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14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

17-19 November 2015,
CCH Congress Centre Hamburg, Germany

The era of change: A panoramic vision of reform, challenge and innovation in clinical trials

The Partnership Landscape: Past, Present and Future

Christopher Rull,
Vice President, Head Alliance Management,
Merck Serono, USA

Vanessa Cooke,
Vice President, Global Head Strategic Sourcing R&D,
Bayer HealthCare Procurement, UK

Barbara Tardiff,
Vice President, Global Head Clinical Innovation and Informatics,
Pfizer, USA

Partnerships in Clinical Trials Question Time

Dr Guy Yeoman,
Vice President Patient Centricity,
AstraZeneca, UK

Paulo Moreira,
Vice President, GCO Head of External Innovation,
Merck Serono, USA

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

The Latest From Transcelerate

Iris Loew-Friedrich,
Executive Vice President, Biopharma Development Solutions and Chief Medical Officer,
UCB, Belgium

Rob DiCicco,
Vice President, Clinical Pharmacology Sciences and Study Operations,
GlaxoSmithKline, USA

Associate Sponsors

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To register: +44 (0) 20 7017 7481 registrations@informa-ls.com www.ct-partnerships.com

14th Annual
PCT PARTNERSHIPS IN CLINICAL TRIALS

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> I am attending to meet leaders in the field to determine what I can implement in my organisation today or in the future
>
> Global Head Outsourcing, Eisai Product Creation Systems, Eisai UK

LinkedIn
Keep up-to-date with the latest news and network with over 3900 members by joining our LinkedIn group – **Partnerships in Clinical Trials**.

Twitter
Join over 2500 followers on Twitter **@PartnershipsCT** for updates, special articles and news announcements about the event. **#PCTrials**

WordPress
Sign up to the **PCT blog** for exclusive content and speaker interviews - **www.clinicaltrialpartnershipsblog.com**

A NOTE FROM AN ADVISORY BOARD MEMBER....

Partnerships in Clinical Trials 2015 is set to be a spectacular event, with 120+ speakers, 1000+ senior clinical outsourcing decision makers and 8 informative streams. This year the focus will be on patient centricity, implementation of RBM and innovation. PCT 2015 is the one event you need to attend!

The event will address the most critical topics that industry really needs to know, understand and more importantly implement in our day-to-day role.

Thought-provoking questions that PCT 2015 will tackle:

- The economy and the future of the clinical industry: Who is putting the patients first?
- What will be the impact of the new clinical regulation to your day-to-day role?
- Risk based monitoring: At what point will you make the change to a new system and how will this be implemented?
- How will the patient centricity movement effect CRO operating strategy?
- When it comes to innovation, how innovative are we?
- How were Ebola clinical trials fast tracked and what can be learnt from this case study?
- What do we need to do to evolve and grow as an industry?

New for PCT 2015:

- The collaboration zone - an entire stream dedicated to interactive discussion
- It's all about the patient: patient recruitment and retention and becoming more patient centric
- Partnerships and strategies for small and mid-size pharma and biotech
- Inspirational plenary sessions
- Lifetime Achievement Award on conference day one
- Ask the experts: one-to-one opportunities for tailored guidance and advice
- A choice of 3 new pre-conference focus days on RBM, Outsourcing Forum and INVENT

This year the Partnerships in Clinical Trials Congress is taking place in Germany's second largest city, Hamburg. Hamburg has Europe's largest Japanese garden, the first zoo without cages, 2 lakes and has the oldest opera house in Germany - so plenty to see and a great place to visit should you wish to stay on after PCT.

We look forward to welcoming you to Hamburg this November for the number one networking event for all clinical development outsourcing professionals.

Best wishes,

Dr Graham Belgrave
Senior Vice President, Head Global Clinical Development Operations,
Grünenthal GmbH, UK

For a full list of advisory board members see **www.ct-partnerships.com**

FORMATS FOR 2015:

In addition to unique presentations, case studies and panels, the 2015 programme will deliver practical solution-driven content. The following sessions will encourage interactivity, collaboration and benchmarking to provide participants with robust take-home answers.

CANDID INTERVIEW Industry panellists will be questioned by Phil Hammond, GP and Broadcaster. Phil will push panellists to reveal brand-new information address difficult questions, and provide real answers.

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

COLLABORATION ZONES Interactive roundtable industry-led discussions taking place during Stream 8 on Day Two. Participants will discuss the table topic along with industry peers.

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.

INNOVATION DEN New for 2015: Exploring innovative technologies and processes. Hosts will have 10 minutes to present their innovation or idea to the audience. The audience will vote for the process that they deem to be most innovative

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

ASK THE EXPERTS New for 2015: Delegates will have the opportunity to discuss individual challenges on a one-to-one basis with leading industry experts. These meetings will take place in the Exhibition Hall during the lunch break on Day One. Sign up at the registration desk - first come first served!

14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

AGENDA AT A GLANCE

SPECIAL FOCUS DAY: Tuesday 17 November 2015

09:45 **Registration and coffee**

10:20 **Opening remarks from the chair**

Workshop X: The Outsourcing and Partnership Forum

WORKSHOP Y: INVENT: Leadership and Change Management for the Clinical Trial Industry

WORKSHOP Z: The Fundamentals of Risk Based Monitoring

16:45 **End of special focus day**

17:30 **Welcome reception hosted by** COVANCE SOLUTIONS MADE REAL

CONFERENCE DAY ONE: Wednesday 18th November 2015

07:30 Registration and morning coffee

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

09:00 **The partnership landscape: The past, present and future**

10:00 **12 Months Later: The latest on TransCelerate**

10:40 Morning coffee and Networking sponsored by World Courier AmerisourceBergen

11:20 **Innovation in strategic site monitoring**

11:50 **How Ebola clinical trial and regulatory pathways were fast tracked - what worked, what did not and how can this be applied?**

12:20 Lunch and networking time with **partneringONE**

12:20 – 13:00 **Ask the Experts**

- **Clinical development - resource and finance management**
- **Negotiation skills: Aiming high – Knowing the limits: Professional negotiation in the sponsor-CRO relationship**
- **Resolving GCP Issues**
- **Expanding your CRO business into Europe**

