Partnerships in Clinical Trials Europe

28-29 November 2017
RAI Amsterdam

PARTNER YOUR WAY TO CLINICAL SUCCESS

The future of clinical trials is here

Keynote Speakers:

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Director, REshape Center for Health(care) Innovation, Radboud University Nijmegen Medical Centre, Netherlands

Matthew Bonam
Director, Intelligent Pharmaceuticals, AstraZeneca R&D, UK

Sheryl Jacobs
Vice President, Global Development, Amgen Inc, USA

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

Stephane Garelli
Professor of competitiveness (nations and enterprises), IMD Business School in Lausanne and University of Lausanne, Switzerland

Daisy Daeschler
Research Partnerships Officer, The Michael J Fox Foundation, USA

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Neurologist and Clinical Triallist, Kings College Hospital NHS Foundation Trust, UK

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Partnerships in Clinical Trials Europe

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Partnerships in Clinical Trials 2017 unites stakeholders from across the clinical spectrum to deliver expert knowledge so you can improve your clinical strategies

Discuss, debate and explore the following issues that have made headlines over the past 12 months

- The advances of mobile health and clinical technology: What does this mean for clinical research and what are the barriers?
- Myth busting – Overcoming the biggest hurdles for patient involvement in clinical research
- Are partnerships living up to what they promised in terms of cost, efficiency and service quality? What is a typical Partnership in the 21st Century?
- Defining strategies and the end to end process for vendor management – How to qualify vendors and ensure they deliver on what they promise?
- Regulatory updates – ICH E6 Addendum: What will this mean for Clinical trials and what are the implications for the industry?
- Assessing the performance of oversight and governance models: How much is enough?
- How to incorporate the patient perspective into clinical trials, how to operationalise a process for this
- How to attract funding of rare disease and how to engage more pharmaceutical companies in this field?

What can you expect from PCT 2017?

- New Streams for 2017: Mobile Health - What are the quality and regulatory implications from acquiring data from wearables and smartphones? And Investigator and Industry how can they work together? - Site Support- How to drive down administration whilst ensuring compliance?
- Supplement your time out of the office with a Briefing Day on the outsourcing and partnering forum and three Pre-Conference Workshops: • Making new treatments more patient focused  
  - Clinical trial budget management  
  - Forecasting and project management and conflict and communication
- Join the Innovation Den and find out about novel technology and processes that can help you and your company in the clinical trial process
- Stephane Garrelli a leading economist from IMD Business School in Lausanne, and University of Lausanne, will give an opening plenary talk on "the new world competitiveness landscape and its impact on the pharmaceutical industry" with a particular focus on BREXIT and Trump - what impact on the European and Global landscape of clinical research
- The Financial Times recently declared it the most successful crowdfunded medical trial ever, a keynote presentation from Alexander Masters, Campaigner and Co-Founder of iCancer.org.uk on their story of how in eight months, thanks to 2,000 supporters £2million was raised to start their first clinical trial
- For decades Marc Koska OBE fought to stop the reuse of syringes. He is one of the most impressive and inspirational entrepreneurs in the world. Marc faced and broke down bureaucratic barriers to fight one of the most virulent contributors to the spread of AIDS, with his non-retractable syringe, which was endorsed by the World Health Organisation in 2015.
- Join an interactive PCMG Oxford Debate: This house believes that strategic partnerships are not fit for purpose. Which way will you vote?

This year PCT is taking place in Amsterdam, a great location for those wishing to stay on after the event. We look forward to welcoming you to the premier networking event in the clinical trial calendar

Louisa Maitland  
Conference Director

DUAL DIALOGUE  Two speakers will discuss how they have worked together including real-life data, what has gone wrong, and what has been learned.

INTERACTIVE HUBS  Look out for these hubs in the conference streams. Each session will be expert-led and deliver interactive discussions, workbooks, takeaway solutions and further action plans.

CASE STUDY  Speakers will divulge behind-the-scenes stories using real-life data, anecdotes, what went wrong and what has been learned. Each speaker will provide 3 key takeaways or action points in their final message.

PRESENTATION  Thought-leaders will reveal specialist knowledge on brand new innovations – delegates will discover how to implement these innovations in their own companies. Each speaker will provide 3 key takeaways or action points in their final message.

PANEL DISCUSSIONS  Panellists from various companies will put forward their thoughts on strategies, different models, different mind sets and different experiences on the same subject. The panel chair will provide 3 key takeaways or action points at the end of the session.
### Agenda at a glance

**CONFEREE DAY ONE: Tuesday 28th November 2017**

#### MORNING PLENARY

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>9:00</td>
<td>The world in reset mode: The new world competitiveness landscape and its impact on the pharmaceutical industry</td>
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<tr>
<td>9:40</td>
<td>The partnership landscape - New partnerships, new innovations, new processes</td>
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#### Partnerships in Clinical Trials Europe

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>11:00</td>
<td>Developing a risk and reward based clinical outsourcing strategy - &quot;make or buy&quot; process for the optimal definition of the outsourcing strategy</td>
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<td>11:30</td>
<td>A partnership collaboration from Bayer through setting up and implementing a global FSP strategy on a local level</td>
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<td>12:00</td>
<td>Eli Lilly and Covance clinical pharmacology: A partnership that has existed for more than 10 years</td>
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<td>14:00</td>
<td>Are partnerships living up to what they promised in terms of cost, efficiency and service quality?</td>
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<tr>
<td>16:00</td>
<td>Assessing the value of partnerships</td>
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<tr>
<td>16:30</td>
<td>Defining the resourcing strategy and the end to end process for vendor management</td>
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#### Early Clinical Development

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>11:00</td>
<td>New data and insights characterizing the changing CRO landscape and its role in integrating clinical research with clinical care</td>
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<td>11:30</td>
<td>Long term collaborations within a study program</td>
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<td>12:00</td>
<td>The importance of patient retention - recruit to retain</td>
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<tr>
<td>14:00</td>
<td>Informed consent and participant engagement in the age of digital platforms</td>
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<td>16:00</td>
<td>Future of investigator and industry collaboration</td>
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#### Clinical Trial Supply

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<thead>
<tr>
<th>Time</th>
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<tr>
<td>11:00</td>
<td>Using patients own devices to capture quality of life and other health data</td>
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<tr>
<td>11:30</td>
<td>Integrating two large vaccine companies: How to integrate the oversight of vendors?</td>
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<td>12:00</td>
<td>Using regulatory inspection trend data to optimize vendor qualification and management programs</td>
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<td>14:00</td>
<td>Experiences and lessons learned from conducting global mHealth enabled trials</td>
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<tr>
<td>16:00</td>
<td>Vendor oversight, challenges and regulatory frameworks</td>
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<tr>
<td>16:30</td>
<td>Site Support: How to drive down administration whilst ensuring compliance</td>
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### Lifetime Achievement Award

**Inspirational Talk: Marc Koska**
<table>
<thead>
<tr>
<th>Time</th>
<th>STREAM 5 Partnership Management</th>
<th>STREAM 6 Patients as Partners</th>
<th>STREAM 7 Disruptive Innovation, Technology and Big Data</th>
<th>STREAM 8 Small to Mid-Size Pharma and Biotech</th>
<th>STREAM 12 Regulatory and Science</th>
<th>STREAM 13 Operational Strategies – Patient Recruitment</th>
<th>STREAM 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:00</td>
<td>Future of healthcare: Integration of healthcare and research to better understand disease and improve health</td>
<td>Implementation of patient engagement in drug development</td>
<td>Opportunities to innovate in the way we collect data in clinical trials and how to manage volume, variety and veracity in a clinical study setting</td>
<td>Patient group and Pharmaceutical company collaboration - Experience of AKU Society collaborating with Sobi for the DevelopAKUre clinical trials</td>
<td>Modelling and biomarkers: The Role of Human Models of Disease State to Accelerate Early Clinical development in Healthy Volunteers and Patients</td>
<td>Patient Centricity and Patient Recruitment: Getting the balance right in the design of early phase patient studies</td>
<td>Case study: Best practice for selecting and managing relationships with new service providers in the clinical trial supply chain</td>
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<td>11:30</td>
<td>Maximizing outcomes in asset transfers</td>
<td>Sponsored talk by KCR</td>
<td>Sponsored talk by Bioclinica</td>
<td>Better trial management through clarity and collaboration</td>
<td>Role of PK/ PD Modeling in supporting design of FIH- trials of high risk molecules</td>
<td>Building unique partnerships to facilitate the transition from healthy volunteer to patient studies</td>
<td>GS1 perspective: Exploring how global standards can be used to address efficiency, accuracy and surety in the clinical trial supply chain</td>
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<td>12:00</td>
<td>PCMG Oxford Debate: This house believes that strategic partnerships are not fit for purpose</td>
<td>How to incorporate the patient perspective into clinical trials execution and how to operationalise a process for this Big Data - What to do with this data that is collected and how will it be analysed and leveraged?</td>
<td>Outsourcing and finding the ideal partner for a small to mid-size sponsor</td>
<td>Cell-based biomarkers as a means of confirming target engagement and mechanism in early clinical trials</td>
<td>Recruiting patients in early clinical development through effective collaborations</td>
<td>Highlighting the importance of quality sample management in the development of immunotherapies</td>
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<td>14:00</td>
<td>Sponsored talk by PRA</td>
<td>Working with patient groups for clinical research</td>
<td>The use of mHealth to study musculoskeletal disease</td>
<td>Challenges faced by Pharma companies during inspections from National Competent Authorities at clinical study sites</td>
<td>Translational Modeling in support to safety and efficacy assessment during early development</td>
<td>Presentation to be delivered by Quintiles</td>
<td>Identifying comparators for clinical trials in China: Challenges and resolutions</td>
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<td>14:30</td>
<td>Amgen has recently implemented a new FSP model of their clinical program management function, with our partner ICON</td>
<td>Virtual trial design and execution with an academic medical centre</td>
<td>Sponsored talk by Bracket Global</td>
<td>Patient funded trials</td>
<td>ICH guideline E14. Regulatory perspective on cardiac safety assessment</td>
<td>Patient recruitment presentation</td>
<td>Overcoming the challenges in designing the clinical trials for complex generics and innovative generics (new therapeutic entities)</td>
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<td>15:00</td>
<td>Sponsored Speaking Slot Available</td>
<td>Moving glioblastoma from terminal to treatable, powered by patients</td>
<td>Innovations in terms of clinical trial designs – the use of precision medicine in oncology</td>
<td>Cardio safety and the use of early trials data instead of the TQT trial</td>
<td>Patient-centric trial design: Involving patient groups in early clinical development</td>
<td>Exploring different blinding options for comparators</td>
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<tr>
<td>15:30</td>
<td>The Northern Health Science Alliance and application of real world data for clinical research</td>
<td>Myth busting – overcoming the biggest hurdles for patient involvement in clinical research</td>
<td>Commercialisation and business strategy: Delivering clinical evidence to support reimbursement and market access</td>
<td>How to attract funding of rare disease - How to engage more pharma companies in this field?</td>
<td>PANEL DISCUSSION: QT Prolongation: Implementation guidance for industry</td>
<td>Gene therapy for monogenic rare diseases: Early clinical development challenges</td>
<td>Using risk assessments and mapping tools for effortless temperature mapping studies</td>
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<td>15:50</td>
<td>Paediatric specificities for clinical research</td>
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**MORNING PLenary**

