Clinical Trials Europe VIRTUAL

2-4 November 2020
Delivered in GMT time zone

Event partner: Citeline
Informa Pharma Intelligence

ACCELERATE YOUR CLINICAL DEVELOPMENT THROUGH PARTNERSHIPS, OUTSOURCING, OPERATIONS & TECHNOLOGY

Be Part of Europe's Largest Event Dedicated to Streamlining Clinical Trials and Improving Patient Outcomes, Without the Need to Travel

Including Leading Perspectives on the Clinical Developments Surrounding COVID-19

KEYNOTE SPEAKERS

Professor Kenneth Getz
Deputy Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine, *USA*

Professor Robert Dingwall
Professor of Sociology at Nottingham Trent University, *UK*

Janis A. Little
Vice President, R&D Quality, Moderna, Inc., *USA*

Pamela Tenaerts
Executive Director, Clinical Trials Transformation Initiative (CTTI), *USA*

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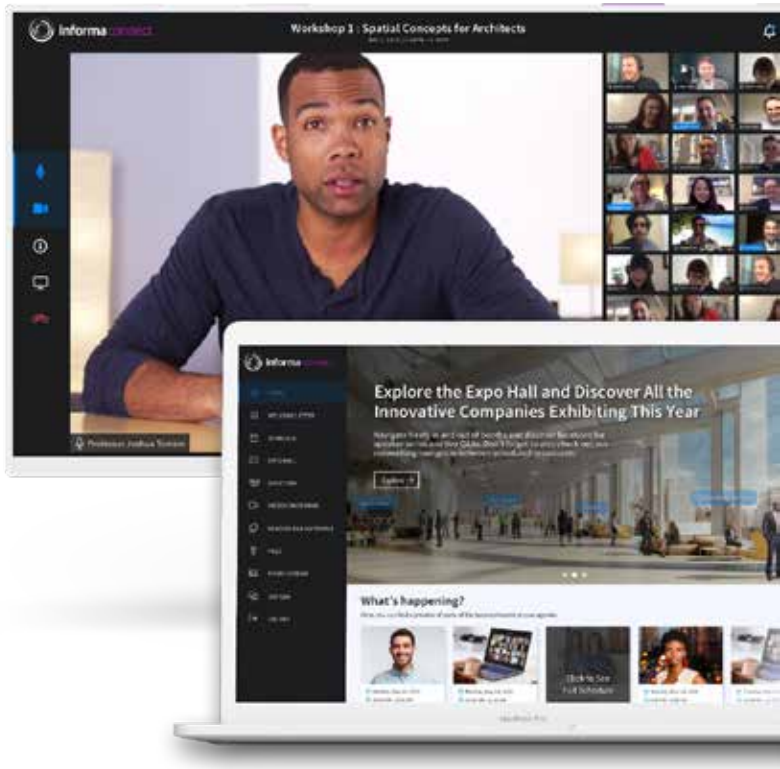
WHY CHOOSE CLINICAL TRIALS EUROPE VIRTUAL?

- Access the clinical industry's leading experts and their insights at the click of a button
- Attend live presentations, panel discussions and Q&As
- Access presentations on-demand for 30 days*
- Benefit from a seamless virtual networking experience
- Identify new solutions to your biggest challenges

*Excluding sessions limited to live viewings only. Subject to speaker permissions.



A SEAMLESS NETWORKING EXPERIENCE:

Embrace our sophisticated and interactive virtual networking experience and gain access to expertise from around the world.

- Browse the full attendee list
- Identify, connect and swap private messages with fellow attendees
- Participate in interactive networking forums
- Schedule one-to-one video meetings with fellow attendees, speakers and exhibitors

CLINICAL TRIALS EUROPE AT A GLANCE

Partnerships and Outsourcing in Clinical Trials		Operations in Clinical Trials		Technology in Clinical Trials	
2 NOVEMBER 2020					
PLENARY: Covid-19 - Impact on Clinical Development Future of Medicine					
3 - 4 NOVEMBER 2020					
Regulatory Updates Different Partnership Approaches Sustainability Covid-19 Patient Diversity Lean Methadology Risk Based Everything	Regulatory Updates Inspections Privacy and Data Protection	Patient Engagement Patient Recruitment and Retention Site Selection & Site Perspective	New Innovative Trial Designs for Clinical Trials Real World Evidence & Real World Data Rare Diseases Paediatrics Covid-19	Decentralized Trials/ Hybrid Trials Digital Health Technology	Artificial Intelligence, Machine Learning & Data Management Data Flow & Analytics

CONFIRMED SPEAKERS TO DATE

Ahmed Albaiti, CEO and Founder, **Medullan,** *USA*

Alexandra König, Clinical Researcher, Memory Clinic at Nice University Hospital, **University of Côte d'azur, and INRIA Nice,** *France*