	STREAM 1 Partnering and Sourcing Models	STREAM 2 Implementing Risk Based Monitoring (RBM)	STREAM 3 It's all about the Patient: Patient Recruitment, Retention and becoming more Patient Centric	STREAM 4 Advances in Disruptive Innovation
13:50	**Opening remarks from the chairs**			
14:00	**Assessing true CRO usage and identifying actionable steps to optimise team effectiveness**	**TransCelerate and RBM**	**Are trials becoming more patient-centric?**	**Remote monitoring in clinical trials: Getting closer to objective and actionable data**
14:30	**5 minute change over**			
14:35	**2 CRO's collaborating within a sponsor to enhance ways of working and help create a win:win:win partnership**	**How to successfully use data analytics tool to support risk based monitoring process**	**Ensuring trials are patient centric to improve patient recruitment and retention**	**Understanding why we innovate**
15:05	**5 minute change over**			
15:10	**Driving strategic success through a harmonised, 'one-voice' approach within Sponsor and CRO**	**Real life experience of implementing and best practice of risk based monitoring (RBM)- Lessons learnt**	**Optimising clinical trial management- improving the relationship with the Investigator site**	**The Innovation Den: Exploring innovative technologies and processes**
15:40	**Afternoon Tea and Networking Time sponsored by** MEDPACE			
16:20	**The evolution of outsourcing strategies: Managing change in stakeholders during outsourcing and strategic partnerships**	**How to assess the quality of monitoring – QA/Audit perspective**	**Optimising the protocol design and enhancing patient identification /recruitment for clinical studies by leveraging Electronic Health Record Data: The IMI HER4CR Project**	**How disruptive technology enables companies to possess a differentiating capability with their eTMF**
16:50	**5 minute change over**			
16.55	**Learning from other industries: Exploring Nestlé business outsourcing organisation**	**Investigator/site perspective of RBM – Experiences and challenges**	**The use of social listening to build recruitment /retention strategies and understanding the patient pathway to influence protocol design**	**Revolutionising sponsor and site communications through the shared investigator platform**

17:25	**5 minute change over**
17:30	**Inspirational: From Ice to Dust – taking medicine to extremes: Survival of the fittest - World authority in human endurance and nutrition**
18:00	**Lifetime achievement award at the Partnerships Bar**
18:15	**Partnerships Bar and Drinks Reception in the Exhibition Hall Sponsored by** THEOREM SIMPLIFYING COMPLEX TRIALS™

CONFERENCE DAY TWO: Thursday 19th November 2015

08:15 Morning coffee
08:50 Opening remarks from the chair
09:00 **Partnerships in Clinical Trials- Question Time**
10:00 **Trends and drivers shaping the clinical trial industry: Where will this lead to?**
10:30 **Addressing the changing needs of clinical trial development**
11:00 Morning tea and networking time with **partneringONE**®

	STREAM 5 Governance, Oversight and Change Management	STREAM 6 Outsourcing Partnerships and Strategies for Small to Mid-Size Pharma and Biotech	STREAM 7 Changes in Clinical Trials Regulation and Compliance	STREAM 8 Collaboration Zone: Interactive Sessions
11:40	**Opening remarks from the chairs**			
11:50	**How do you govern the relationship management between a CRO and pharma- an operational perspective**	**Outsourcing models and Partnering challenges for Biotech and Small-mid-sized Pharma**	**The New EU Clinical Trials Regulation: What does it change and what will the impact be to drug development in the EU?**	**Achieving a standard level of service excellence** **or** **Sponsors, CRO's and sites: How to improve the site selection process**
12:20	**5 minute change over**			
12:25	**Development of a high-functioning quality management organisation**	**Precision medicine for biotech and small to mid-sized pharma, success for any size trial**	**Corporate Social Responsibility (CSR) in Pharma – a case story**	**Continued above**
12:55	**Lunch and networking break in the exhibition hall With partneringONE**®			
13:00 – 13:40	**Ask the Experts**			
14:25	**Sponsor-CRO relationship. What have we learned from our front line perspective?**	**Consolidation in the CRO industry**	**Some policy and legal comments on the new EU Clinical Trials Regulation**	**Role of academic research sites and clinical research units in clinical trials** **or** **Current initiatives to ensure the quality of clinical trial data**
14.55	**5 minute change over**			
15:00	**Outsourcing Data Management to a Vendor, a strategic partnership**	**Sponsor-CRO relationship. What have we learned from our front line perspective?**	**Clinical Trial Regulation: What major changes will be relevant to your role?**	**Continued above**
15:30	**5 minute change over**			
15:35	**The Role of Procurement and Category Management**	**Update on Celgene's partnership model**	**Clinical Trial Regulation: What major changes will be relevant to your role?**	**How to manage non interventional studies?** **or** **How clinical hypnosis can add value to the clinical trial process and enhance patient centricity**
16:05	**Networking break in the Plenary Room**			
16:20	**Patient and Doctor: An inspiring story of saving faces through innovative clinical and surgical trials- Exploring a patient's perspective**			
16:50	**Closing remarks and end of PCT 2015**			

14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

SPECIAL FOCUS DAY: Tuesday 17 November 2015

Workshop X – The Outsourcing and Partnership Forum

This will be a day dedicated to outsourcing and partnership strategies. It will be highly interactive with panel sessions, debates and interactive group sessions. It is designed to complement the 2-day conference at PCT.

We will start the day with informal networking and group introductions. Then we will engage in several panel discussions and group debates.