**CONFERENCE DAY TWO: Wednesday 29th November 2017**

- **Is disrupting health(care) the next frontier?**
- **The advances of mobile health and clinical technology: What does it mean for clinical research and what are the barriers?**
PRE-CONFERENCE WORKSHOP A  Monday 27th November

Briefing Day: The Outsourcing and Partnering Forum

09:00  Registration

09:55  Chairperson Opening Remarks

10:00  CASE STUDY: Patient engagement: What you need to know and what you need to do
• Engaging patients in clinical development needs to start early on
• Although there is not a straightforward recipe for success, there are key areas to focus on
• Patient Organizations can provide very useful input to support the planning and execution of clinical trials
• What are some of the considerations for involving patients in clinical trials
• How does indication and organizational size play a role in this?
  Nancy Meyerson-Hess, Associate Partner, admedicum
  Business for Patients, Previously Head of Clinical Operations & Compliance, Grunenthal, Germany

10:30  CASE STUDY: Partnerships with Pharma, CRO, and the NHS, with access to patients, ideas, data
  Caroline Potts, Head of Research and Development, Northumbria Healthcare NHS Trust, UK

11:00  Morning Break

11:30  CASE STUDY: Patient centricity in action at the largest fundraising medical research charity in the world – Cancer Research UK
• Implementation of an organisation-wide patient involvement strategy
• Challenges and opportunities for a patient centric approach in the early phase oncology trial setting
• Patients as key stakeholders in the development of trial protocols and informed consent documents
• Collection of feedback using a questionnaire patients complete mid-study
  Dr Stephen Nabarro, Head of Clinical Operations and Data Management, Cancer Research UK Centre for Drug Development, UK

12:00  Sponsored Speaking Slot Available
  Please contact: Alexander Zenonos
  +44 (0) 207 017 7742
  Alexander.zenonos2@knect365.com

12:30  Lunch

13:30  CASE STUDY: The Accidental HTA case
  Marleen Kaatee, Founding President, PSC Patients Europe, Netherlands

14:00  CASE STUDY: Home care visits in clinical trials – reduce the burden of study participation for your patients!
• How home care visits can be organized
• Which tasks can be offered in the home of the patients
• Benefits for patients and sites
• Effects on recruitment rates and retention
  Bettina Bergholdt, Managing Partner, Emovis GmbH, Germany

14:30  Afternoon Break

15:00  CASE STUDY: An industry perspective on third party contracting from PCMG
  Lan Bandara, Global Head of Outsourcing, Eisai Limited, UK

15:30  Title TBC
  Dorte Pedersen, Senior Outsourcing Manager, Lundbeck, Denmark

16:00  CASE STUDY: Clinical QMS – a conceptual framework
  The TransCelerate Quality Management System Initiative has identified potential benefits that could be captured from the development of a proactive and flexible conceptual framework focused on assisting an organization in creating a quality management system (QMS) designed to better manage and navigate its complex clinical trial environment. The Clinical QMS Conceptual Framework will ultimately serve as a resource to help expedite the drug development process and improve quality across the spectrum of clinical activities.
  James Muller, Head of Quality Management System Oversight, Medical Quality Assurance, Pfizer, UK

16:00  End of Workshop
Patient engagement, patient-centric and patient-focused are all terms that are now frequently used in the context of developing new treatments. But what do they mean? There is increasing evidence that effective patient engagement can improve the quality, relevance and success of research but often a lack of support, guidance and training to do so is a barrier to meaningful patient engagement. Many initiatives are now in place both nationally and internationally to break down the barriers to industry and patients working collaboratively to develop new treatments but there is more to be done. European Patients’ Academy of Therapeutic Innovation (EUPATI) is one of many training initiatives that have been developed to support patients to engage and work with the research and development community as well as with regulators and Health Technology Assessment (HTA). To compliment this type of exemplary training, Patient Focused Medicines Development (PFMD) and Parkinson’s UK have worked with a group of stakeholders including patients, pharmaceutical representatives, researchers and experts in the field of patient engagement to develop a practical and interactive training session to support industry representatives to work with patients.

This workshop will present evidence that patient engagement improves medicines research and development processes and benefits the stakeholders involved when done right, draw on case studies of best practice, and tackle practical questions of how to effectively involve patients to produce more targeted outcomes.

**Topics to be covered:**
- What do we mean by patient engagement and why is everyone talking about it?
- When to involve patients in R&D and how?
- What do we know about the practical impact of patient engagement?
- Planning your own patient engagement.
- Evaluating the impact of patient engagement.
- What support and resources are available?

**Who should attend:**
Anyone involved in the planning and design of research studies and clinical trials, and in particular, those who are not sure where to start patient involvement and engagement in medicines development continuum. This may also be suitable for people responsible for patient involvement and engagement as a tool to support their work.

**What will you gain from attending?**
The participants in the workshop will gain an understanding of the importance of involving patients in developing ideas in different aspects of research. They will gain some insight into the challenges and benefits of working with patients as well as practical information, advice and tools into how to meaningfully work with patients in this way.

**Workshop Leaders:**
Claire Nolan, Research Involvement Manager, Parkinson’s UK
Nicholas Brooke, Chief Executive, PFMD (Patient Focused Medicines Development) and The Synergist

**Guest speakers/co-leaders:**
David Gray, Senior Director, Neuroscience Research Unit, Pfizer, USA
Ben Cromarty, North Yorkshire AIDS Action (NYAA), UK
Community Advisory Board (UK-CAB), Medical Research Council
Clinical Trials Unit, University College London Patient and Public Involvement Group, UK
Pre-Conference Workshop C  Monday 27th November

Project Management in Clinical Trials and Conflict and Communication

09:00 Registration

MORNING: Advances in Project Management

09:55 Chairperson Opening Remarks
  Roger Joby, R. & N.R. Consulting Ltd.

10:00 CASE STUDY: Organisational Justice, (the perception of fairness), and its impact on project performance
  • Outsourcing in the construction industry
  Christine Unterhitzenberger, DBA Programme Leader, Liverpool John Moores University

10:30 DUAL DIALOGUE: Pain and gain risk sharing contracts
  • What can clinical research learn from the HS2 (High Speed Railway line)
  • How to introduce this contract into clinical research.
  • What can clinical research learn from HS2?
  Simon Taylor, Head of Programme Planning, HS2 Ltd and Roger Joby, R. & N.R. Consulting Ltd.

11:00 Morning Break

11:30 CASE STUDY: Agency problems and their impact on outsourced projects
  • Strategies for dealing with difficult stakeholders
  • 4 case studies 2 from construction and 2 from clinical research
  Professor David Bryde, Professor in Project Management, Liverpool John Moores University

12:00 Ask the Expert: Question and Answer

Current Project Management Research
  • Ideas on project success
  • Principle Agent Theory
  • Fairness in the workplace

PM Tools
  • Earned Value Management
  • Risk Analysis
  • Planning
  • Scheduling
  • Stakeholder engagement

Communication
  • The art of good communication
  • Leadership
  • Motivation

Outsourcing Models
  • Types of contracts
  • Lessons from other industries
  • Risk sharing models

PM Trends
  • Agile project management
  • The Digital Revolution

12:30 Lunch
AFTERNOON: Improving Communication and Conflict Awareness to Better Manage Yourself and Your Partnerships

Project Management in Clinical Trials and Conflict and Communication (continued)

13:30 to 16:30 **Aim of the workshop session**
As a participant to this workshop, we would like you to come prepared mentally with some prior examples of disputes and miscommunications. We will apply these to processes and tools in order to increase awareness of yourself when in disputes, how to manage your emotions and demonstrate that you are actively listening. Communicate what is important to you beyond blame or positions, with the objective to improve your communication and its impact both in and outside of the conflict circle.

**Content:**
- Communication – perception vs reality vs our identity/values
- Engaging with the complexity of conflict- Understanding the nature of disputes
- Conflict Disorientation - How people respond in conflict and how our communication changes - looking beneath the surface of disputes to understanding the impact on yourself and others
- Dispute exploration utilising the conflict circle– How conflict is expressed through our emotions, cognitions, behaviour and our verbal communication & identifying core fears and elements that distort our interaction
- Strategic questions to ask yourself/other at stages of the circle, how to practically increase information between parties, overcome conflict and optimise your understanding in a dispute
- The value of communication in re-framing the dispute
- Ingredients to enhance communication based on scientific and psychological principles- To constructively engage, manage, and resolve disputes

16:00 to 16:30 **Communication for Successful Negotiation – Jennifer Emerson**
All successful negotiations have one thing in common, nobody leaves the bargaining table feeling like they were taken advantage of. But how do you get there in today’s competitive environment where critical conversations sometimes focus more on personal agendas rather than on collective goals?
In this workshop, participants will learn actionable strategies. We will begin with the 3 steps all successful negotiators take to prepare for negotiations, including questions you should answer before you even sit down at the bargaining table. You will learn techniques to use during the negotiations to help you understand the other party’s position. This content also includes material to help participants understand the ways that culture can affect negotiations. This workshop offers strategies for before, during, and after the time you meet your negotiation partner at the bargaining table.

**Workshop Objectives**
Participants will be able to: use questions to prepare for any negotiation situation; evaluate which negotiation tools and techniques to use for best effect during different negotiation situations; and identify important follow up steps to ensure successful future negotiations

**Workshop Leaders:**
Anna Matranga, Strategic Sourcing R&D, Consultant, AMC Alliances & Consulting, France
Jennifer Emerson, Consultant, Emerson Consulting & Clinical Research Services, Germany
Clinical Trial Budget Management and Forecasting

Registration 09:00 · Start 10:00 · Finish 16:00

Introduction:
The pharmaceutical industry experiences difficulty in predicting spending for its most costly area - clinical development - and struggles to create accurate, realistic and stable clinical study budgets. This results in very high cost variances from baseline forecast to actual.

Topics to be covered:
• Trial Design – underlying cause of problems
• Feasibility and Patient recruitment – underinvested step
• Single study budget versus portfolio budget management
• Trial site negotiations – investigator needs
• Trial Site Compensation – What Trial Sites have to consider to work cost-effectively?
  o Site compensation: investigator perspective
  o Exploring budgeting, direct costs and indirect costs
• Change control and budget monitoring – to keep on track

Who should attend:
Clinical Trial Managers, Finance and Procurement Managers

What will you gain from attending?
During this workshop we will look into key aspects of clinical trial design and conduct and discuss what common mistakes are usually made that lead to failure of budget forecasting and how we can avoid it. We will discuss how to prepare and implement more strategic approach to budgeting and we will share best practice and knowledge from successful trials.