Alexandre Malouvier, Director Global Data Strategy, **PRA Healthsciences,** *France*

Alison Holland, Head of Decentralized and Remote trials, **Medable,** *UK*

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

Amelia Hursey, Research Participation Lead, **Parkinson's,** *UK*

Amer Alghabban, Senior Director, Clinical Compliance and Training, **Freeline Therapeutics,** *UK*

Anita Nelsen, Senior Vice President and Head, Translational Medicine, **Parexel International,** *USA*

Anna Matranga, Managing Director, **AMC Alliances & Consulting,** *France*

Anthony Costello, Senior Vice President, **Medidata,** *USA*

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

Begonya Nafria Escalera, Patient Engagement in Research Coordinator, **Hospital Sant Joan de Déu,** *Spain*

Birgitte Denlow, GCP Advisor Specialist, Global Clinical Quality & Intelligence, **Novo Nordisk A/S,** *Denmark*

Bruce Hellman, CEO and Co-Founder, **uMotif,** *UK*

Danny Hasselbaink, Global Feasibility Lead, **Janssen Biologics B.V.,** *The Netherlands*

Deepak Bandyopadhyay, Associate Director of Quality Analytics, **Janssen,** *USA*

Diana Sims-Silbermann, Specialist General and Emergency Medicine, Anesthesie, SeniorTrial Manager, Early Development and Clinical Pharmacology, Janssen-Cilag GmbH, **Johnson & Johnson**

Diderik Boot, Director Global Clinical Development Operations, **Neuroscience, Janssen Biologics B.V.,** *The Netherlands*

Dr Andre Krzeminski, Lead Research GP, **Albany House Medical Centre,** *UK*

Dr Bodo Lutz, Clinical Risk Management and Data Integrity QA, **Novartis Global Development Quality,** *Germany*

Dr Corrette Ploem, Associated Professor, Amsterdam University Medical Centre, **University of Amsterdam,** *The Netherlands*

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

Dr Maren von Fritschen, Regulatory Affairs, **European Confederation of Pharmaceutical Entrepreneurs (EUCOPE),** *Belgium*

Dr Michelle Longmire, Founder and Chief Executive Officer, **Medable,** *USA*

Dr Oren Cohen, Chief Medical Officer and Head of Clinical Pharmacology Services, **Covance,** *USA*

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

Dr Sarah Blagden, Associate Professor of Medical Oncology, University of Oxford, Lead Author of the **ECMC Consensus Paper,** *UK*

Dr Sol Yates, Associate Director Global Regulatory Affairs, **Grünenthal GmbH,** *Germany*

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

Elinor Olesen, VP DM Change Management, **Novo Nordisk,** *Denmark*

Elizabeth Eagling-Vose, Senior Director, Head of Clinical Operations, **Vaccitech,** *UK*

Faisal Shahzad, Project Manager (EU), **Greenphire,** *UK*

Francis P. Crawley, Executive Director, **Good Clinical Practice Alliance - Europe (GCPA) & Strategic Initiative for Developing Capacity in Ethical Review (SIDCER); Leuven/Brussels,** *Belgium*

Helen Todman, Associate Project Director, **Parexel International,** *UK*

Janis A. Little, Vice President, R&D Quality, **Moderna, Inc.,** *USA*

Jennifer Goldsack, Executive Director, **Digital Medicine Society (DiMe),** *USA*

Jennifer Logue Nielsen, Process Development Specialist, **Novo Nordisk,** *Denmark*

Joana Claverol Torres, Clinical Research Unit Manager, **Hospital Sant Joan de Déu**

Joanne North, Analytics Lead, Metrics, Reporting and Analytics, BioResearch Quality and Compliance, **Johnson & Johnson,** *UK*

Julianne Hull, CEO, **WenStar Enterprizes,** *UK*

Kai Langel, Director, **Janssen Clinical Innovation (JCI), Janssen,** *Spain*

Karen Maduschke, Senior Director & General Manager, Patient Consent, **IQVIA Technologies,** *Germany*

Karin Tulzer, Global Quality Strategy Lead, **Merck KGaA,** *Austria*

Kevin Landells, Vice President, Project Management at Cenduit, Head of Global Project Management and Helpdesk, **IQVIA,** *UK*

Kristof Van Quathem, Of Counsel – Advocaat, **Covington & Burling LLP**

Mairéad Lyons, Group Lead, Clinical Project Management, **Novartis,** *Ireland*

Maria Kuthning, Executive Global Clinical Operations - Digital Transformation, **Formerly Johnson & Johnson,** *Germany*

Mariangela Lupo, Communication and Patient Advocacy Manager, **TEDDY European Network of Excellence for Paediatric Research,** *Italy*

