiency. Early clinical pharmacology studies, such as first-in-human studies, are particularly well-suited for adaptive designs, since preclinical data can help guide the design, but may not perfectly predict what will happen in humans. Adaptations allow us to learn from the real-time data collected, and to make necessary changes to ensure safety is maintained or optimal dosing is achieved. We will review case studies where adaptations enabled studies to be completed more efficiently, with fewer protocol amendments or exposing fewer subjects. We will also present cases where the adaptations were insufficient to prevent protocol amendments but did allow us to better prepare for potential adaptations in future studies. Finally, we will review feedback from regulators and IRBs regarding the optimal method of presenting adaptations in our protocols to ensure the limits of the adaptations are clear.

Dr Graham Wood, Chief R&D Officer, **Altasciences**, *Canada*

15:30 Afternoon break

16:00 The uses and abuses of Adaptive Clinical Trial Designs

- The 60 to 90s were a golden time for drug development, many of these were based on classic receptor/enzyme pharmacology: β Blockers/ β Agonists/ Ca^{++} antagonists/ACE inhibitors/Statins (HMGCoA reductase inhibitors)/SSRIs/5-HT3 antagonists
- Since the Millenium life has in general become more difficult - Developing drugs for stroke or Alzheimer's Disease
- However, some success: Oncology, (Neuro) Inflammation: MS, RA
- How to tackle this: New Targets /Biologicals/Gene Modification/'New' CT Designs
- Examples to Follow: Oncology/Stroke /Alzheimer's/Migraine/Osteoarthritis

Martin Lunnnon, Clinical Pharmacologist, Specialist in Early Clinical Development and Visiting Senior Lecturer, **King's College London**, *UK*

16:30 PANEL DISCUSSION: Patient recruitment for special populations: paediatrics, geriatrics, and oncology

- Explaining the need for specific recruitment for paediatric, geriatric, or oncology studies
- How to effectively and efficiently recruit healthy volunteers and patients for these studies
- Understanding the importance of applying patient centricity for children, geriatrics, and oncology patients and the best methods to do this

MODERATOR: Dr Javier García-Corbacho, Head of Clinical Trials Unit of Clinic Institute of Haematological and Oncological Diseases (ICMHO), Early Phase Clinical Trials, **Hospital Clinic**, *Spain*
Shaila Shabbir, Clinical Development Management, Respiratory Global Clinical Sciences & Delivery (GCSD), R&D Projects, **GlaxoSmithKline**, *UK*

Dr Siru Virtanen, ECMC Programme Office, Research and Innovation Directorate, **Cancer Research UK**, *UK*

08:50 Chairpersons opening remarks

Nigel Blackburn, Director of Drug Development, **Cancer Research UK, UK**

09:00 Putting the patient first: Practically applying a patient centric approach to early phase study design

- Implementing patient centricity from PoC to ensure drug doesn't fail in later stages
- The benefits of early involvement of patient support groups to guide development
- Use of social media to foster patient centricity
- Best ways for detection of possible benefit of the drug: Stratification, biomarkers, endpoints, PROs

Wolfgang Eglmeier, Head ZKS-UW/H, Centre for Clinical Studies, **Witten/Herdecke University, Germany**

09:30 Facilitating collaboration between industry and academia in the discovery and development of new medicines: A Cancer Research UK Perspective

- Drug Discovery and Development at Cancer Research UK
- CRUK Centre for Drug Development infrastructure and capabilities
- fostering innovation through industry-academic partnership
- our partnering models

Nigel Blackburn, Director of Drug Development, **Cancer Research UK, UK**

10:00 Increasing the value of your asset: Considerations for Phase I hybrid trials

Amitava Ganguli, Medical Director, Medical & Scientific Affairs, Clinical Pharmacology Services, **Covance**

10:30 Morning coffee and networking

11:20 CASE STUDY: NIMA – Advancing Science and Drug Development through Public – Private Collaborations

- Joined forces in a Consortium:
 - From Preclinical to Clinical
 - Clinical focus on Phase 1b/2 studies
- A win-win situation: focus on advancing science and leveraging into clinical development strategies
- What are the operational challenges and opportunities

Anja Hijzen, Associate Director Clinical Scientist, **Janssen, Pharmaceutical Companies of Johnson & Johnson, Belgium**

11:50 Challenges in early phase patient recruitment and ensuring representative populations

- Understanding how to ensure the most realistic population possible
- Defining the right endpoints for more efficient population samples
- Selecting patient populations to prevent side effects from only showing in later phases
- Practical advice on streamlining recruitment processes to reduce cost and time

Javier Garcia-Corbacho, Head of Clinical Trials Unit of Clinic Institute of Haematological and Oncological Diseases (ICMHO), Early Phase Clinical Trials, **Hospital Clinic, Spain**

12:20 PANEL DISCUSSION: Outsourcing early clinical trials

- Experiences and challenges with outsourcing to CROs in the early phase
- What are we looking for in an early phase CRO?
- Should sponsors adopt a different approach to using/managing CRO's in early phase vs late phase?
- CROs vs. academic institutions
- Studies in patients vs studies in healthy volunteers

MODERATOR: Anja Hijzen, Associate Director Clinical Scientist, **Janssen, Pharmaceutical Companies of Johnson & Johnson, Belgium**

Nigel Blackburn, Drug Development Director, **Cancer Research UK, UK**

Jaclyn Patterson, Senior Director, Early Dev. Clinical Trial Management, **Regeneron, USA**

Shaila Shabbir, Clinical Development Manager, Respiratory Global Clinical Sciences & Delivery (GCSD), R&D Projects, **GlaxoSmithKline, UK**

13:00 Preclinical development, Research Infrastructures and CRO partnership.

- Increased involvement of academic institution in translational medicine, opportunities and challenges.
- Success rate in late clinical development, how to improve it?
- CRO and preclinical development, how to get involved?
- European research infrastructures. EPTRI, a new kid on the block in the preclinical and clinical development.
- Cost-Benefit and the non-profit approach to drug development

Giovanni Migliaccio, Scientific Director, **Consorzio per Valutazioni Biologiche e Farmacologiche**

13:30 Lunch and Pain Clinic in the Patient Pavilion Zone in the Exhibition Hall

THERAPEUTIC AREAS

14:50 Chairpersons opening remarks

Julianne Hull, Chief Executive Officer, **Wenstar, UK**

15:00 Early clinical development in neuromuscular rare disease

- Challenges and opportunities
- Development strategy
- Exceptional, not conventional approach

Wojciech Smoron, Assoc. Global Trial Director, **Novartis, Switzerland**

15:30 Early phase clinical trials for rare diseases and oncology

Gianluca Laus, Indication Lead Director role, Tagrisso Team, **AstraZeneca UK Ltd**

16:00 End of Conference Day Two

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