09:45 **Registration and Coffee**

10:20 **Opening remarks from the Chairperson**

Dr Lan Bandara,
Director, Clinical Outsourcing,
Eisai Product Creation Systems,
Eisai Limited, UK
&
Richard J. Mayewski,
Associate Director, Clinical Trial Intelligence,
Novartis, USA

FULL SERVICE, STRATEGIC AND TACTICAL PARTNERSHIPS

10:30 **Case study: Sponsor and three CROs working collaboratively in a full service outsourcing model**

- Benefits & real life experience of working in a 4 way collaborative forum
- Single Description of Services - focussing on the what, not the how
- Single set of performance indicators and approach to target setting
- Consistent and pragmatic approach to governance
- Agreed co-innovation and continuous improvement framework
- Commitment to change management

Dr Nadia Turner,
Alliance Management Director, Clinical Operations,
AstraZeneca, UK

Dr Stephen Walker,
Alliance Management Director, Clinical Operations,
AstraZeneca, UK

11:00 **Implementing a strategic regulatory partnership**

Marina Friese,
Associate Director, Outsourcing & Contracts Management,
UCB BioSciences, Germany

A Representative,
Global Regulatory Affairs,
UCB BioPharma, UK

11:30 **Morning networking break**

12:00 **Strategic versus tactical**

- Evaluation of which is best for various scenarios
- Do strategic partnerships result in more transparency?
- Can there ever be a true strategic partnership when CRO 's and Sponsors have different goals?

Panel Chair:
Pasi Piitulainen,
Senior Director, Clinical Development Finance & Strategic Sourcing,
Actelion Pharmaceuticals, Switzerland

Panellists:
Lidia Cappellina,
Head of Outsourcing Management,
Chiesi, Italy

Carl Emerson,
Managing Director,
Inside Outside Solutions, UK

Christian Tucat,
SVP Business Development,
INC Research, UK

OPTIMISING THE SPONSOR-CRO PARTNERSHIP

12:30 **Lessons to be learnt from other industries on managing outsourced suppliers and on contracting services**

- Moving from war to peace with your suppliers
- How other industries build alliances and partnerships
- Apparently inconsequential essentials of contracting

Dr Pete Harpum,
Client Director,
Mannaz A/S, UK

13:00 **Networking lunch**

> Excellent opportunity to get a pulse-check on the state of the clinical outsourcing industry
>
> Dave Webber, Associate Director, R&D Compliance, Biogen Idec

14:00 **How CROs (and Pharma) should handle themselves at bid defence meetings and how to submit proposals.**

- 'Agreements' before and after a bid defence
- Purpose, Costs, Aims and Outcomes of bid defences
- Is this a good time to mention past Relationship Health Questionnaires?
- Value of an MSA and being a 'Partner' of the client when at a bid defence

Mike Sitton,
Chief Executive Officer,
Haoma Medica, UK

14:30 **Optimising the Sponsor-CRO partnership: Quality oversight in outsourced clinical trials**

- The role of quality management agreements: How to set the right foundation for the quality management relationship between the CRO and sponsor
- Defining a risk based approach to Sponsor and CRO quality oversight: what is the right amount and type of data to monitor?
- Developing and implementing the right tools for Sponsor and CRO quality oversight
- How much oversight is overkill?
- Tips for effective Sponsor and CRO collaboration when quality in outsourced clinical trials is at risk
- Guidelines for ongoing evaluation of the quality management partnership between CROs and Sponsors

Panel Chair:
Dr Jennifer Emerson,
Corporate CDMQ Europe,
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Panellists:
Charlotte Tvermoes Rezai,
Senior Director QA,
Genmab, Denmark

Nancy Meyerson-Hess,
Head Clinical Operations & Compliance,
Grünenthal Innovation-Development, Germany

Doug Schantz,
US Head, Site Management and Monitoring,
AstraZeneca, USA

Sally Osmond,
Executive Vice President and General Manager,
INC Research, UK

15:30 **Afternoon networking break**

16:00 **KPIs: Managing performance and risk in clinical development**

- What is key to the success of clinical trials?
- Setting a clinical strategy: managing performance and risk
- Strategic alignment: let's work together
- Using performance data without drowning in numbers
- Making the right decisions at the right time
- Big data analytics can support decision making

Dr Dimitri Stamatiadis,
Founder and CEO,
MAIA Consulting, Switzerland

16:30 **Summary remarks**

16:45 **End of special focus day X**

PCT Welcome Reception

17:30 - 19:00, Congress Centre

Kicking off the main two days of PCT, the Welcome Reception provides a great opportunity to catch-up with friends and peers. We look forward to seeing you there.

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14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

SPECIAL FOCUS DAY: Tuesday 17 November 2015

Workshop Y – INVENT: Leadership and Change Management for the Clinical Trial Industry

09:45 **Registration and Coffee**

10:20 **Opening remarks from the Chairperson**

Dr Anna Matranga,
Strategic Sourcing R&D, Senior Director,
Global Scientific Affairs & Strategic Sourcing,
Ipsen Innovation, Canada

'**INVENT**' for the clinical trial industry is a new concept to help you and your organisation effectively implement a robust change management strategy, based upon core communication and leadership skills. This training course will help develop vital leadership skills and provide practical guidance and advice on change management. To function efficiently, organisations need to align themselves with their surroundings, develop strategies, plan functional actions and adopt key leadership skills. People are organisations biggest assets so investing in your team should not be undervalued. Together you and your team are ultimately responsible for the success of your clinical trial.

The clinical trial industry has in recent years seen a trend in mergers and acquisitions. Organisations in order to grow need to adapt and change. Change can impact team dynamics and create uncertainly, impacting all those involved.

Change management and leadership is of fundamental importance. This workshop is designed to provide optimum training in change management and leadership, with a focus on communication, in order to succeed during challenging times.

Session 1: Leadership

Session 2: Change Management

Session 3: Communication and Change Management: Skill Based Training to Improve Productivity and Performance

10:30 **Session 1: Topics to address:**

- The fundamentals of leadership
- Strategic leadership training and applying this to your organisation
- High quality project leadership
- Leading complex projects successfully
- Case studies and group work

11:30 **Morning networking break**

12:00 **Session 2: Change management**

- The theory including "Lewin's Freeze Phases" and "Kotter's eight steps for change".
- Putting Lewin's theory into practice
- Introducing Project Risk Analysis and Management to a clinical research programme.
- Changing from outcome based to behavioural based contracts – let's see if our expert host can convince you by taking you through the Kotter model

13:00 **Networking lunch**

14:00 **Change management case study from UCB**

Exploring change management in practice. Learn from UCB who initiated an innovative solution which has been implemented to accelerate studies and R&D activities. This was a change for many people including sponsors, CROs, investigator sites and health care professionals. It required a change of mindset, a lot of communication, some organisation and training but saved a lot of time and administrative resources!