Workshop Leader:
Dr Frank Berger, Head, Study Budget CoE, Clinical Operations, Boehringer Ingelheim
Biomarkers in Early Clinical Development

9:00  Registration

10:00  Opening remarks from the Chair
Maria Burian, Associate Director, Innovation Unit Speciality Therapeutics, Grünenthal Group

10:15  Presentation to be delivered by CHDR

11:00  Morning break

11:30  Challenges of implementing biomarkers to early clinical development
- Why we need biomarkers in early clinical development
- Case studies where biomarkers have made a significant contribution to early phase studies
- Challenges; scientific for pharmacodynamics and patient selection
- Challenges; logistical, operational, sponsor, analysing lab and beyond
Sidath Katugampola, Biomarker Development Specialist, Centre for Drug Development, Cancer Research UK

12:15  Lunch

13:15  Biomarkers and translational research: Using biomarkers for early phase clinical trials to demonstrate the drug is doing what it is supposed to be doing
- Biomarker qualification process and regulatory data submission
- Biomarker utilization in stratified medicine
Maria Burian, Associate Director, Innovation Unit Speciality Therapeutics, Grünenthal Group

14:00  Immunoassay validation for a biomarker qualification process
- The IMI SAFE-T consortium approach for drug induced organ injury biomarker qualification in a public-private partnership
- Immunoassay validation for the quantification of biomarkers in clinical samples
- A generic scientific qualification strategy for translational safety biomarkers.
Dr. Thomas Joos, Deputy Managing Director, NMI

14:45  Summation panel

15:30  Chair’s closing remarks

15:45  End of workshop
PRE-CONFERENCE WORKSHOP F  Monday 27th November

Ensuring Temperature Controlled Distribution and Storage of your IMP

Registration 09:00 · Start 10:00 · Finish 16:00

Topics to be discussed will include:

Understanding how to guarantee efficient temperature controlled distribution of your IMP

• Exploring the current challenges surrounding ensuring effective temperature controlled distribution
• Overcoming these challenges within deadlines and with complex trial designs
• Reviewing latest technology available for collecting end-to-end temperature data records to eliminate risk of temperature excursions
• Outlining GDP requirements for temperature controlled distribution and implications for industry

Case study: Best strategies for ensuring temperature control at clinical sites

• Overcoming key challenges with ensuring efficient temperature control at clinical sites
• Ensuring clinical sites are equipped to deal with the specific temperature requirements of your IMP
• Assessing the steps which should be taken to ensure clinical sites remain compliant
• Outlining the technologies available to ensure better temperature control
• Providing sufficient evidence that products were never in a temperature outside their specification

Kate Chapman, Director, Clinical Technology Consultants Ltd, UK
Jeroen Gerritsen, Clinical Supply Chain Expert, Geronimo Consultancy, The Netherlands
07:30 Registration and Morning Coffee

08:50 Opening remarks from the Chairperson
Anna Matranga, Strategic Sourcing R&D, Consultant, AMC Alliances & Consulting, France

09:00 The world in reset mode: The new world competitiveness landscape and its impact on the pharmaceutical industry

- BREXIT and Trump - what impact this will have on the European and Global landscape of clinical research?
- Skepticism about globalisation increases the complexity of managing enterprises globally.
- Governments’ debt, escalating social expenses, low or negative yields, new international taxation rules, extensive compliance and market consolidation heavily impact on business prospects and confidence levels.
- Many positive developments exist such as new players and new brands from emerging economies, new market segments and new technology-driven business models.
- Competitiveness will also be a question of mindset. The management of efficiency, change, and complexity remain top priorities. A mindset of imagination (why not?), of energy (why not now?) and of commitment (why not me?) will also be decisive. How?

Stephane Garelli, Professor of competitiveness (nations and enterprises), IMD Business School in Lausanne and University of Lausanne, Switzerland
10:55 Opening remarks from the Chairperson

09:40 PANEL: The Partnership Landscape - New partnerships, new innovations, new processes:

• News flash over the 12 months: significant changes and news from the panel’s perspective

• Industry’s and CRO’s greatest challenges and exploring the next generation of future collaborations that will be needed

• Partnerships – are we seeing any new trends across industry when it comes to partnering strategy?

• Next Generation Risk-Based Monitoring models and partnerships

• Across industry harmonisations: How can partnerships benefit from more standardization? Where is the competitive advantage?

Moderator: Phil Hammond, GP and Broadcaster, UK

Barbara Voith, Vice President, Head Global CS Operations, Bayer HealthCare, Germany

Sheryl Jacobs, Vice President, Global Development Operations, Amgen Inc, USA

Anthony Johnson, SVP, Early Clinical Development, UK

INC

Inventiv

10:20 Morning Coffee and Networking
CONFERENCE STREAM 1  Day One • Tuesday 28th November

Partnerships and Collaboration

10:55 Opening remarks from the Chairperson
Dr. Raphaele Mary, Director, Capability and Strategy, Central Clinical Planning & Solutions, Global Clinical Operations, Bristol-Myers Squibb, France

KEYNOTE
11:00 CASE STUDY: New data and insights characterizing the changing CRO landscape and its role in integrating clinical research with clinical care
- Overview of drug development enterprise trends and the necessity to move into clinical care
- Insights into CRO segment strategies and their role in supporting the evolution of the drug development enterprise
- Review of data characterizing structural CRO landscape changes
- Profiles of innovative transactions redefining the positioning of major CROs
- Discussion of patient engagement technologies and solutions supporting landscape evolution

Professor Ken Getz, Director, Tufts Center for the Study of Drug Development, Tufts University (CSDD), USA

11:30 PRESENTATION: Developing a risk and reward based clinical outsourcing strategy - "make or buy" process for the optimal definition of the outsourcing strategy
- Current Drug Development framework
- The "Make or Buy" decision in context
- Key process steps
- Core competencies analysis
- Risk analysis
- Costs and Resources analysis
- Risks and rewards of your outsourcing strategy

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

12:00 SPONSORED CASE STUDY
PRA

12:30 Lunch

14:00 JOINT CASE STUDY: Eli Lilly and Covance Clinical Pharmacology: A partnership that has existed for more than 10 years
- Historical review of how the partnership started
- Success of the partnership (including some key metrics)
- Issue management and challenges
- What makes this a unique relationship
- Why is this successful from Lilly and Covance’s point of view?
- Potential for the future

Dr Tamzin Blagbrough, Sourcing Consultant, Clinical Pharmacology Study Delivery Solutions, Eli Lilly and Company Limited, United Kingdom
Ted Broering, Vice President & Global Head, Covance, USA

14:30 PANEL: Are partnerships living up to what they promised in terms of cost, efficiency and service quality?
- What is a typical Partnership in the 21st Century?
- How to improve transparency between CRO and sponsors: How to align systems, avoid duplicating work and manage mergers and acquisitions
- Delivering a clinical trial? Do we both have the same goal?
- What are the cultural difference between CRO and Pharma?
  How do you bridge these cultural differences?
- Why partnerships don’t always work: Why did it fail and what could have been done to avoid this?
- What type of communication is needed to get the best of the partnership?
- Vendor oversight and expectations to degree of outsourcing.
- Examples of partnerships that survived challenging times and how this was done

Julianne Hull, Chief Executive Officer, WenStar, UK
Nicole Jansen, Senior Outsourcing and Contract Manager, Grunenthal GmbH, Germany
Isabelle Naëije, Clinical Trial Head, GDO Trial Management Oncology, Novartis Pharma AG, Switzerland
Birgitte Søgaard, Divisional Director, Clinical & Quantitative Pharmacology, H. Lundbeck A/S, Denmark
INC Research

15:10 Afternoon Break
16:00 **KEYNOTE PRESENTATION: How to evaluate partnerships, i.e. value-for-money, value-for-people, value-for-future.**

- Partnerships in the context of globalization and SDGs
- Are partnerships evaluable?
- Value for money and value for people

**Dr Michael Mihut,** Portfolio Management Officer, The Special Programme for Research and Training in Tropical Diseases, World Health Organization, Switzerland

16:30 **PANEL: Defining resource strategy and the end to end process for vendor management**

- How to select the right type of service that you want to outsource
- Discuss the type of model - FSO (Full Service Outsourcing) over FSP (Full Service Provider)
- How to qualify vendors and ensure they deliver on what they promise
- How to define and implement the right oversight (including performance measurement)
- How to manage a huge number of vendors
- What makes a good performance measures and how do you assess quality?
- How can you check up front whether a CRO can deliver on what they promise?

**Anne Merritt,** Director, R&D Supplier Governance and Clinical Pricing, Amgen, UK

**Stephen Walker,** Outsourcing Programme Director (SGT lead), AstraZeneca, UK

**Laurent Zecchinon,** Strategic Partners & Resourcing Strategy, GlaxoSmithKline, USA

**Dr MaryAnne Rizk,** Global Vice President, CRO & Biopharma Business Partnerships & Alliances, Oracle Health Sciences, UK

**Mark Scullion,** SVP, Strategic Resourcing, inVentiv Health, USA

17:10 Move to Plenary Room

17:15 **Lifetime Achievement Award**

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18:00 Join us for the PCT drinks and networking party
CONFERENCE STREAM 2  Day One • Tuesday 28th November

Investigator and industry – How can they work together?