Marion Wolfs, Head/Senior Director Risk Management & Central Monitoring, **Janssen,** *The Netherlands*

Marta Garcia Manrique, Patient Officer-Clinical Development, Patient In R&D, **Servier International,** *Spain*

Maxime Schuchewytsch, Project Management Consultant at Cenduit, Head of System Design Centre of Excellence, **IQVIA,** *Switzerland*

Michael Walega, Director, Centralized Monitoring, Global Data Management & Centralized Monitoring, **BMS,** *USA*

Michel Arnoult, Chairman, **Arnoult.org,** *France*

Nicholas Brooke, Executive Director, **PFMD (Patient Focused Medicines Development,** *Belgium*

Nicklas Linz, Researcher, **German Research Centre for Artificial Intelligence (DFKI),** *Germany*

Nurcan Coskun, Global Risk Based Monitoring Program & Technology Solutions Manager, formerly **Medtronic Plc.,** *Switzerland*

Olivia Barnes, Senior Research Nurse, **Sherbourne Medical Centre,** *UK*

Pamela Tenaerts, Executive Director, **Clinical Trials Transformation Initiative (CTTI),** *USA*

Professor Hans van Delden, Prof in Medical Ethics, Vice-Chair, The Central Committee on Research Involving Human Subjects (CCMO), **Utrecht University,** *Amsterdam*

Professor Hans van Delden, Prof in Medical Ethics, Vice-Chair, The Central Committee on Research Involving Human Subjects (CCMO), **Utrecht University,** *The Netherlands*

Professor Kenneth Getz, Deputy Director and Professor, Tufts Center for the Study of Drug Development, **Tufts University School of Medicine,** *USA*

Ralphael Oghagbon, Health Economist, **Imperial College Health Partners,** *UK*

Rasmus Hogreffe, VP, Decentralized Clinical Trial Innovation, **Medable,** *USA*

Richard Stephens, National Cancer Research Institute Consumer Forum, Former Clinical Trial Participant, *UK*

Rosamund Round, Vice President, Patient Innovation Center, **Parexel**

Sebastian Stratmann, Senior Manager Clinical Innovation, **Merck Healthcare KGaA Biopharma,** *Germany*

Sheuli Porkess, Executive Director Research Medical & Innovation, **Association of the British Pharmaceutical Industry (ABPI),** *UK*

Stefan Dürr, Senior Director, Client Delivery at **Cenduit**, Head of Drug Supply Center of Excellence, **IQVIA,** *UK*

Stephen Walker, Outsourcing Programme Director, Alliance Management, **AstraZeneca,** *UK*

Todd Georgieff, Global Consortia Program Lead, **Genentech and Roche,** *Canada*

Virginie van de Velde, Senior Manager Oversight Data Manager, **GSK,** *Belgium*

Zach Hales, Product Manager (US), **Greenphire,** *USA*

11:00	**Opening to Clinical Trials Europe** **Louisa Maitland,** Conference Director, **Informa**
11:05	**Chairperson's Opening Plenary Remarks** **Professor Kenneth Getz,** Deputy Director and Professor, Tufts Center for the Study of Drug Development, **Tufts University School of Medicine,** *USA*
	OPENING PLENARY: COVID-19 – IMPACT ON CLINICAL DEVELOPMENT
11:15	**Changes and challenges to clinical trials during and after a worldwide pandemic** **Janis A. Little,** Vice President, R&D Quality, **Moderna, Inc.**, *USA*
11:35	**Biotech experience of the rapid and nimble acceleration of clinical programmes in the light of SARS CoV2** **Elizabeth Eagling-Vose,** Senior Director, Head of Clinical Operations, **Vaccitech,** *UK*
11:55	**Vaccine acceptability** **Professor Robert Dingwall,** Professor of Sociology, **Nottingham Trent University,** *UK*
12:15-13:15	**LIVE Virtual Hub Networking, Tech Tours and Roundtable Discussions** • 12:15: **Tech Tour - Medidata** • 12:20: **Tech Tour- ERT** • 12:25: **Tech Tour- Kayentis**
13:15	**Change of operational model during COVID-19 pandemic** **Dr Bodo Lutz,** Clinical Risk Management and Data Integrity QA, **Novartis Global Development Quality,** *Germany*
13:35	**Effects of an unpredictable pandemic on clinical trials and the need for virtualization** **Anthony Costello,** Senior Vice President, **Medidata, USA**
13:55	**LIVE Panel, Q&A and Audience Interaction Combating Coronavirus – Lessons learnt and challenges ahead** MODERATOR: **Pamela Tenaerts,** Executive Director, **Clinical Trials Transformation Initiative (CTTI),** *USA* **Elizabeth Eagling-Vose,** Senior Director, Head of Clinical Operations, **Vaccitech,** *UK* **Professor Robert Dingwall,** Professor of Sociology, **Nottingham Trent University,** *UK* **Dr Bodo Lutz,** Clinical Risk Management and Data Integrity QA, **Novartis Global Development Quality,** *Germany* **Oren Cohen**, Chief Medical Officer and Head of Clinical Pharmacology Services, **Covance,** *USA* **Fiona Maini,** Principal - Global Compliance and Strategy, **Medidata,** *UK* **Janis A. Little,** Vice President, R&D Quality, **Moderna, Inc.,** *USA*
14:55-15:55	**LIVE Virtual Hub Networking, Tech Tours and Roundtable Discussions** • 14:55: **Tech Tour- SureClinical** • 15:00: **Tech Tour- Medullan** • 15:05: **Tech Tour- Covance**
15:55-16:35	**LIVE Networking Reception: Mixologist – Welcome Cocktails to Start the Week!**
16:35	*End of Day One*