Session 3: Leadership and change management: Skill based training to improve productivity and performance

This forms the final session to INVENT. It will be highly interactive, creative and it is intended that you leave this session with new information that you can implement in your day-to-day role.

14:30 **Strategically optimising communication**

- Exploring a multitude of elements that are required for effective communication
- Mirror neurones and their role in overall communication
- Examples of individual communication preference
- How communication can break down
- Hidden communication (hidden agendas that distort communication)
- Introduction to conflict: Recognising warning signals in yourself and others
- Optimisation & strategic approaches to improve communication

15:00 **Implementing effective global communication skills**

- Assessing the gaps in communication that exist internally and externally
- Making the best use of tools technologies for effective communication
- Finding the root cause of communication problems to promote success
- How to successfully manage cultural and time zone challenges

15:30 **Afternoon networking break**

16:00 **Interactive discussion on conflict management: Constructive troubleshooting and conflict management**

Troubleshooting and conflict management remain an integral feature of the Sponsor-CRO relationship. In this session, we will explore the root causes of conflict on both the Sponsor and CRO side, and discuss best practices for constructive issue resolution.

- Is conflict avoidable in Sponsor-CRO collaborations?
- Root causes of dissatisfaction and conflict
- The main pitfalls in conflict resolution
- Best practices, rules and tools for constructive conflict management
- What would you have done? A case study

16:30 **Summary remarks**

INVENT: Leadership and change management for the clinical trial industry hosted by:

Gavin Emerson,
CEO,
Emerson Strategies, UK

Pia Larsen,
R&D Outsourcing Manager,
Clinical Partnership Management,
Leo Pharma, Denmark

Dr Elizabeth Baldauf,
Consultant & Trainer,
Baldauf Training & Consulting, Germany

Dr Pete Harpum,
Client Director,
Mannaz A/S, UK

16:45 **End of special focus day Y**

PCT Welcome Reception

17:30 - 19:00, Congress Centre

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"Opportunity to exchange a variety of opinions an experience on oversight and management of clinical trials among industry experts"

Baxter

14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

SPECIAL FOCUS DAY: Tuesday 17 November 2015

Workshop Z – The Fundamentals of RBM

Quality Risk Management (QRM), Quality by Design (QbD), Risk-based Monitoring (RbM), data driven monitoring or centralised monitoring have become interrelated terms of a hot topic. There is hardly an organisation that does not claim to already apply or considers to implement such an approach for clinical development and pharmacovigilance. This begs the question: is it just hype or a shift in paradigm? We are convinced that this is more than just hype. However, the shift in paradigm has not yet happened either. We observe many approaches to a risk-based study management but came to the conclusion that it is too early to celebrate an advent of a new era in clinical trials and development. We notice that the majority of approaches proposed lack fundamental elements of Quality by Design and Quality Risk Management strategies.

This day will be divided up into interactive sessions and case studies. It will be highly interactive and is designed to complement the main conference days at PCT.

09:45 **Registration**

10:20 **Opening remarks from the hosts**

10:30 **Introduction to risk management and risk-based monitoring**

11:00 **Session A: Interactive discussion addressing:**

- Is it true that only larger pharma or device companies can apply a risk-based approach?
- Do I need sophisticated IT tools to implement a risk-based approach?
- Is it true that we need to change the way we write protocols and set up trials to implement successfully a risk-based approach?

11.45 **Morning networking break**

12:15 **Session B: Interactive discussion addressing:**

- What are KRIs and KPIs, and how can they support a risk-based approach?
- Will a risk-based approach make site selection/qualification and patient recruitment into my trials any easier, and will it help to get better data faster and cheaper?

12:45 **Session C: Case Study from Mitsubishi Tanabe Pharma**

Aldir Medeiros Filho, *Senior Data Quality Reviewer- Data Sciences Department,* **Mitsubishi Tanabe Pharma Europe, UK**

13:15 **Networking lunch**

14:15 **Session D: Case Study: RBM retrofit, transforming risks into returns**

- Letting regulators, data and systems drive change
- Incorporating data driven reporting retroactively
- Driving awareness & control of site risk
- Reducing manual effort

Adam Baumgart, B.Sc., CPM, *Director, Process Excellence, Business Lead, Risk-Based Monitoring,* **Covance, UK**

> Very impressed by the enthusiasm of industry wanting to hear more about how we engage with patients post talks and on stands wanting to discuss this- great opportunities for collaborations
>
> Past speaker PCT 2014

14:45 **Session E: Interactive discussion addressing:**

- Will a risk-based approach allow me to stop SDV (Source Document Verification) and reduce the burden of on-site monitoring?
- How much money do I save by implementing a risk-based approach?
- How will Health Authorities react if they discover a major or critical finding that was not detected or not addressed through your risk management approach?

15:45 **Networking break**

16:15 **Session F: Interactive discussion addressing:**

- How does a risk-based approach impact on my organisation, i.e., study site, quality assurance, data management, clinical operations, drug safety, biometrics, etc.?
- What is the best implementation strategy for a risk-based approach?

16:45 **Summary remarks and end of special focus day Z**

Facilitators:
Dr Beat Widler,
Managing Partner,
Widler & Schiemann AG, Switzerland

Dr Peter Schiemann,
Managing Partner,
Widler & Schiemann AG, Switzerland

PCT Welcome Reception

17:30 - 19:00, Congress Centre

Kicking off the main two days of PCT, the Welcome Reception provides a great opportunity to catch-up with friends and peers. We look forward to seeing you there.

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14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

CONFERENCE DAY ONE: Wednesday 18th November 2015

Plenary Sessions

07:30 **Registration and morning coffee**
Plus sign up for Ask the Experts

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

Jean Edwards,
Procurement Director, Europe, Australia & Japan,
Eli Lilly, UK

09:00 **The partnership landscape: The past, present and future**

- 5 years down the line how will we be running clinical trials?
- What innovation ideas are there?
- Looking to the future: What will the next 10 years hold in the way we work in outsourcing?
- Will the main focus be cost or quality?
- Do we expect an increase in volume of work, longer studies and more data collection?
- Will there be a clever way of working: Exploring innovation in the market place
- RBM: Should we decrease clinical trial costs? Hear data that demonstrates how this innovative approach works
- What will be the impact of the new clinical regulation?