10:55 Opening remarks from the Chairperson
Paul Quinn, VP - Clinical Operations, Vectura Limited, a member of the Vectura Group of companies, UK

11:00 CASE STUDY: Long term collaborations within a study program
- Site collaboration instead of project contracts
- Harmonisation of contracts, training and procedures
- Roles in clinical research. The investigator investigates, the recruiter recruits and the coordinator completes documents.
- Statistical rationale; why is it better to have 10 sites recruiting 10 subjects versus 50 sites recruiting 2 subjects

Peter Van Der Ark, Clinical Research Manager, Experimental Medicine Neuroscience, Janssen – Pharmaceutical Companies of J&J, Belgium

11:30 JOINT PRESENTATION: CASE STUDY: The Importance of patient retention - recruit to retain
- Importance of a thorough informed consent
- What motivates patients to take part in Clinical Trials
- What motivates patients to remain in a trial if IMP is discontinued
- Patient incentives

Kate O’Brien, Senior Research Nurse, Albany House Medical Centre, UK
Amanda Perry, Research Practitioner, Albany House Medical Centre, UK

12:00 PANEL: Cost savings realized with an integrated budget to payments solution
- Investigator Payment challenges realized by each stakeholder (sites, CROs and Sponsors)
- How each stakeholder can benefit from a true end-to-end budget to payment solution
- Process cycle time reduction
- Manual or duplicate data entry elimination
- Support for visit and procedure based negotiations and payments
- Traceability and reporting clarity with one data stream between budget negotiation, EDC and payment
- Auditable, real-time tracking of accrued costs against the budget schedule
- On-demand funding to eliminate cash escrow account

Moderator: April Mulroney, Managing Director, Medidata Payments, Medidata Solutions, USA
Anne Merritt, Director, R&D Supplier Governance and Clinical Pricing, Amgen, UK
Victoria Moore, VP, Investigator Payment, INC, USA

14:00 CASE STUDY: Informed consent and participant engagement in the age of digital platforms
- Consenting in the modern clinical trial
- The demographic bias – digital versus non-digital populations
- The clinical scenario bias – acute trials versus chronic disease
- Are digital signatures worth the bother?
- Informed consent from a web page or web app

Dr James Teo, Neurologist and Clinical Trialist, Kings College Hospital NHS Foundation Trust, UK

14:30 PANEL: Recruitment from the perspective of an investigative Site – pitfalls and strategies
- Recruitment Feasibility Process from CRO/Sponsor: Why are recruitment estimates so often incorrect?
- Importance of feedback opportunities to In/Ex in the feasibility process
- Recruitment strategies for sites with pros/cons - Patient database, advertisements (newspaper, radio, web), social media, referrals from other doctors (hospitals, private practices)
- Importance of an open discussion about state of recruitment with CROs/Sponsors
- Problems in recruiting and especially the reasons should be discussed early on and without hesitation.

Philipp Badorrek, Head of Department, Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, Germany
Bettina Bergholdt, Managing Partner, Emovis GmbH, Germany
Fraser Inglis, Consultant Physician & Director, Glasgow Memory Clinic, UK
Dr Helena Sigal, Managing Director, Sigal Site Management and Support, Germany
Dr Diana Sims-Silbermann, Senior Trial Manager, Early Development and Clinical Pharmacology, Janssen-Cilag GmbH, Johnson & Johnson, Germany
Joana Claverol Torres, Coordinator of the Clinical Trials Unit, Sant Joan de Deu Hospital, Spain
Hans van Dijk, Chief Operating Officer, Julius Clinical, The Netherlands

15:10 Afternoon break
16:00 PRESENTATION: Future of investigator and industry collaboration

Collaboration will reduce costs and promote quality through:

• Improved understanding of natural history and realistic feasibility assessments, particularly for stratified medicines and rare diseases
• Standardised procedures and shared infrastructures
• Early involvement in the design of trials and planning implementation
• The enthusiasm among regulators to engage with research networks

Dr Mark Turner, Chair, European Network of Paediatric Research, European Medicines Agency and Liverpool University, United Kingdom

16:30 PANEL: Site Support- How to drive down administration whilst ensuring compliance

• Every company entering new systems, implementing e-systems – how to make it easier for the sites team or requirement to ease this
• Not enough training for sites to use electronic equipment and devices
• Site initiation visit - send someone who knows the electronic devices – connections work – programme correctly
• Single portal sign on? Reducing the burden on the site team with all the different e-systems, websites and passwords
• Raising invoices and receiving payments – the pain of time consuming and error prune site payment process, is automation the solution?

Jeannett Dimsits, Senior Director, Trial Management Anchor, NovoNordisk, Denmark
Carlo Giaquinto, President, The Paediatric European Network for Treatment of AIDS -PENTA Foundation, Italy
Tim Lee, Director, European Cystic Fibrosis Society Clinical Trial Network, Leeds Children’s Hospital, UK
Guido Mathews, Head of Operational Governance & Support, Bayer, Germany
Viviënne van de Walle, Director, VivMedical - Life Science Consulting, The Netherlands

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18:00 Join us for the PCT drinks and networking party
CONFERENCE STREAM 3  Day One • Tuesday 28th November

Mobile eHealth

10:55 Opening remarks from the Chairperson

11:00 PRESENTATION: Using patient’s own devices to capture quality of life and other health data
• The rise in patients tracking their own health data
• Use of validated mobile platforms to capture study-specific health data
• Engaging participants throughout studies
• Opportunities for direct-to-patient site-less studies
• New forms of eCOA/ ePRO data capture
• Combining smartphones, wearables and sensor data for new insight
Bruce Hellman, CEO, Co-Founder, UMotif, UK

11:30 Title TBC
Vanessa Reddy, Strategic Innovation Leader, Roche

12:00 INNOVATION DEN:
• What are the advances of technology and for supporting the patient?
• Using technology for patient recruitment
• Using technology to improve the patient outcome
• New technology systems to review and monitor data – companies provide these solutions.
Moderated: Julianne Hull, Chief Executive Officer, WenStar, UK

Characterization of individual patient placebo response: Positive impact on clinical trial results
• Placebo effect in clinical research problem statement
• Development of methodologies to predict individual patient placebo response score (IPPRS)
• Deployment of these methodologies in clinical research and analysis of and control for IPPRS
• Demonstrated impact on clinical study power, Type II error, and sample size
• Potential positive impact on therapeutic development time and cost
Dominique Demolle, Chief Executive Officer, Tools 4 Patient, Belgium

Digital transformation of clinical research
• Pivot to patient - Meeting the needs of patient-consumer behaviour
• Holistic End-to-End solutions -Integrate new technology across the value chain
• Embrace digitalization -Extract full value from digital solutions
Jonas Billing, Co-Founder, Trialbee, Sweden

14:00 KEYNOTE JOINT CASE STUDY: Experiences and lessons learned from conducting global MHealth enabled trials
• Through a collaboration between The Michael J. Fox Foundation (US), Radboud University Medical Center (Netherlands) and Intel Corporation (Israel), a mobile application with a paired wearable device was developed to collect data from the daily lives of people with Parkinson’s disease.
• Multiple longitudinal, observational studies have utilized this platform, including trials in the US and the Netherlands.
• The focus of these trials vary from assessing the feasibility of using this platform in large populations over long periods of time to assessing wearable sensor data utility in clinical care management.
• Additional studies have also explored the utility of remote monitoring tools for PD patients’ disease management.
• This presentation will discuss findings, lessons learned, and key take aways from these efforts.
Daisy Daeschler, Research Partnerships Officer, The Michael J Fox Foundation, USA
Dr Marjan Faber, Senior Research Fellow in Patient Participation for Quality Improvement in Health Care, Radboud University Medical Center, The Netherlands

14:30 Sponsored Speaking Slot Available
Please contact: Alexander Zenonos +44 (0) 207 017 7742
Alexander.zenonos2@knect365.com

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15:10 Afternoon break

16:00 CASE STUDY: Supercharging clinical trials - utilising longitudinal linked patient level data to improve the commercial and academic research environment in the NHS
• North West London is building the first Consent to Contact database in England that will significantly reduce the costs of running clinical trials
• It will consent patients once enabling repeat feasibility studies and sits on top of the largest longitudinal linked data in the UK bringing together EPR systems from primary, secondary, and community care as well as some social care and prescribing data.
• There is significant interest from academia and industry to work with this data and we are also exploring how to link into user generated data e.g. from smartphones
Dr Axel Heitmueller, Managing Director, Imperial College Health Partners

12:30 Lunch
16:30 **PANEL: What are the quality, regulatory and privacy implications from acquiring data from wearables and smartphones**

- What is the level of accuracy and validation that is needed to use this data?
- There are no regulatory guidelines at the moment- so assess what is needed in clinical trial and make a measure of instrument and does it fit my needs?
- What are the implications for improved consent – from a quality point of view?
- What are the issues with data security?
- What are the implications for improved consent? From a quality point of view
- Safe harbour- data collected in Europe then transported to US. Issues with the privacy shield- sponsors companies need to think about that. Where will the data finally land?
- General Data Protection Regulations will come in in 2018 – standards are going to be set and take effect in
- Sponsor responsibilities- what should they be looking for when qualifying the mhealth providers? Sponsor companies are ultimately responsible for the data
- How do you maintain inspection readiness?
- What should the monitors be looking for to be sure about the quality of the data?

Nadir Ammour, Head Patients & Partner Management, **Sanofi, France**

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

Noemi Alonso Calvo, Head of Data Privacy for Global Drug Development, **Novartis, Germany**

Dr Frits Lekkerkerker, Chairman at the Research Ethics Committees in Netherlands, **Medical Ethical Testing Committee (METC) Twente, The Netherlands**

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

Peter Coë, Founder, **Tudor Reilly**

17:10 **Move to Plenary Room**

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18:00 **Join us for the PCT drinks and networking party**
Governance, Oversight and Quality

10:55 Opening remarks from the Chairperson
Dr. Estrella García, Director Global Clinical Operations, Site Coordinator in Lugano, R&D, Almirall, Spain

11:00 CASE STUDY: Integrating two large vaccine companies, how to integrate the oversight of vendors?
- How was the integration implemented and what were/ are the day to day challenges?
- How to integrate the oversight of multiple vendors
- Adaptive Oversight, a new approach?
- How to allow a smooth transition
- Adaptation of ‘new’ technologies
Marcel Bisschop, Senior Manager Oversight Data Management (ODM), GSK Vaccines, The Netherlands

11:30 PRESENTATION: Using regulatory inspection trend data to optimize vendor qualification and management programs
- What are the most significant and relevant trends in the regulatory inspection data for Vendor qualification and management?
- What changes to Vendor qualification processes are needed to address the identified risks in the regulatory inspection trend data?
- How can analysis of regulatory inspection trend data guide companies toward a more targeted use of their resources when it comes to Vendor management?
- What are some best practices to address the risks identified from regulatory inspection trend data?
- How can Sponsors ensure that their Vendor qualification and management programs are addressing the most important risks?
Jennifer Emerson, Consultant, Emerson Consulting & Clinical Research Services, Germany

12:00 PRESENTATION: The EU Clinical Trials Regulation: Are you prepared for its implementation?
- How the evolving needs within the industry drive momentum towards the implementation of the regulation?
- What are its key changes and challenges?
- What is the impact to your organisation?
- What are the changes you can start to make now to be ready?
- How are both Sponsors and CROs preparing?
- What impact will this have on vendor relationships?
- Where does the responsibility reside for regulatory submission, with the Sponsor or the CRO?
Dr Martine Dehlinger-Kremer, Vice President, Global Medical and Regulatory Affairs, SynteractHCR