DAY TWO • Tuesday 3rd November 2020

	Partnerships and Outsourcing in Clinical Trials		Operations in Clinical Trials		Technology in Clinical Trials	
09:30	Start your day with Yoga and Relaxation					
10:00	**Welcome to Day Two of Clinical Trials Europe** **Louisa Maitland,** Conference Director, **Informa**					
	LEAN METHODOLOGY	**PRIVACY AND DATA PROTECTION**	**PATIENT RECRUITMENT & RETENTION**	**NEW INNOVATIVE TRIAL DESIGN**	**DECENTRALIZED/HYBRID TRIALS**	**ARTIFICIAL INTELLIGENCE, MACHINE LEARNING & DATA MANAGEMENT**
10:05	**How to reduce the lead time and improve the DM processes using a lean methodology approach** **Virginie van de Velde,** Senior Manager Oversight Data Manager, **GSK,** *Belgium*	**GDPR: General overview, implementation, debated issues and learnings so far** **Kristof Van Quathem,** Of counsel – advocaat, **Covington & Burling LLP,** *Belgium*	**The future of research in primary care and collaborations with primary care federations/primary care networks to facilitate recruitment** **Dr Andre Krzeminski,** R&D Lead, **Albany House Research,** *UK*	**Collaborative working from the very start –view from a primary care site perspective.** **Olivia Barnes,** Senior Research Nurse, **Sherbourne Medical Centre,** *UK*	**Remote informed consent and reconsents: A critical building block for your unique DCT strategy** **Rasmus Hogreffe,** VP, Decentralized Clinical Trial Innovation, **Medable,** *USA*	**A real world evaluation using NHS data to compare 100% remote digitally-enabled Type 2 Diabetes structured education & behaviour change programmes Vs face to face Type 2 diabetes structured education programmes** **Ralphael Oghagbon,** Health Economist, **Imperial College Health Partners,** *UK*
10:25	**How can Quality Tolerance Limits support COVID-19 impact assessments** • What are QTLs **Marion Wolfs,** Head/Senior Director Risk Management & Central Monitoring, **Janssen,** *The Netherlands*	**REGULATORY UPDATES** **EU Clinical Trials Regulation; An update of the current status and some thoughts on its implementation** **Dr Sol Yates,** Associate Director Global Regulatory Affairs, **Grünenthal GmbH,** *Germany*	**The application of data Science in Feasibility - how to get a better predictability of average recruitment and retention rate?** **Danny Hasselbaink,** Global Feasibility Lead, **Janssen Biologics B.V.,** *The Netherlands*	**eCOA setup: How to ensure a successful launch by navigating complexities** **Estelle Haenel,** Medical Director, **Kayentis,** *France*	**Novo Nordisk's learnings from implementing DTP (Shipment of IMP from site to patients' home)** **Birgitte Denlow,** GCP Advisor Specialist, Global Clinical Quality & Intelligence, **Novo Nordisk A/S,** *Denmark*	**The ethics of clinical trials and the ethics of AI: Establishing real-world common ground between researchers and patients** **Francis P. Crawley,** Executive Director, **Good Clinical Practice Alliance - Europe (GCPA) & Strategic Initiative for Developing Capacity in Ethical Review (SIDCER); Leuven/Brussels,** *Belgium*
10:45	**Conducting clinical trials during the COVID-19 pandemic** **Mariska Beukers,** Director Project Management, **QPS,** *The Netherlands*	**Spotlight Presentation** *Please contact:* Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar	**Innovative trial design during COVID-19** **Covance**	**Setting up COVID-19 clinical trials during the pandemic** **Dominiek Staelens,** Global Clinical Marketing Manager, **SGS Lifesciences,** *Belgium*	**How current decentralized studies will influence clinical research? Where we are and where we need to be.** **Alexandre Malouvier,** Director Global Data Strategy, **PRA Healthsciences,** *France (10 Minute Presentation)*	**Title TBC** **Dr Prakriteswar Santikary,** Chief Data Officer, **ERT,** *USA*
11:05-12:05	**LIVE Virtual Hub Networking, Tech Tours and Roundtable Discussions**					
11:05	**Tech Tour: Improving clinical research access: Lessons learned from minority patient and physician feedback** **Rosamund Round,** Vice President, Patient Innovation Center, **Parexel**					
11:10	**Tech Tour: Delivering patient centric decentralised trials in 2020** **Alison Holland,** Head of Decentralized and Remote trials, **Medable,** *UK*					
11:15	**Tech Tour: Trilogy Writing & Consulting**					