Interviewer:
Phil Hammond,
GP and Broadcaster

Panellists:

Vanessa Cooke,
Vice President, Global Head Strategic Sourcing R&D,
Bayer HealthCare Procurement, UK

Christopher Rull,
Vice President, Head Alliance Management,
Merck Serono, USA

Dr Graham Belgrave,
Senior Vice President, Head Global Clinical Development Operations,
Grünenthal GmbH, UK

Barbara Tardiff,
Vice President, Global Head Clinical Innovation and Informatics,
Pfizer, USA

Alistair Mcdonald,
Chief Operating Officer,
INC Research, UK

Bart Valdez,
President, Strategic Resourcing,
inVentiv Health, USA

10:00 **12 months later: The latest on TransCelerate**

- Highlights on TransCelerate accomplishments, benefits and supporting metrics delivered to the industry in the last 12 months
- Share success stories working collaboratively across Sponsors, Investigators, CROs and Regulators
- Learn what assets and solutions are available for Sites, CROs and non-member companies to leverage
- Preview of new initiatives that will continue to streamline clinical development

Panel Chair:
Phil Hammond,
GP and Broadcaster

Panellists:

Rob DiCicco,
Vice President, Clinical Pharmacology Sciences and Study Operations,
GlaxoSmithKline, USA

Iris Loew-Friedrich,
Executive Vice President, Biopharma Development Solutions and Chief Medical Officer,
UCB, Belgium

Janice Chang,
Head of Delivery Excellence and Corporate Affairs,
TransCelerate, USA

10:40 **Morning Coffee and Networking sponsored by** World Courier AmerisourceBergen

> PCT is an excellent networking event for clinical research professionals working in all functions.
>
> Global Development - Portfolio & Operations

11:20 **Innovation in strategic site monitoring**

- Selecting the right analytics and benchmarks in a risk-based monitoring study
- Innovations in technology to optimise CRA workflows including; onsite and remote management
- Success stories on documenting and reporting key site activities - what have we learnt?

Patricia Ward,
Senior Director, Product Management,
Medidata, UK

11:50 **How Ebola clinical trial and regulatory pathways were fast tracked - what worked, what did not and how can this be applied?**

- What were the challenges with Ebola and were they specific or generic?
- Companies and health organisations fast tracked development and clinical to get into patients - did this work and if so how?
- How to do this rapid and targeted clinical development - What were the timelines achieved and what could they have been avoided?
- What was the pricing, marketing and access strategy and how was this decided?
- How were the drug and vaccine trials set up in this disease outbreak situation?
- What can be learnt in terms of rapid product development and setting up such trials?

Trudie Lang,
Professor of Global Health Research, Director,
University of Oxford, UK

12:20 **Lunch and Networking Time with partneringONE®**

Lunch and networking break in the exhibition hall plus sign up for "Ask the Experts"

12:20 – 13:00 **Ask the Experts – Day One**

Experts are waiting to advise you on burning questions with one-on-one sessions. This is the place to be for ideas, inspiration or ways around a specific problem.

Clinical development - resource and finance management

Lesley Mathews,
Global Development - Portfolio & Operations, Resource Management & System Integration,
Bayer Healthcare, UK

Negotiation skills: Aiming high – Knowing the limits: Professional negotiation in the sponsor-CRO relationship

Dr Elizabeth Baldauf,
Consultant & Trainer,
Baldauf Training & Consulting, Germany

Resolving GCP Issues

Patricia Hall,
Director,
Deighton Hall Associates Ltd, UK

Alec Deighton,
Director,
Deighton Hall Associates Ltd, UK

Expanding your CRO business into Europe

Ineke Rijnhout,
Business Development Executive,
Kenko Consulting, The Netherlands

14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

CONFERENCE DAY ONE: Wednesday 18th November 2015

Stream 1 – Partnering and Sourcing Models

13:50 **Opening remarks from the Chairperson**

Dr Anna Matranga,
Strategic Sourcing R&D, Senior Director,
Global Scientific Affairs & Strategic Sourcing,
Ipsen Innovation, Canada

14:00 **Assessing true CRO usage and identifying actionable steps to optimise team effectiveness**

- Review the results of a recent Tufts CSDD study assessing actual CRO usage on phase II and III clinical programs
- Discuss areas where relationship inefficiency and tensions exist
- Identify primary causes of unintended partnership practices
- Explore actionable ways to improve collaborative effectiveness and realise partnership strategies

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

14:35 **2 CRO's collaborating within a sponsor to enhance ways of working and help create a win:win:win partnership**

- Outline an approach taken by UCB and its 2 strategic partners, PRA & PAREXEL to enhance the partnerships
- Increasing connectivity and de-mystifying the partnership
- Fostering a way of working together to allow all 3 partners to live a true partnership

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

Holger Liebig,
Senior Director eClinical Solutions,
PAREXEL, Belgium

Tracy Cyr,
Project Director,
PRA Health Sciences, USA

15:10 **Driving strategic success through a harmonised, 'one-voice' approach within Sponsor and CRO**

- Sponsors and CROs partnering with a 'one voice' approach achieve greater strategic and tactical success
- Collaboration focusing on proactive strategy and tactical delivery in parallel with continuous evaluation of objectives - both established and evolving to meet a changing landscape - results in sponsor and CRO achievement of mutual goals
- Focusing on harmonisation between organisational business units across sponsor / CRO partnerships leads to operational efficiency, leveraging shared experiences to drive quality improvement, and improved results with shared key performance indicators
- Governance teams spanning harmonised business units are able to better oversee and support program development due to a more consistent approach to strategic and tactical decision making

Cynthia Hauck,
Director, Vendor & Outsourcing Management,
Bristol-Myers Squibb, Switzerland