12:30 Lunch

14:00 CASE STUDY: Implementation of a global governance structure to manage and oversee SOPs/training distribution to global and local external partners
- Performing a gap analysis
- Identify and define standards for services incl. global and local SOPs/trainings
- How to manage distribution to >200 vendors?
- Using a risk based approach, but increasing quality and compliance
- What are the expectations from the regulators regarding:
  - Timeliness of provision of training
  - Handling of new hires at the vendor
- Oversight on vendor training implementation
- Use of external access to LMS and DMS vs. "manual" distribution
- Reduction of internal administration efforts focus on content related processes
- Outsourcing of administrative SOP distribution tasks to support SOP/training distribution to vendor
Oliver Fink, Quality Medicine, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

14:30 PANEL: Focus on operational risk based approaches to oversight and quality management with the new ICH E6R2 guidelines - How to interpret this and how are companies dealing with it?
- In light of the ICH E6 R2 guidelines Avoca will announce their findings on risk-based approaches to oversight and quality management they will discuss their research findings on how the industry is assessing and managing risk in outsourced trials.
- Evaluate whether the perceptions of quality in outsourced trials has improved or declined. This data will be a catalyst for the discussion.
- How should we as an industry interpret and put into actions what is in the guidelines?
- How are companies approaching risk management both from a pharm and CRO perspective?
- Do they fill equipped to be able to deliver- skill set, tools and capabilities?
- What is the dynamic between sponsor and CRO: How well do they work together?
- How are people looking at risk when selecting vendors?
- How do they ensure that they are working with oversight?
- Hear from a regulatory authority -how will it impact their approach in inspecting? What do they see the most important changes?
MODERATOR: Patricia Leuchten, President & Chief Executive Officer, Avoca Group
Hayley Jewell, Regional Director Clinical Operations, Eli Lilly
Geoff Taylor, Director, Clinical Quality Assurance, Eisai Product Creation Systems, UK
Dr Michael Zörer, Head of Clinical Operations, AOP Orphan Pharmaceuticals AG, Austria
Van Zyl Engelbrecht, Director, Clinical Research, UBC, UK

15:10 Afternoon break
16:00 CASE STUDY: Vendor oversight, challenges and regulatory frameworks

- Vendor oversight scope due to regulations
- Regulatory derived oversight challenges
- Development of vendor oversight principles
- Translation into governance
- Exemplary fictional case discussion

Christian Langelueddecke, Regional External Partner & Relationship Manager, Boehringer Ingelheim RCV GmbH & Co KG

16:30 PANEL: Assessing the performance of oversight and governance models: How much is enough?

- Matching the right model with the size of your company and outsourcing strategy
- Assessing what is the most realistic level of investment needed for oversight
- Measuring the resource that is put into governance and oversight versus what you can expect to gain
- Which specific tools have worked best for fulfilling the sponsors requirements and obligations?

Marco Salami, Head of Clinical Outsourcing Management, Chiesi Farmaceutici SpA, Italy
Barbara Voith, Vice President, Head Global CS Operations, Bayer HealthCare, Germany
Brion Regan, Product Manager, ERT, UK
Patricia Moenaert, AD, Portfolio Sourcing and Relationship Management (PSRM), Celgene Intl, Switzerland
Mary Mueller, Vice President Strategic Alliance Management, ICON, Switzerland

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18:00 Join us for the PCT drinks and networking party
MORNING PLENARY  Day Two • Wednesday 29th November

08:50 Opening remarks from the Chairperson
Bruce Hellman, CEO, Co-Founder, uMotif, UK

09:00 PRESENTATION: Is disrupting health(care) the next frontier?
• We’re facing serious challenges
• Technology is speeding up exponentially
• Citizens and patients are becoming increasingly tech savvy
• We need to take the shift from and fix-it into a prevent-it system
• Full service solutions might be one of the options of the future
Lucien Engelen, Director, REshape Center for Health(care) Innovation, Radboud University Nijmegen Medical Centre, The Netherlands

Lucien Engelen is a technologist and innovator who is working to put patients into the healthcare team

09:40 PANEL: The advances of mobile health and clinical technology: What does it mean for clinical research and what are the barriers?
• Future of technology, MHealth, wearables and innovation for clinical trials
• Exploring new technologies and working with a CRO partners, how to integrate such innovations into partnerships?
• Are consumer devices good enough for clinical trials?
• Mobile health devices tackling therapeutics: Advances in this and changes to how clinical trials can be conducted
• Address the disconnect between hype and evidence
Matthew Bonam, Director, Intelligent Pharmaceuticals, AstraZeneca R&D
Dr Marjan Faber, Senior Research Fellow in Patient Participation for Quality Improvement in Health Care, Radboud University Medical Center, The Netherlands
Bruce Hellman, CEO, Co-Founder, Umotif, UK
Anthony Costello, Vice President Mobile Health, Medidata, USA
Willie Muehlhausen, Head of Innovation, ICON

10:20 Morning Coffee and Networking
10:55 Opening remarks from the Chairperson
Lesley Mathews, Global Development - Portfolio & Operations, Resource Management & System Integration, Bayer Healthcare

11:00 KEYNOTE: Future of healthcare: Integration of healthcare and research to better understand the disease

- Health research and health care are traditionally conducted largely within separate domains
- Current trends in medicine increasingly focus on data-driven decision making and personalization
- Integration of health care with health research offers a new paradigm for progress
- Modern technology enables capture, aggregation and analysis of massive data-sets, including real world data
- This presentation describes a practical approach to modernize medicine through integration of healthcare and research that can be achieved today, dramatically impacting efficiency, effectiveness, quality and cost of both care and research, as well as improve health and quality of life for patients.

Dr Greg Koski, Chairman, Co-Founder & President / Chief Executive Officer, ACRES Associate Professor of Anesthesia, Massachusetts General Hospital, Harvard Medical School, USA

11:30 CASE STUDY: Maximizing outcomes in asset transfers
In-licensing or acquiring assets offers tremendous opportunities and presents some risks for the pharmaceutical industry. This presentation will engage with the three phases of successful transfers; from the initial quality and commercial due-diligence before the deal, through the complex practicalities of managing the asset’s transition, to maximizing the development and commercial value of assets after the transfer is completed.

Ben Dudley, Vice President Strategic Account Leader, PAREXEL, UK

12:00 PANEL: PCMG Oxford Debate: This house believes that Strategic Partnerships are not fit for purpose

- A balanced but hard-hitting examination that considers sponsor and provider perspectives
- Strategic Partnerships under the spotlight - can they really deliver in a fluid business environment?
- Is the market polarising to huge and small companies that need to reconsider partnership management?
- Did strategic partnerships ever really deliver or were they a publicity exercise?
- Where next? Collaborations, consortiums, alliances or just more acquisitions?

MODERATOR: Carl Emerson, Managing Director, Inside Outside Solutions

12:40 Lunch
14:00 CASE STUDY: PRA

14:30 CASE STUDY: Amgen has recently implemented a new FSP model of their clinical program management function, with our partner ICON
Eleanor Clark, Amgen
Jon Harris, ICON

15:00 Sponsored Speaking Slot Available
Please contact: Alexander Zenonos +44 (0) 207 017 7742
Alexander.zenonos2@knect365.com
Consortium and Complex partnerships

15:30 CASE STUDY: The Northern Health Science Alliance and application of real world data for clinical research.
The Northern Health Science Alliance (NHSA) is a front door to the North of England’s health research ecosystem. As a partnership established by the leading Universities and NHS Hospital Trusts in the North of England the NHSA provides a portal to its internationally recognised health science excellence. We work across a population of 15 million bringing together research, health science innovation and commercialisation. The NHSA works directly with commercial partners to provide access to researchers, universities, hospitals and leading health research institutions. The NHSA is a focal point for our members and partner organisations to work collaboratively on projects that leverage the combined potential of the North. Our 20 members, including four Academic Health Networks, work as one to harness the resources, infrastructure, intellectual capital and experience of the whole ecosystem. This session will include:
1) The scale and clinical research potential of the North of England.
2) Scaling up the potential of real world data, going beyond the Salford Lung Study
3) Transforming health and social care with real-world insight, the potential for next generation real world studies.
Dr Hakim Yadi OBE, Chief Executive Officer, Northern Health Science Alliance

15:50 CASE STUDY: Paediatric specificities for clinical research
• 20% of clinical trials involve at least one child or young person: it is important to account for the needs of children and their families when designing and conducting paediatric trials
• Children and their families need to be at the heart of each trial
• Growth and development affect key features of trials (formulations, eligibility, assessments, outcomes)
• Ethics and blood sampling can be problematic
• Experienced clinical teams can overcome all these challenges
Dr Mark Turner, Chair, European Network of Paediatric Research, European Medicines Agency and Liverpool University

16:10 End of Conference
Patients as Partners

10:55 Opening remarks from the Chairperson
KCR

11:00 CASE STUDY: Implementation of patient engagement in drug development
- Introduce the concept of behaviour as part of Engagement using the Theory of Planned Behaviour and the Customer Engagement Model
- Re-defining patient engagement based on wider industry practices
- Offer metrics measures that spans across a patient journey
- Share some results from a primary research on internal stakeholders to identify firm based elements for Patient Engagement Behaviours
- Propose Patient Engagement Implementation Plans based that can be tailored to a Biotechnology Company

Adama Ibrahim, Senior Clinical Operations Lead, Biogen, UK

12:00 PANEL: How to incorporate the patient perspective into clinical trials execution and how to operationalise a process for this
- How do we engage our clinical operation colleagues?
- Patient review protocols- does this make any sense or doesn’t it? Are patients qualified to review them? What does it mean?
- Patients/ patients advocacy groups should be partners at very early stage of development of clinical trials: at drug development stage, before designing the trial, and being part of group discussion about new trials plan, design and outcomes (example: we are taking part in steering committee meetings for a natural history study ongoing across Europe)
- How to set up a good collaboration with pharma: from a patients group perspective, it’s important to know the code, conditions and steps to develop an effective partnership
- What skills do researchers need for being an equal partner to patients? How to get this skill. The same for policy makers and board members/management of trials.
- What do participants need to bring the manuals in practice?
- How to decrease the burden of a patient on a study
- Patient consent leaflet- how much information is too much?
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Dr Kieran Doran, Solicitor, Senior Healthcare Ethics Lecturer, College of Medicine and Health
Cathy Emmas, Patient Centricity Partnership Director, AstraZeneca, UK
Thierry Escudier, Head of Clinical Development, Pierre FABRE Medicament, France
Bert Hartog, Director, R&D Operations Innovation, Janssen Pharmaceutica, Belgium
Veronica van Nederveen, Chair, Patients Organization Patientenstem.nl, Chair, Dutch Clinical Research Foundation-working group Recruitment Clinical Trial Subjects, The Netherlands
Dr William van’t Hoff, Clinical Director for NHS Engagement, National Institute for Health Research Clinical Research Network, UK

12:40 Lunch

14:00 CASE STUDY: Working with patient groups for clinical research
- Identifying unmet medical needs and priorities for patients
- Research strategy and healthcare initiatives led by patient groups
- How patient groups promote and facilitate research
- Examples of partnerships with pharma companies
- Extensive network of patients and collaborators