DAY TWO • Tuesday 3rd November 2020

	Partnerships and Outsourcing in Clinical Trials		Operations in Clinical Trials		Technology in Clinical Trials	
	DIVERSITY	REGULATORY UPDATES	SITE SELECTION	REAL WORLD EVIDENCE & REAL WORLD DATA	DECENTRALIZED/HYBRID TRIALS	ARTIFICIAL INTELLIGENCE, MACHINE LEARNING & DATA MANAGEMENT
12:05	**Quantifying participant diversity in clinical trials** **Professor Kenneth Getz,** Deputy Director and Professor, Tufts Center for the Study of Drug Development, **Tufts University School of Medicine,** *USA*	**What is the Regulators' view on the future of clinical research** **Nikolai Brun,** Director of Division, Chair HMA-EMA Taskforce on Big Data, Copenhagen Area, Capital Region, **Denmark Medical Evaluation and Biostatistics, DKMA,** *Denmark*	**How research sponsors can support sites to adopt new technologies to deliver excellence in clinical research** **Jennifer Logue Nielsen,** Process Development Specialist, **Novo Nordisk,** *Denmark*	**Real world trials and RWD in trials and healthcare data related topics** **Amanda Lucas,** Programme Director, **Imperial College,** *UK*	**Decentralized clinical trials – The strategic approach** **Todd McGrath,** Vice President of Project Management and Head of US and Oceania, **Medical Research Network,** *USA*	**Deep machine understanding and predictive modeling of clinical trial quality data to drive consistency and efficiency** **Deepak Bandyopadhyay,** Associate Director of Quality Analytics, **Janssen,** *USA*
12:25	**Partnerships in the pandemic: Deploying eConsent for remote and hybrid studies** **Karen Maduschke,** Senior Director & General Manager, Patient Consent, **IQVIA Technologies,** *Germany*	**Spotlight Presentation** Please contact: Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar	**Optimizing the entire clinical trial financial lifecycle through automation** **Zach Hales,** Product Manager, **Greenphire,** *USA* **Faisal Shahzad,** Product Manager, **Greenphire,** *USA*	**Title TBC** **Matthew McCarty,** Vice President & General Manager, **ERT,** *UK*	**Spotlight Presentation** **TCS**	**Spotlight Presentation** Please contact: Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar
12:45	**LIVE Panel, Q&A and Audience Interaction** **Regulatory challenges for clinical trials** MODERATOR: **Dr Maren von Fritschen,** Regulatory Affairs, **European Confederation of Pharmaceutical Entrepreneurs (EUCOPE),** *Belgium* **Dr Sol Yates,** Associate Director Global Regulatory Affairs, **Grünenthal GmbH,** *Germany* **Kristof Van Quathem,** Of counsel – advocaat, **Covington & Burling LLP,** *Belgium*		**LIVE Panel, Q&A and Audience Interaction:** **Ensuring a good recruitment strategy - How to successfully recruit patients** MODERATOR: **Diana Sims-Silbermann,** Specialist General and Emergency Medicine, Anesthesie, SeniorTrial Manager, Early Development and Clinical Pharmacology, **Janssen-Cilag GmbH, Johnson & Johnson** **Dr Philipp Badorrek,** Head of Department, Clinical Airway Research, **Fraunhofer Institute for Toxicology and Experimental Medicine ITEM,** *Germany* **Olivia Barnes,** Senior Research Nurse, **Sherbourne Medical Centre,** *UK* **Dr Estrella García,** Director Global Clinical Operations, Global Clinical Operations – R&D, **Almirral,** *Spain* **Amelia Hursey,** Research Participation Lead, **Parkinson's,** *UK*		**LIVE Panel, Q&A and Audience Interaction:** **Interaction between all stakeholders on decentralized trials** MODERATOR: **Maria Kuthning,** Executive Global Clinical Operations - Digital Transformation, **Formerly Johnson & Johnson,** *Germany* **Ahmed Albaiti,** CEO and Founder, Medullan, USA **Matthew Bonam,** Head of R&D Digital, AstraZeneca R&D, UK **Birgitte Denlow,** GCP Advisor Specialist, Global Clinical Quality & Intelligence, **Novo Nordisk A/S,** *Denmark* **Jennifer Goldsack,** Executive Director, **Digital Medicine Society (DiMe),** *USA* **Rasmus Hogreffe,** VP, Decentralized Clinical Trial Innovation, **Medable,** *USA*	
13:45-14:45	**LIVE Virtual Hub Networking, Tech Tours and Roundtable Discussions** • 13:45: **Tech Tour - Clinscience** • 13:50: **Tech Tour - SGS** • 13:55: **Tech Tour - Tata Consultancy Services (TCS)**					
13:45-15:05	**Tech Tours** Please contact: Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar		**Tech Tours** Please contact: Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar		**Tech Tours** Please contact: Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar	