Lisa Mummert,
Director, Observational Research,
inVentiv Health, USA

15:40 **Afternoon Tea and Networking Time sponsored by** MEDPACE

Agenda continued on pg. 19

informa
life sciences

> PCT Europe always delivers. Great meeting, excellent networking and in today's climate, great value for money.
>
> Vice President, Commercial Operations, Biocair

www.ct-partnerships.com

PCT EXHIBITION PARTNERSHIPS IN CLINICAL TRIALS

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Hamburg, Germany

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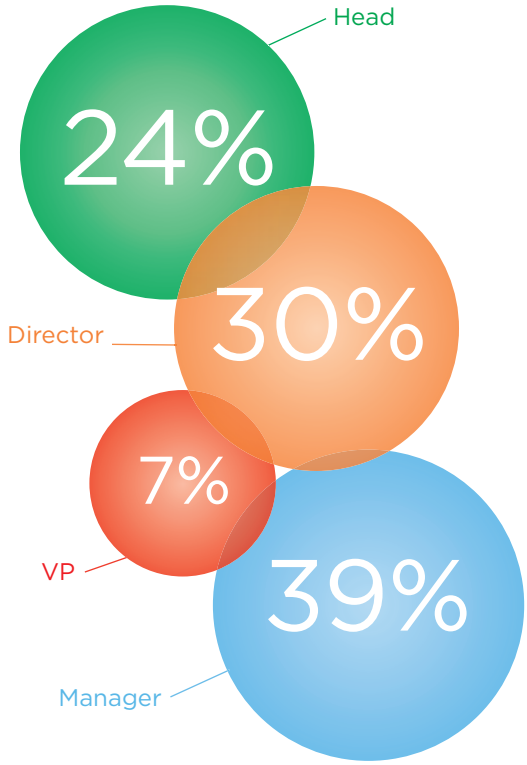
14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

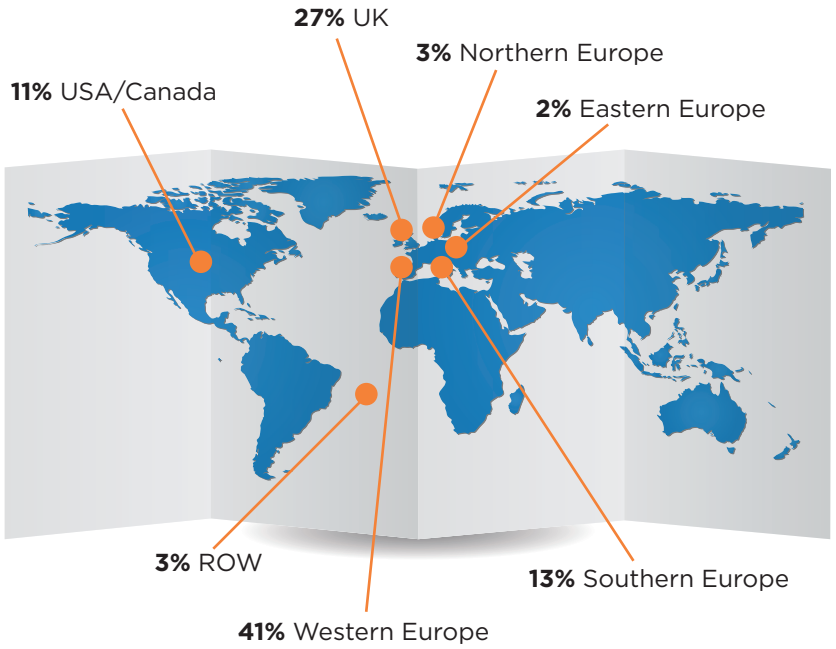
> As a sponsor of PCT, we find it to be a very good show with a good mix of pharma companies. It offered extensive new opportunities with both new companies and existing clients.
>
> Director, Global Marketing, World Courier

PRIMARY AUDIENCE BREAKDOWN

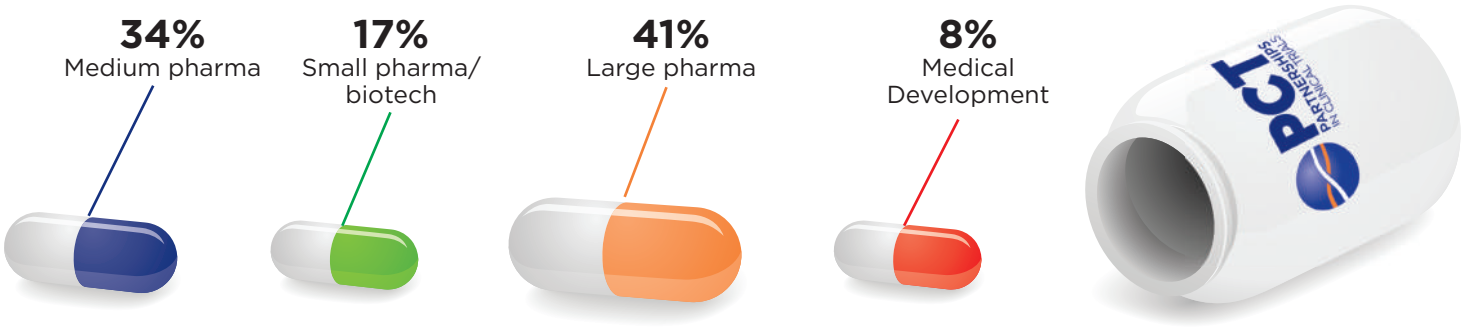
BY JOB TITLE:



BY GEOGRAPHY:



BY COMPANY TYPE:



For information on Sponsorship and Exhibition Opportunities please contact Sukhvir Hayre, sukhvir.hayre@informa.com or +44 (0)20 7017 7131

> As an exhibitor at PCT 2014, we found the delegate traffic was really good and we made some great new leads
>
> Woodley Equipment

FEEDBACK FROM PAST SPONSORS

Don't just take our word for it, direct from 2014 sponsors and exhibitors -

80%
said they would sponsor/ exhibit at PCT again

99%
said PCT delivered the right audience for them to conduct business with

Average rating for PCT is
9/10

90%
would recommend sponsoring/ exhibiting at PCT to other companies

WHO SHOULD EXHIBIT?