Dr Julie Vallortigara, Research Officer, Ataxia UK, UK

14:15 CASE STUDY: TransCelerate’s Patient Engagement Initiative
Dr Tanja Keiper, Director GCO External Innovation, Biopharma, Merck, Germany

14:30 Sponsored Speaking Slot Available
Please contact: Alexander Zenonos +44 (0) 207 017 7742
Alexander.zenonos2@knect365.com

15:00 CASE STUDY: Moving glioblastoma from terminal to treatable, powered by patients
- Constructively deconstructing the patient-centred model
- Being ideologically pragmatic
- Back to the future: carpe diem and amor vincit omnia

Jessica Morris, Co-founder, OurBrainBank, SVP and Partner, FleishmanHillard, USA

15:30 PANEL: Myth busting – overcoming the biggest hurdles for patient involvement in clinical research
- Looking at evidence in pharma led trials with regards to cost saving
- Creating some ‘how to’ guidance- templates on how patient groups can work with pharma
- Regulatory agencies involving patients as early as possible
- Education of all stakeholders
- Clarity of boundaries- what you can do and what you can’t do- rules of engagement
- At which stage do you involve the patients- advantages and disadvantages?
- This has historically been done at a very late stage- after the protocol and treatments have been done at the end of study when thinking of disseminating the drug.
- Better to involve the patients at the protocol, design at the study design stage

Nathalie Bere, Patients Relations Coordinator, European Medicines Agency (EMA), UK
Andy Gibson, Associate Professor in Patient and Public Involvement (PPI), University of Western England, UK
Dr Julie Hapeshi, Associate Director R&D, Gloucestershire Research Support Service
Marleen Kaatee, Founding President, PSC Patients Europe, The Netherlands
Claire Nolan, Research Involvement Manager, Parkinsons, UK
David Spillett, Key Account Director, World Courier UK, UK

16:10 End of Conference
CONFERENCE STREAM 7  Day Two • Wednesday 29th November

Disruptive Innovation, Technology and Big Data

10:55 Opening remarks from the Chairperson

11:00 KEYNOTE: Opportunities to innovate in the way we collect data in clinical trials and how to manage volume, variety and veracity in a clinical study setting

- The explosion of wearable technology and point of care monitoring creates a multitude of opportunities for clinical trials
- Not least is the potential to collect richer data in support of existing endpoints and data from new sources to deliver differentiated endpoints
- But this is not without challenge. For example:
  - How do we engage patients in this additional collection?
  - How do we ensure the veracity of data collected outside of the clinic, particularly using sensors which are not medical grade
  - What challenges are represented by the increased volume of data collected in real time.

Matthew Bonam, Director, Intelligent Pharmaceuticals, AstraZeneca R&D, UK

11:30 SPONSORED TALK: Bioclinica

12:00 PANEL: Big Data - What to do with this data that is collected and how will it be analysed and leveraged?

- What do you do with data that you’ve gathered with Apps?
- Security of data when using an app as this data goes through the cloud and picked up somewhere. Who else can get access to this?
- Can you use Artificial Intelligence (AI) or machine learning-automated to analyse data?
- The use of genome data to provide personalised healthcare/precision medicine
- The use of this data to for improved patient recruitment, investigators and site location

MODERATOR: Dr Steven Anderson, Chief Scientific Officer, Covance, USA
Pablo Graiver, Founder & CEO, Antidote, UK

12:40 Lunch

14:00 CASE STUDY: The use of mHealth to study musculoskeletal disease

- Overview of ‘Cloudy with a Chance of Pain’
- Recruitment and engagement in mHealth studies
- Smartphones to support remote monitoring of rheumatoid arthritis, with integration into clinical care
- Opportunities for developing new outcome measures using smartwatches: example of osteoarthritis

Professor William Dixon, Chair in Digital Epidemiology, The University of Manchester, UK

14:30 SPONSORED JOINT TALK: Bracket Global

15:00 CASE STUDY: Innovations in terms of clinical trial designs – the use of precision medicine in oncology

- What are the opportunities on the critical path to new medical products? To go from stagnation to innovation?
- How does precision medicine fit in these opportunities?
- Precision medicine in clinical development of treatments against breast cancers
- Prevision medicine in clinical development of treatments against renal cancers

Isabelle Naëije, Clinical Trial Head, GDO Trial Management Oncology, Novartis Pharma AG, Switzerland

15:30 PANEL: Commercialisation and business strategy: Delivering clinical evidence to support reimbursement and market access

- The Clinical, health economic and cost effectiveness data required to enable reimbursement and wide product adoption
- Real world data, randomised controlled trials and registries remain the source of the required clinical evidence
- Incorporating novel treatments into standard of care guidelines
- The extent and volume of data required
- How does it impact investment and commercialisation strategies?
- What are the regulators asking for and is it different?
- What are the tools or methodologies to effectively collect real world data in primary and secondary care settings?
- How to make this process as efficient as possible?
- How to best access, analyse, evaluate and apply real world data
- How to best incorporate reimbursement objectives into clinical trial designs?

Peter Bogaert, Partner, Covington and Burling LLP, Belgium
Nermeen Varawalla, SVP Head Clinical Development, Biocompatibles UK Ltd, a BTG International group company, UK
Vanessa Reddy, Strategic Innovation Leader, Roche, UK

16:10 End of Conference
10:55 Opening remarks from the Chairperson
Anna Matranga, Strategic Sourcing R&D, Consultant, AMC Alliances & Consulting, France

11:00 CASE STUDY: Cooperation of Academia with SME for orphan drug developments
- From bench to bedside
- Orphan disease – Neuroblastoma
- Monoclonal antibody
- Academic development since 2000
- EMA scientific advise to find an industrial partner
- Apeiron May 2017 regulatory EMA drug approval of Dinutuximab beta

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

11:30 CASE STUDY: Better trial management through clarity and collaboration
It takes a village to successfully execute a trial, with multiple vendors and partners involved in data collection and information management – and multiple opportunities for inefficiencies and errors along the way. With so many players, data inputs and tracking systems in place, how can you truly get a single, clear picture of how your trial is performing? This presentation will share a real-world example of how sponsors and CROs are leveraging data, analytics and a cutting-edge CTMS to provide near real-time visibility into critical study trends, enable proactive operations, automate repetitive manual tasks across trials, and provide better visibility and collaboration across all trial stakeholders.

Brion Regan, Product Manager, ERT, UK

12:00 PANEL: Outsourcing and finding the ideal partner for a small to mid-size sponsor
- What’s new and what are the trends to higher prices and quality?
- Finding the right partners for an affordable price and delivering the required quality
- Experiences of switching from one CRO to another
  - How did they do it and how did they optimise and get the right quality?
  - What payments did they get?
- Will larger CROs consider them and are the large global CROs a partner at all?
- Is there an ideal size to match biotech and small pharma?
- Marrying up with right partner for the size of the company
- Establish an outsourcing model for smaller pharma - establish strategic partnerships
- Oversight and governance model - Develop governance framework
- Negotiating the best practice - Ensure pay appropriate price
- Pre-qualification of vendor - Vendor oversight

Diego Bersini, Clinical Outsourcing Manager, R&D Outsourcing Management, Chiesi Farmaceutici S.p.A., Italy
Dajana Bougie, Senior Outsourcing & Contract Manager, Grunenthal GmbH, Germany
Paul Bouten, Consultant Interim Manager, PharmConMed, The Netherlands
Jennifer Emerson, Consultant, Emerson Consulting & Clinical Research Services, Germany
Anna Matranga, Strategic Sourcing R&D, Consultant, AMC Alliances & Consulting, France
Rob ten Pas, Director, Global Clinical Research, AM-Pharma, The Netherlands
Dr Wim J Tamminga, Vice President and Global Head of Early Phase Clinical, QPS, The Netherlands

12:40 Lunch
14:00 CASE STUDY: Challenges faced by Pharma companies during inspections from National Competent Authorities at clinical study sites

- Addressing key challenges: quality compliance, inventory, administrative, logistical
- Importance of enough coordinating resources at sites representing pharma companies
- Challenges involved in resolving the major findings: CAPA
- How CROs can play an essential role: the bridge between Pharma companies and NCAs
- Applicable guidelines and regulations

Sambuddha Ghosh, Lead Global Clinical Operations, Medical Affairs, Wörwag Pharma Gmbh & Co. KG, Germany

14:30 KEYNOTE CASE STUDY: Patient funded trials

- A Plutocratic Proposal: A new, ethical way for rich patients to pay for a place on a clinical trial?
- Particularly suited to rescuing neglected drugs (and other interventions) for rare diseases
- Discussed in the current issue of The Journal of Medical Ethics, the No 1 journal of bioethics.
- Online and open access at: http://jme.bmj.com/cgi/content/full/medethics-2016-104050
- A way to raise millions of euros of new money for research into orphan diseases?

Alexander Masters, Author, Campaigner and Co-Founder, iCancer.org.uk, UK
Dominic Nutt, Author, Campaigner and Co-Founder, iCancer.org.uk, UK

15:00 Too big / too small / just right: Guidelines for choosing a clinical technology partner

- Why CROs are getting out of the technology business - and what that means for small and mid-sized biotechs
- How fast you should start running when vendors talk about eClinical “platforms”
- The pros and cons of integrated point solutions and services to meet business requirements (i.e. a “pragmatic platform”)
- How to find a clinical technology partner in the “Goldilocks” zone
- 5 questions to ask a technology vendor
- 5 questions to ask your CRO about their technology choices

Mike Lange, Senior Director, Product Marketing, Bioclinica, USA

15:30 PANEL: How to attract funding of rare disease - How to engage more pharma companies in this field?

- How to attract Pharma’s to invest in the rare disease field and run trials
- Highlighting the knowledge and resources available from patient’s groups (centre of excellence, connections with academics and clinical researchers, patient’s registry)
- How to attract more pharma companies in this field?
- Using the patient advocacy groups to support the trial
- Commercial investment that needs to be done?
- Specificities of young patient advocacy and the collaboration with the stakeholders involved in paediatric drug development
- The role of the families to funding research addressed to rare diseases
- Patient centricity in the research and clinical trials in rare diseases
- Repurposing drugs

Luke Sergott, Senior Managing Director, ISI Group LLC, USA
Cees Smit, Rare Disease Commercialisation and Business Strategy/Patient Advocate, European Genetic Alliances Network (EGAN), The Netherlands
Dr Julie Vallortigara, Research Officer, Ataxia UK, UK
Begonya Nafria Escalera, Patient Advocacy Manager in Research, Hospital Sant Joan de Déu, Spain
Professor Ruth Ladenstein, Senior Consultant in Paediatric haematology–Oncology, OKIDS, Austria

16:10 End of Conference
11:00 Dual Dialogue: Examining the impact of the FIH guideline update: Sponsor experience

- Assessing the extent to which the FIH guideline update is focused on HVs vs. patients
- FIH guideline update: is it fit for purpose?
- Examining the outcome of the whitepaper
- Oncology and the FIH guideline update
- Clarifying non-clinical aspects
- How will the FIH guideline impact how studies are designed in the future?