DAY TWO • Tuesday 3rd November 2020

	Partnerships and Outsourcing in Clinical Trials		Operations in Clinical Trials		Technology in Clinical Trials	
	RISK BASED EVERYTHING	REGULATORY UPDATES	PATIENT ENGAGEMENT & CENTRICITY	PAEDIATRICS	DECENTRALIZED /HYBRID TRIALS	DATA FLOW AND ANALYTICS
14:45	**Embedding quality holistically: How do quality risk management and risk based monitoring work together?** **Michael Walega,** Director, Centralized Monitoring, Global Data Management & Centralized Monitoring**, BMS,** *USA*	**European Medical Device Regulation - May 2020- what will be the requirements?** **Nurcan Coskun,** Global Risk Based Monitoring Program & Technology Solutions Manage**r, Formerly Medtronic Plc.,** *Switzerland*	**The importance of giving feedback to patients and results about the transparency of the clinical work** **Amelia Hursey,** Research Participation Lead, **Parkinson's** UK	**The Patient Centricity Effect – How it benefits patients, sites and sponsors – Practical cases from paediatric studies** **Mariangela Lupo,** Communication and Patient Advocacy Manager, **TEDDY European Network of Excellence for Paediatric Research,** *Italy*	**How digital health technology will shape the trials of 2030** **Pamela Tenaerts,** Executive Director, **Clinical Trials Transformation Initiative (CTTI),** *USA*	**What's really needed to transform information flow in clinical development** **Todd Georgieff,** Global Consortia Program Lead, **Genentech and Roche,** *Canada*
15:05	**The Suppliers perspective- What makes a good sponsor?** **Willie Muehlhausen,** Managing Director/Founder, **Muehlhausen Ltd,** *Ireland*	**Covid-19 related impact on drug development in the EU?** **Dr Maren von Fritschen,** Regulatory Affairs, **European Confederation of Pharmaceutical Entrepreneurs (EUCOPE),** *Belgium*	**PATIENT ENGAGEMENT & CENTRICITY** **Regulatory expectations of working with audit trails** **Jennifer Logue Nielsen,** Process Development Specialist, **Novo Nordisk,** *Denmark*	**Pilot study/simulation using paediatric patients input in clinical trial development** **Joana Claverol Torres,** Clinical Research Unit Manager, **Hospital Sant Joan de Déu,** *Spain* **Begonya Nafria Escalera,** Patient Engagement in Research Coordinator, **Hospital Sant Joan de Déu,** *Spain*	**Taking a people-first approach to decentralised trials technology** **Bruce Hellman,** CEO and Co-Founder**, uMotif,** *UK*	**Regulatory challenges of using of new technologies in clinical trials** **Michel Arnoult,** *Chairman,* **Arnoult.org,** *France*
15:25	**Managing Complexity: COVID-19 Road to Recovery** **Graham Ilsley,** Vice President Global Clincal Delivery, **Covance,** *UK* **Monica Malcarne,** Site Head, Senior Director Operations and Board President, **Covance,** *Switzerland* **Oren Cohen,** Chief Medical Officer and Head of Clinical Pharmacology Services, **Covance,** *USA*	**Spotlight Presentation** Please contact: Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar	**Spotlight Presentation: Syneos**	**Spotlight Presentation: Aparito**	**Learnings from a paediatric decentralised clinical trial** **Helen Todman,** Associate Project Director, **Parexel International,** *UK*	**Spotlight Presentation** Please contact: Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar
15:45-16:30	**LIVE Networking Activity: Clinical Trials Europe Quiz Sponsored by Covance** **Test your Knowledge and WIN PRIZES**					
16:30	*End of Day Two*					

DAY THREE • Wednesday 4th November 2020

10:00 **Welcome to Day Two of Clinical Trials Europe** **Louisa Maitland,** Conference Director, **Informa**

Partnerships and Outsourcing in Clinical Trials

DIFFERENT PARTNERSHIP APPROACHES

10:05 **Good partnership relationship with industry and investigator site with an Investigator initiative trial**
Dr Wolfgang Eglmeier, Head ZKS-UW/H (Centre for Clinical Studies), **Witten/Herdecke University,** *Germany*