Our market research with the industry has identified clear categories of companies that our pharma and biotech audience would like to meet. The key areas are in the following sectors -

- Patient recruitment and retention
- Niche CRO services
- Technology/software
- Mobile health technology
- Logistics
- Lab services
- Equipment
- Life sciences consultancy
- Telemedicines
- Translation services

NETWORKING PROGRAMME FOR 2015

GUARANTEED 1-TO-1 MEETINGS

New for PCT 2015 is the chance to build relationships that matter through organised one to one meetings with key clients. If you would like to take advantage of this service please contact **Katie Birch** at **katie.birch@informa.com**

LEADERSHIP BOARDROOM

Offering targeted networking in a business atmosphere, these boardroom meetings are a tailored solution for companies looking to meet specific high-level attendees.

PARTNERINGONE®

Building on the success of last years' event, we will be using the partneringONE networking tool at PCT. partneringONE is an industry recognised partnering system that allows you to:

- Arrange one-to one meetings at the event
- Engage in pre-event discussions
- See a full list of event attendees

Please visit our event website **www.ct-partnerships.com** for more details.

14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

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Quanticate A Passion For Excellence
SanaClis
SCOPE INTERNATIONAL
SGS
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THERAPAK PHARMA SERVICES LTD
trifecta
Unilabs Drug Development Services
WOODLEY EQUIPMENT COMPANY LTD.

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> The Informa Partnership in Clinical Trials annual conference is the best meeting in Europe to keep appraised of what is going on in outsourcing, whether it is information on new strategic alliances, updates on more mature partnerships or just the considerations for the ever changing environment we are working in
>
> Julianne Hull, Managing Director, WenStar Enterprises, UK

CONFERENCE DAY ONE: Wednesday 18th November 2015

Stream 1 – Partnering and Sourcing Models (Continued)

16:20 **The evolution of outsourcing strategies: Managing change in stakeholders during outsourcing and strategic partnerships**

- Real-life experience of what can go wrong in a partnership and how can this be avoided
- How to keep partnerships strong and avoid them failing
- Highlighting processes of quality oversight during a fully outsourced study, including pitfalls and solutions
- Change in stakeholders: How do you still take forward the partnership? How does this impact the trial? How to keep fresh and on-track when this happens
- Is there a company out there that off-shored everything to a CRO / several CROs and then decided to pull work back in house? What were the challenges and what were the solutions How did they manage it?
- When there is a change of stakeholders, what do you with on-going trials? Do you take in house or move from one CRO to another?

Panel Chair:
John Gate,
European Procurement Executive,
Eli Lilly & Co Ltd, UK

Panellists:
Anne Merritt,
Director, Global Supplier Governance and Clinical Pricing,
Amgen Ltd, UK

Dr Michael Betke-Hornfeck,
Vice President Global Dept. Sourcing R&D+M,
Boehringer Ingelheim, Germany

David Shalhevet,
Senior Regional Clinical Trial Manager,
Global Clinical Operations - EMIA APAC Region,
Teva, Israel

Achim Schwarz,
Senior Outsourcing & Contracts Manager,
UCB, UK

16:55 **Learning from other industries: Exploring Nestlé's business outsourcing organisation**

- Outsourcing strategy overview
- Exploring governance at Nestlé
- Continuous improvement to ensure a successful outsourcing model
- Forecast of outsourced volume of work
- Next steps and future considerations

Sara Lamberti,
Business Outsourcing Manager,
Nestlé, France

CLOSING PLENARY:

17:30 **Inspirational: From Ice to Dust – taking medicine to extremes. Survival of the fittest - world authority in human endurance and nutrition**

Mike Stroud is a hospital doctor who has interspersed his work with far-flung expeditions and research on endurance, nutrition and survival. He and Sir Ranulph Fiennes were the first men to walk across Antarctica entirely unaided by animals or machines and more recently were the first to complete 7 marathons on 7 continents in 7 days. Together, they have raised millions for good causes and both were awarded the Polar Medal for Antarctic and Arctic exploration and the OBE for Human Endeavour and Services to Charity. Mike holds many advisory roles in UK Healthcare particularly leading the efforts by the National Institute of Clinical Excellence (NICE) to ensure that 'optimal nutrition and hydration lie at the heart of 'Quality Care'.

Dr Mike Stroud OBE

18:00 **Lifetime Achievement Award**

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Partnerships Bar and Drinks Reception

18:15-19:30 Exhibition Hall

Back by popular demand the Partnerships Bar will once again offer attendees a chance to recharge after a full day. Join us for Theorem's signature cocktail!

Sponsored by THEOREM SIMPLIFYING COMPLEX TRIALS™

14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

CONFERENCE DAY ONE: Wednesday 18th November 2015

Stream 2 – Implementing Risk Based Monitoring (RBM)

13:50 **Opening remarks from the Chairperson**

David Holloway,
Head of Clinical Development Operations,
Grünenthal Pharma S.A., Spain

14:00 **TransCelerate and RBM**

- Quantitative and qualitative lessons learned from RBM trials using the TransCelerate methodology
- Technology considerations and needs to enable success
- SDV and SDR – where are we?
- Investigator site feedback
- Considerations for data integrity and GCP misconduct
- What are next steps for TransCelerate RBM?

Panel Chair:
Andy Lawton,
Global Head, Data Management,
Boehringer Ingelheim Ltd, UK

Panellists:
Gary Thompson,
Senior Director, Data Sciences and Solutions,
Eli Lilly & Company, USA

Sina Djali,
Senior Director, Risk Management-Central Monitoring: Global Clinical Operations,
Janssen R&D, USA

Phillip Wallis,
Director of Compliance Analytics and Intelligence
Pfizer, UK

14:35 **How to successfully use data analytics tool to support risk based monitoring process**

- Implementing a process that complies with latest health authorities' requirements
- Using standardised automated tools like TAPAS to manage inherent risks in clinical research
- Collecting data through the Data Warehouse to assign risk assessments to sites
- Reviewing progress and lessons learnt

Roland Rich,
Operations Expert,
Novartis, Switzerland

15:10 **Real life experience of implementing and best practice of risk based monitoring (RBM)- Lessons learnt**