Sam Hariry, Head of Clinical Strategy, Novartis, Switzerland

Jeroen Bos, Global Therapeutic Area Lead - Drug Regulatory Affairs, Novartis, Switzerland

11:30 PANEL: An update on the FIH guideline: Where are we now?

Kirsty Wydenbach, Deputy Unit Manager, MHRA, UK

Dr Jan Willem van der Laan, Senior Pharmacological-Toxicological Assessor, Medicines Evaluation Board, The Netherlands; Section on Pharmacology, Toxicology and Kinetics (FTK), Medicines Evaluation Board, Netherlands

Jeroen Bos, Global Therapy Area Lead - Drug Regulatory Affairs, Novartis, Switzerland

David Jones, Expert Pharmaco-Toxicologist, Clinical Trials Unit, MHRA, UK

Sam Hariry, Head of Clinical Strategy, Novartis, Switzerland

12:05 FIH Cannabis Trial: Overview of the pharmacokinetic and pharmacodynamic results from single- and multi-ascending doses of dried cannabis delivered by smoking/inhalation

- Does this fixed THC and Cannabidiol dose format provide adequate information for future therapeutic use?

Marc Lefebvre, Vice President Scientific and Regulatory Affairs, Altasciences, US

14:00 Translation of animals to humans: business as usual?

- Prediction of human efficacy, off target pharmacology and adverse effects
- Animals are not small humans

Anja Slikkerveer, Scientific Director Translational Science, Astellas Pharma, Netherlands

14:30 Safety assessment during early phase development

- How to transfer knowledge from non-clinical studies into the design for clinical studies
- Biomarker in FIH/ early patient studies supporting safety assessment and dose-escalation decision
- Dose selection in FIH-studies: from starting dose to maximum dose – and dose schedule “in-between”

Gezim Lahu, Senior Director and Global Head of Pharmacometrics, Takeda, Switzerland

15:00 Afternoon refreshments

16:00 How to mitigate risks and uncertainties identified in the preclinical setting in a first in human protocol

Ann Marie Janson Lang, Assoc. Prof, Expert, Medical Products Agency, Sweden

16:30 An update on the clinical trial regulation: Regulatory authority feedback

- The latest on the Clinical Trial Regulation: how should industry prepare for implementation?
- When will the Clinical Trial Regulation be implemented?
- What will the impact be on early development?
- What are the opportunities and threats to early medicines development?
- How will the UK implement? What impact will Brexit have?

Lene Grejs Petersen, Senior Adviser, Clinical Trials, Danish Medicines Agency, Denmark
CONFERENCE STREAM 10   Day One • Tuesday 28th November

Early Clinical Development

Operational Strategies

Chair: Wolfgang Eglmeier, Head Centre for Clinical Studies, Witten/Herdecke University, Germany

11:00 PANEL: Adapting to the new landscape for early clinical development: where are we now?
- Adapting to more complex early clinical studies
- Biomarkers
- Pricing and reimbursement
- Segmenting patients and personalised healthcare
- Examining the increasing use of patient cohorts in early clinical development
- Innovation in trial management and data collection

Tony Johnson, VP, Early Clinical Development, AstraZeneca, UK
Muna Kugler, Strategic Sourcing Manager, Global Operations, Idorsia Pharmaceuticals, Switzerland
Marc Hoffman, Chief Medical Officer, Celerion, US

11:30 Dual Dialogue: Boehringer Ingelheim case study: Adaptive trial case study: Strategies for improving efficiency through technology and achieving more for less

Thomas Bogenrieder, Boehringer Ingelheim, Germany
Plus statistician to be confirmed

12:05 What’s HAP-pening: A Current Primer in the Assesment of Human Abuse Potential
- Overview of the latest regulatory guidance
- Human Abuse Potential Study Design elements including selection of positive controls in HAP and identifying the subject population
- Two case studies: evaluation of a stimulant and an abuse deterrent formulation

Ryan Turncliff, Senior Director, Global Scientific Affairs, PRA, US

12:35 Networking lunch

14:00 Choosing the right CRO with the right sites for your early clinical study
- Finding a CRO that has experience of using patients in their early clinical studies - do you know if the site you’ve chosen can produce the patients?
- Establishing what’s important for early development: Multiple sites, standard PK sampling and having patients overnight
- Niche providers or generalist? What are the opportunities and limitations?
- The changing nature of early clinical studies – how does this impact CRO/sponsor relationships?

Lorraine M. Rusch, President, High Point Clinical Trials Center, US

14:30 Towards greater use of collaboration between industry and academia to expedite early clinical development
- Examining the need for earlier access to patients in drug development
- How might collaboration between industry and academia help get compounds into development?
- The obstacles for such a collaboration and how to overcome those
- Risk assessing industry academic partnerships
- How can industry/academic partnerships help to offer targeted therapies? (personalised/stratified medicine)

Wolfgang Eglmeier, Head Centre for Clinical Studies, Witten/Herdecke University, Germany

15:00 Afternoon refreshments

16:00 Presentation title to be confirmed

16:30 PANEL: Examining outsourcing models in early clinical development: What are the challenges and opportunities?
- How much early clinical work should be outsourced?
- Understanding the cost saving associated with outsourcing
- Establishing a preferred list of sites for early phase work and maintaining a close relationship with the sites
- Which model should you use? What are the limitations and opportunities?
- Improving communication between sponsor and CRO: defining the parameters and highlighting where to focus
- Why should we do it internally?
- Overcoming the challenge of privacy breaches and inadvertent un-blinding
- Contracts and budgets – what are the issues?
- Data sets: What are the challenges and how can they be overcome? Internal issues and external requirements

Guido Wuerth, Global Head Clinical Operations, Hexal, Germany
Birgitte Søgaard, Divisional Director, Clinical & Quantitative Pharmacology, Lundbeck, Denmark
Plus additional panellist to be confirmed
Early Clinical Development
Regulatory and Science

Chair: Corina Dota, Director, AZ Cardiovascular Safety Centre of Excellence, AstraZeneca, Sweden

11:00 Modelling and biomarkers: The Role of Human Models of Disease State to Accelerate Early Clinical development in Healthy Volunteers and Patients
• Which disease states can be modelled in a clinical setting
• Importance of validation, reproducibility and predictive validity
• Patients v Healthy volunteers
• Integration of human models into a FIH package
Dr John Connell, Chief Research & Development Officer, MAC Clinical Research, UK

11:30 Role of PK/PD Modeling in supporting design of FIH- trials of high risk molecules
• Early application of modeling focused on prediction of human pharmacokinetics (PK) e.g. allometric scaling & mechanistic PBPK methods
• An increased focus on pharmacodynamics (PD) prediction (using drug-target binding, receptor occupancy, in vitro & in vivo pharmacology)
• New approaches such as MABEL is key for high risk molecules due to the tragic event of the CD28 agonist antibody (TGN1412) in 2006
• Predicting human PD extensively discussed after the recent deadly event of the FAAH inhibitor BIA-10-2474 in 2016
Youssef Hijazi, Expert Clinical Pharmacokinetics, Sanofi, Germany

12:00 Cell-based biomarkers as a means of confirming target engagement and mechanism in early clinical trials
• The use of PD biomarkers in early clinical trials has the potential to substantially de-risk projects and enhance value
• For many novel therapeutics, soluble analytes are not sufficient as suitable markers of mechanism and proof of concept
• While the use of cell based markers, and even functional assays, is logistically challenging, with suitable validation and expertise they can provide high quality confirmation of effect
• By applying an ‘intelligent design’ approach from project initiation, KWS can determine therapeutic and potential toxicological effects of novel therapeutics on immune function in the clinic, adding value to development candidates
Neil Williams, CSO, KWS BioTest, US

12:30 Networking lunch

14:00 Translational Modeling in support to safety and efficacy assessment during early development
• Value of integrating translational PKPD in early development
• Understand the requirements for translational PKPD
• Illustrate use of exposure-response modeling to:
  › optimize FIH study designs
  › aid dose selection for proof of concept studies
  › translate from preclinical to clinical
Thierry Lave, Principal Leader, Head Project Leader and M&S, Pharmaceutical Sciences, Pharma Research and Early Development (pRED), Roche, Switzerland

14:30 ICH guideline E14: Regulatory perspective on cardiac safety assessment
• Understanding the current status of the ICH E14 guideline
• Assessing the latest developments
• Opportunities and challenges
Colette Strnadova, Senior Scientific Advisor / Health Products and Food Branch, Health Canada, Canada

15:00 Cardiac safety and the use of early trials data instead of the TQT trial
• What QT data from early trials can replace the TQT study?
• How to design, collect and analyze the data?
• When is the right time to submit the data?
Corina Dota, Director, AZ Cardiovascular Safety Centre of Excellence, AstraZeneca, Sweden

15:30 PANEL: QT Prolongation: Implementation guidance for industry
• Examining the ICH Q&A doc to support the guideline
• When is it appropriate to perform concentration-response modelling and when isn’t it? How can it best be done? Is there a standardised convention that is followed?
• Strategies for modelling the process
• Assessing the additional weight given to non-clinical studies using it in induced in silico simulations
• Increasing the predictive value of non-clinical assays and confirming them in clinical QT studies
• Exploring case studies: situations in which the concentration-response approach was useful or misleading
• Strategies for collecting the right amount of data to support and clear the drug from CV safety effects
Corina Dota, Director, AZ Cardiovascular Safety Centre of Excellence, AstraZeneca, Sweden
Colette Strnadova, Senior Scientific Advisor / Health Products and Food Branch, Health Canada, Canada
Early Clinical Development
Operational Strategies

11:00 Patient Centricity and Patient Recruitment: Getting the balance right in the design of early phase patient studies
- Addressing the challenges of recruiting patients to early phase studies, where there is no expectation of patient benefit
- Challenge of multiple informative endpoints vs patient burden and limited recruitment
- Seeking patient insight into the design of the study and content of patient information sheet
- Case studies
  Stephen A Harrison, Ph.D., GSK Associate Fellow, Clinical Program Lead, Clinical Pharmacology Study Science and Operations UK, GSK, UK

11:30 Building unique partnerships to facilitate the transition from healthy volunteer to patient studies
- Evolving the early stage clinical trial design; more patient access earlier in development
- Addressing the challenge of patient recruitment in early clinical development
- Establishing and maintaining a network of doctors in hospitals to expand patient recruitment: What are the benefits and challenges?
- Case Studies
  Jim Bush, MBChB, Ph.D., MRCS, MFPM, Medical Director, Covance Clinical Pharmacology Services, US
  Dr Richard FitzGerald, Consultant Physician and Director, Clinical Research Unit, Royal Liverpool University Hospital, UK