10:25 **SUSTAINABILITY**

Environmental sustainability - Novartis
Mairéad Lyons, Group Lead, Clinical Project Management, **Novartis,** *Ireland*

10:45 **Spotlight Presentation**
Please contact: Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar

INSPECTIONS

10:05 **Inspection preparation -conduct, organisation and managing a Regulatory Inspection and hear experiences of inspections**
Karin Tulzer, Global Quality Strategy Lead, **Merck KGaA,** *Austria*

10:25 **Facilitating optimisation of the performance of clinical trials through enhanced analysis of data from audits and inspections of clinical trials**
Joanne North, Analytics Lead, Metrics, Reporting and Analytics, BioResearch Quality and Compliance, **Johnson & Johnson,** *UK*

10:45 **Industry research highlights the latest trends and strategies to modernize clinical operations**
Pinar Bérénice Bénet, Senior Director Strategy, Clinical Operations, Veeva Systems, **Veeva,** *France*

Operations in Clinical Trials

PATIENT ENGAGEMENT & CENTRICITY

10:05 **Conducting clinical trials with COVID-19**
Amer Alghabban, Senior Director, Clinical Compliance and Training, **Freeline Therapeutics,** *UK*

10:25 **Impact of patient centered initiatives in clinical trial design and execution**
Sebastian Stratmann, Senior Manager Clinical Innovation, **Merck Healthcare KGaA Biopharma,** *Germany*

10:45 **Spotlight Presentation**
Please contact: Nick Matthews: Nicholas.Matthews@informa.com +44 (0) 20 337 73905 if you are interested in participating as a speaker, panellist, moderator or hosting webinar

NEW INNOVATIVE TRIAL DESIGN

10:05 **Designing cancer trials for the 21st century**
Dr Sarah Blagden, Associate Professor of Medical Oncology, **University of Oxford,** Lead Author of the **ECMC Consensus Paper,** *UK*

10:25 **Regulator's perspective for complex clinical trials and innovative trial designs**
Beatrice Panico, Senior Medical Assessor, Clinical Trials Unit, **Medicines and Healthcare Products Regulatory Agency,** *UK*

10:45 **Manage for complexity – optimizing IRT design and management**
Maxime Schuchewytsch, Project Management Consultant, **Cenduit,** Head of System Design Centre of Excellence, **IQVIA,** *Switzerland*

Kevin Landells, Vice President, Project Management, **Cenduit,** Head of Global Project Management and Helpdesk, **IQVIA,** *UK*

Stefan Dürr, Senior Director, Client Delivery, **Cenduit,** Head of Drug Supply Center of Excellence, **IQVIA,** *UK*

Technology in Clinical Trials

DIGITAL HEALTH TECHNOLOGY

10:05 **Build a collaborative development framework for novel digital endpoints**
Kai Langel, Director, Janssen Clinical Innovation (JCI), **Janssen,** *Spain*

10:25 **An applied framework for evaluating connected sensor technologies**
Jennifer Goldsack, Executive Director, **Digital Medicine Society (DiMe),** *USA*

10:45 **Driving patient-centric trials: Moving beyond the hype**
Bola Oyegunwa, Product / Corporate Strategy & Innovation, **Covance,** *UK*

Gabrielle Monetti, Senior Director of Data Strategy and Integration, **Covance,** *UK*

ARTIFICIAL INTELLIGENCE, MACHINE LEARNING & DATA MANAGEMENT

10:05 **AI-powered recruitment of a digital readiness cohort for Alzheimer's Disease (AD)**
Nicklas Linz, Researcher, **German Research Centre for Artificial Intelligence (DFKI),** *Germany*

10:25 **Clinical applications of AI and automatic speech and language analysis with dementia patients to better detect early signs of cognitive decline as well as monitoring disease progression**
Alexandra König, Clinical Researcher, Memory Clinic at Nice University Hospital, **University of Côte d'azur, and INRIA Nice,** *France*