12:00 Recruiting patients in early clinical development through effective collaborations
- Highlighting the importance of the vendor selection process and the early alignment of expectations
- Pre-selecting countries and sites in collaboration with CROs
- Establishing long lasting collaboration with the sites through the CRO for successful recruitment
- Establishing and collaborating with a network of sites with regional support, i.e. facilities where patients can stay overnight
- Providing support at an early stage to the CROs to achieve better engagement of investigators and the patients
  Muna Kugler, Strategic Sourcing Manager, Global Operations, Idorsia Pharmaceuticals, Switzerland

12:30 Networking lunch

14:00 Presentation to be delivered by Quintiles

14:30 Patient recruitment presentation
Sue Pavitt, Professor Translational & Applied Health Research, University of Leeds, UK

15:00 PANEL: Patient-centric trial design: Involving patient groups in early clinical development
- What does the current landscape look like for the pharma industry to use patient groups?
- What are the benefits of involving patient groups in early clinical development?
- What are the risks of involving patient groups in early clinical development?
- Lessons for industry
  Panelists:
  Uwe Gudat, Head of Safety, Biosimilars, Merck Biosimilars, Switzerland
  Michael Binks, VP Rare Disease Clinical Research, Pfizer, US
  Peter Van Der Ark, Clinical Research Manager, Experimental Medicine Neuroscience, Janssen – Pharmaceutical Companies of J&J, Belgium

15:30 Gene therapy for monogenic rare diseases: Early clinical development challenges
Michael Binks, VP Rare Disease Clinical Research, Pfizer
Clinical Trial Supply

11:00 Key regulatory changes including the EU Clinical Trial Regulation (CTR), and how they impact the clinical trial supply chain
- Outlining how the CTR Annex VI requirements will impact the clinical trial supply chain
- Understanding the concerns behind the CTR Annex VI requirements for clinical labelling and expiry dating
- Reviewing the timelines surrounding the CTR and when these requirements will be in force
- Examining how EU GMP Annex 16 on QP Certification and Batch Release impacts the clinical trial supply chain
- Exploring any other changes to GCP, GMP and GDP guidance that might impact the clinical trial supply chain

Cristiana Spontoni, Partner, JONES DAY®, Belgium

11:30 INTERACTIVE ROUNDTABLES: Sharing experiences with using latest strategies and tools for clinical supply chain forecasting and planning
- Are there any new ways to implement clinical trial supply chain forecasting and planning?
- What forecasting tools are available for supporting more complex clinical trial designs?
- How can you ensure cross-functional optimisation and efficient communication with all stakeholders?
- How can you overcome the key challenges and pitfalls?

Anuja Shukla, Clinical Supply Lead, UCB Pharma S.A., Belgium

12:00 Exploring latest progress and practicalities of direct-to-patient clinical trials
- Assessing any regulatory guidance available for direct-to-patient trials and how this varies between different countries
- Best practice for forecasting and managing the clinical supply chain for direct-to-patient trials
- Examining methods and tools for improving patient compliance during direct-to-patient trials
- Ensuring data privacy for the patient during direct-to-patient clinical trials
- Overcoming key pitfalls experienced

Ramón López, Clinical Research Manager, Thrombotargets Europe, Spain

12:30 Lunch

14:00 Ensuring a patient-centric clinical trial supply chain to improve patient compliance and engagement
- Understanding how to ensure the clinical trial supply chain incorporates patient needs
- Discussing how an efficient clinical trial supply chain can improve patient retention and compliance
- Exploring latest tools available for monitoring and improving patient compliance and engagement
- Overcoming key challenges when ensuring the clinical trial supply chain is patient-centric

Frauke Bruns, Group Leader Clinical Trial Supply, Actelion Pharmaceuticals Ltd., Switzerland

14:30 INTERACTIVE ROUNDTABLE DISCUSSION: Discussing the challenges of and technology to monitor patient compliance
- What technology is available and what are people using to enhance or monitor patient compliance?
- What are the key challenges that have been faced with patient compliance?
- How have these challenges been overcome?

Nina Cianfanelli Svennum, Clinical Supply Specialist, H. Lundbeck A/S, Denmark

15:10 Afternoon break

16:00 Exploring the practicalities of Investigator initiated trials (IIT) and clinical trial supply chain considerations
- Outlining different strategies for managing the clinical trial supply chain for IIT
- Reviewing the practicalities of IIT storage and sites
- Establishing a robust sponsor/investigator relationship during IIT and ensuring clear communication channels
- Best practice for handling drugs, ancillary products and hardware during IIT

Samantha Carmichael, Lead Pharmacist Clinical Trials / R&D, NHS Greater Glasgow & Clyde, UK

16:30 Clinical pharmacy perspective: Cooperation with industry at early stages of clinical trial supply and working successfully with partners
Marija Tubic Grozdanis, Lead Pharmacist Clinical Trials, University Medical Center of the Johannes Gutenberg University Mainz, Germany

17:10 Move to plenary room
Clinical Trial Supply

09:00 Assessing latest advancements in Interactive Response Technology (IRT) and practically using this to improve efficiency of the clinical trial supply chain
- Reviewing key ways in which IRT can be used to improve the clinical trial supply chain
- Sharing experiences of how IRT was set up
- Understanding how to ensure an efficient interface between IRT and electronic data capture
- Successfully selecting and working with IRT service providers
- Exploring any new developments or additional functionalities in IRT
Kate Chapman, Director, Clinical Technology Consultants Ltd, UK

09:40 Best strategies for managing the clinical trial supply chain in emerging markets
- Outlining examples of challenging clinical trial supply chain requirements in different countries
- Success stories in emerging markets
- Understanding how to work with external partners for clinical trial supply chain management in these regions
- Overcoming the key challenges involved in managing the clinical trial supply chain in emerging markets
Amer Alghabban, Vice President GxP Quality Assurance, Compliance Training, Karyopharm Therapeutics Inc., US

10:10 Q&A from the morning session

10:20 Morning break

11:00 Case study: Best practice for selecting and managing relationships with new service providers in the clinical trial supply chain
- Discussing how selecting and managing relationships with service providers is covered in the regulations and guidelines
- Understanding the selection criteria and assessment procedures for service providers
- Reviewing how relationships are built and maintained to ensure efficiency
- Exploring new and creative approaches for how industry is working with service providers and outsourcing strategies used
Laurence Ricatte, Global Clinical Logistics Manager, Sanofi Pasteur, France

11:30 GS1 perspective: Exploring how global standards can be used to address efficiency, accuracy and surety in the clinical trial supply chain
- Understanding global standards for the commercial supply chain and how these can also be applied to the clinical trial supply chain
- Reviewing what GS1 standards will look like for the clinical trial supply chain and how industry will apply these
- Examining timelines for when these GS1 standards will come into place
- Discussing the importance of industry feedback to help to shape these standards
Tania Snioch, Director Healthcare, GS1 Global Office, Belgium

12:00 Highlighting the importance of quality sample management in the development of immunotheathies
- Bridging the gap between research and clinical operations teams to design custom sample management processes
- Emphasizing the significance of real-time sample tracking to deliver high quality data
- Exploring new innovations and partnerships to enable efficient and improved sample management
- Reducing development timelines to bring effective immunotherapy to patients
Jennifer Brandl, Associate Manager, Clinical Trials, Immune Design, USA

12:40 Lunch

14:00 Identifying comparators for clinical trials in China: Challenges and resolutions
Jasmin Hellwig, Sr. Comparator Sourcing Specialist, Merck MSD, Switzerland

14:30 Overcoming the challenges in designing the clinical trials for complex generics and innovative generics (new therapeutic entities)
- Discussing different types of complex generics, line extensions and label expansions (new therapeutic entities)
- Outlining the clinical requirement guidelines and understanding the grey areas in regulations
- What are the clinical trial supply challenges and regulatory challenges in the clinical development of complex generics and innovative generics?
- Overcoming challenges and globalizing the clinical trial design approach
Siddharth Chachad, Founder & Chief Strategist, ReguClin Consulting, Czech Republic

15:00 Exploring different blinding options for comparators
- Outlining the pros and cons of different blinding approaches
- Understanding the strategies behind deciding which way to blind comparators
- Discussing methods used for qualifying blinding approaches
- Reviewing whether there are any new and upcoming blinding techniques available
- Assessing the pitfalls experienced with blinding comparators and how these can be overcome
Denise Hager, Senior Scientist, Pfizer, USA (presentation to be delivered via teleconference)

15:30 Using risk assessments and mapping tools for effortless temperature mapping studies
- Thermal mapping is a requirement of the GDP’s. This has to be performed prior to commencement of use of a warehouse or transportation system, and when making modifications to the facility or temperature controlling equipment. Risk assessments can hereby help to handle the different mapping operations in order to reduce the workload and still assure GDP compliance
- What are the parameters to take into account when performing a temperature mapping study? Can we assume that a transportation system is a warehouse on wheels, or do other factors play a role? How to we cope with the multitude of situations and their possible combinations?
- Performing a temperature mapping can therefore become a very tedious operation. We achieve effortless temperature mapping by combining IoT loggers with a performant processing tool. We’ll give you a glimpse of the future.
Frank Peeters, Managing Director, Tobeas bvba, Belgium

16:10 End of conference
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- CEO
- Patient Recruitment Expert
- Regulatory Affairs Manager
- Head Of Procurement
- Head Of Clinical Operations
- Governance Manager
- CRO Relationship Partner
- Head Of Partnerships
- CRO Manager
- Head Of Governance
- Purchasing
- Chief Operating Officer
- Clinical Outsourcing Manager
- Clinical Project Manager
- Director Clinical Research
- Clinical Trial Manager
- Contract Manager
- Clinical Data Manager
- Medical Director
- Head Of Operations
- Director Of Partnerships
- Head of R&D
- Business Development Director
- Clinical Operations
- Investigator

What regions do attendees come from?

80% Europe
20% Rest of world

Which industry companies can you expect to meet at PCT 2017?

Sanofi
Novartis
GlaxoSmithKline
UCB
Boehringer Ingelheim GmbH
Bayer Healthcare
Covance
Grunenthal
INC
Eisai Limited
Amgen Ltd
Inventive
Medidata
Chiesi Farmaceutici SpA
ERT
GSK – Vaccines
Merck
Biogen Idec
Inventive
Celegene
Janssen
AstraZeneca

Amgen Ltd

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VIP access
Host a closed-door event with the top 1-3% stakeholders in the clinical trial community – all catered for! Leave a lasting memory with potential clients.

1-2-1 Meeting Service
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Exhibition Hall
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PCT Digital Engagement
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