10:45 **Spotlight Presentation**
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	Partnerships and Outsourcing in Clinical Trials		Operations in Clinical Trials		Technology in Clinical Trials	
	DIFFERENT PARTNERSHIP APPROACHES	INSPECTIONS	PATIENT ENGAGEMENT & CENTRICITY	NEW INNOVATIVE TRIAL DESIGN	DIGITAL HEALTH TECHNOLOGY	ARTIFICIAL INTELLIGENCE, MACHINE LEARNING & DATA MANAGEMENT
11:05	**LIVE Panel, Q&A and Audience Interaction: Ensuring adequate oversight and overcoming the challenges of using external versus internal staff** Moderator: **Anna Matranga,** Managing Director, **AMC Alliances & Consulting,** *France* **Stephen Walker,** Outsourcing Programme Director, Alliance Management, **AstraZeneca,** *UK* **Karin Tulzer,** Global Quality Strategy Lead, **Merck KGaA,** *Austria* **Virginie van de Velde,** Senior Manager Oversight Data Manager, **GSK,** *Belgium*		**LIVE Panel, Q&A and Audience Interaction: KPI's (Key Performance Indicator) - Quality assessment if undertaking patient engagement correctly?** Moderator: **Nicholas Brooke,** Executive Director, **PFMD (Patient Focused Medicines Development),** *Belgium* **Sebastian Stratmann,** Senior Manager Clinical Innovation, **Merck Healthcare KGaA Biopharma,** *Germany* **Begonya Nafria Escalera,** Patient Engagement in Research Coordinator, **Hospital Sant Joan de Déu,** *Spain* **Marta Garcia Manrique,** Patient Officer-Clinical Development, Patient In R&D, **Servier International,** *Spain* **Mariangela Lupo,** Communication and Patient Advocacy Manager, **TEDDY European Network of Excellence for Paediatric Research,** *Italy* **Niraj Vyas,** Assistant General Manager, Life Sciences, **Tata Consultancy Services**, *India* **Paul Robinson,** European Lead, Patient Innovation, **MSD,** *UK*		**LIVE Panel, Q&A and Audience Interaction: What are the main challenges of AI and what advancements have been made?** Moderator: **Deepak Bandyopadhyay,** Associate Director of Quality Analytics, **Janssen,** *USA* **Dr Corrette Ploem,** Associated Professor, Amsterdam University Medical Centre, **University of Amsterdam,** *The Netherlands* **Michel Arnoult,** Chairman, **Arnoult.org,** *France* **Alexandra König,** Clinical Researcher, Memory Clinic at Nice University Hospital, **University of Côte d'azur,** and **INRIA Nice,** *France*	
12:05-13:05	**LIVE Virtual Hub Networking, Tech Tours and Roundtable Discussions**					
12:05-12:25	• 12:05: **Tech Tour - Egnyte** • 12:10: **Tech Tour -Medical Research Network (MRN)** • 12:15: **Tech Tour - Aris Global** • 12:20: **Tech Tour - Synevo/Medicover**					

DAY THREE • Wednesday 4th November 2020

	Partnerships and Outsourcing in Clinical Trials	Operations in Clinical Trials	Technology in Clinical Trials
	AFTERNOON PLENARY		
13:05	**Chairperson's Closing Plenary Remarks** **Bruce Hellman,** CEO and Co-Founder, **uMotif,** *UK*		
13:15	**Accelerating the drug development paradigm during and post pandemic** **Professor Kenneth Getz,** Deputy Director and Professor, Tufts Center for the Study of Drug Development, **Tufts University School of Medicine,** *USA*		
13:35	**BREXIT – What impact will this have on clinical trials in the UK?** **Sheuli Porkess,** Executive Director Research Medical & Innovation, **Association of the British Pharmaceutical Industry (ABPI),** *UK*		
13:55	**The future of precision medicine** **Anita Nelsen,** Senior Vice President and Head, Translational Medicine, **Parexel International,** *USA*		
14:15	**Clinical development's new normal: Lessons learned from decentralizing clinical trials** **Dr Michelle Longmire,** Founder and Chief Executive Officer, **Medable,** *USA*		
14:35	**LIVE Panel, Q&A and Audience Interaction The future of clinical trials** Moderator: **Julianne Hull,** CEO, **WenStar Enterprizes,** UK **Professor Kenneth Getz,** Deputy Director and Professor, Tufts Center for the Study of Drug Development, **Tufts University School of Medicine,** *USA* **Anita Nelsen,** Senior Vice President and Head, Translational Medicine, **Parexel International,** *USA* **Richard Stephens,** National Cancer Research Institute Consumer Forum, Former Clinical Trial Participant, *UK* **Sheuli Porkess,** Executive Director Research Medical & Innovation, **Association of the British Pharmaceutical Industry (ABPI),** *UK* **Kai Langel,** Director, Janssen Clinical Innovation (JCI), **Janssen,** *Spain*		
15:35-16:35	**LIVE Virtual Hub Networking**		
16:35	**Christine Pierre Lifetime Achievement Award in Association with mdgroup** PRESENTED BY: **Tarquin Scadding-Hunt,** Chief Executive Officer, **mdgroup,** *UK*		
16:45	**Inspirational Speaker: Medical Aspects of Space travel** **André Kuipers,** Astronaut, Physician and Ambassador of **the Earth**		
17:45-18:45	**LIVE LIVE Virtual Hub Networking**		
18:45	*End of Conference*		

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