- Re-aligning SOP with RBM: How to do this well and how to organise yourself
- What point will you completely make the change over and how do you transition to a new system?
- What are the pitfalls in implementation and how to overcome them?
- Comparing different models used for RBM: Which model to choose and what were the outcomes?
- How much money will be saved or not and what is the contractual arrangement?
- Demonstrating the added value of RBM

Panel Chair:
Mireille Zerola,
Clinical Data Management Expert,
Boehringer Ingelheim Ltd, UK

Panellists:
Marion Reiser,
Associate Director Clinical Operations & Site Monitoring Organisation,
Bristol-Myers Squibb, Belgium

Courtney McBean,
Vice President Clinical Innovation,
BioClinica, USA

Aldir Medeiros Filho,
Senior Data Quality Reviewer- Data Sciences Department
Mitsubishi Tanabe Pharma Europe, UK

Nicole Stansbury,
Executive Director, Remote Site Management and Monitoring,
PPD, USA

15:40 **Afternoon Tea and Networking Time sponsored by** MEDPACE

16:20 **How to assess the quality of monitoring – QA/Audit perspective**

- Analysing the training that goes into monitoring
- How the role of site monitor will evolve
- What will companies do differently during a time of radical change?
- Technologies will advance: expectation and will this drive forward innovation?

Dr Jan Van Parijs,
Senior Director, Quality Assurance Operations,
Janssen Pharmaceutical, Belgium

> Nice mix of presentations and discussions with good networking opportunities
>
> BMS

16:55 **Investigator/site perspective of RBM – Experiences and challenges**

- What are the proposed benefits of RBM? To the Sponsor/CRO/Site?
- With increased regulatory requirements is RBM a move in the right or the wrong direction?
- Do investigators see RBM as a step in the right direction?
- How should this change be implemented at the site?
- RBM and the changing role of the CRA: Effectively working with the investigator site and the impact this will have on CROs and AROs
- Paradigm of running clinical trials with changes to RBM

Panel Chair:
Dr Estrella García,
Head of Global Clinical Operations, R&D,
Almirall, S.A, Spain

Panellists:
Dr Fraser Inglis,
Director, **Glasgow Memory Clinic Ltd, UK**

Dr Jutta Beier,
Managing Director, **insaf Respiratory Research, Germany**

Professor Diederick E. Grobbee,
Professor of Clinical Epidemiology, **University Medical Center Utrecht, The Netherlands**

Helena Sigal,
Managing Director, **Sigal Site Management and Support, (SIGAL SMS), Germany, ACRES representative, Germany**

CLOSING PLENARY:

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14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

CONFERENCE DAY ONE: Wednesday 18th November 2015

Stream 3 – It's all about the Patient: Patient Recruitment, Retention and becoming more Patient Centric

13:50 **Opening remarks from the Chairperson:**

Jeremy Gilbert,
Vice President Product And Strategy,
PatientsLikeMe, USA

14:00 **Are trials becoming more patient-centric?**

- What does patient centricity mean for clinical research
- The strategic and operational opportunities for patient engagement in research
- Examples of patient engagement in research: Study simulation, Patientslikeme

Dr Guy Yeoman,
Vice President Patient Centricity,
AstraZeneca, UK

14:35 **Ensuring trials are patient centric to improve patient recruitment and retention**

- What do we mean by patient centricity?
- The importance of the patient centricity and the patient perspective: Experiences of being involved in a clinical trial, what was good, what wasn't?
- Guidance from site investigators and nurses on how to help with patient engagement and retention
- Utilising different methodologies for collecting and using patient insights in trial design and conduct

Panel Chair:
David Wright,
Head of Planning & Platform Services,
Amgen, USA

Panellists:
Dr Stephen Nabarro,
Head of Clinical Operations and Data Management,
Cancer Research UK Centre for Drug Development (CRUK), UK

A Patient from a CRUK clinical trial

Melissa Jean Mottolo,
Patient Recruitment Strategist,
Roche Basel, Switzerland

Dr Julie Hapeshi,
Associate Director R&D / Deputy Director SW RDS,
Gloucestershire Research Support Service, NHS, UK

Professor Sue Pavitt,
Professor in Applied Health & Translational Research,
University of Leeds, UK

15:10 **Optimising clinical trial management - improving the relationship with the investigator site**

- Addressing implications of remote communication and gaining advice on how to improve communication between partners and investigator sites
- What is the best model to ensure fewer change overs of vendors?
- Addressing the concept of strategic partnerships with sites to improve efficiencies and keep stakeholders
- Feedback from site investigators and study nurses on CRO relationships with sites: how to nurture site relationships? What can you do? What are others doing?
- Working with academia and universities: the challenges and guidance for a better working relationship

Panel Chair:
Jeannett Dimsits,
Vice President, Scientific Affairs, Haemophilia R&D,
Novo Nordisk, Denmark

Panellists:
Dr Tobias Arkenau, *Director, Drug Development,*
Sarah Cannon Research, UK

Dr Steve Martindill, *Director, Clinical Operations International,* **Gilead Sciences Europe Ltd, UK**

Jess Sohal, *Executive Director, Clinical Operations, Europe,*
UBC, UK

15:40 **Afternoon Tea and Networking Time sponsored by** MEDPACE

16:20 **Optimising the protocol design and enhancing patient identification/recruitment for clinical studies by leveraging Electronic Health Record Data: The IMI HER4CR Project**

- The Networking breakthrough HER4CR platform will enable the trustworthy re-use of patient-level data from hospital Electronic Health Records (HER) for enhancing clinical research processes.
- Improved protocol design by avoiding protocol amendments and by developing smarter protocols right from the beginning
- Faster site identification and potentially patient identification for clinical trials through direct access to electronic medical records
- Long term avoiding data transcription from EHRs into EDC systems by a data transfer mechanism from one to the other application

Dr Johann Proeve,
Global Strategy and Development Advisor,
Bayer Vital GmbH, Germany

16:55 **The use of social listening to build recruitment/retention strategies and understanding the patient pathway to influence protocol design**

- Developing protocols with the patient in mind: Why shall a patient take part in a clinical study? A detailed look at study protocols
- Utilising different methodologies for collecting and using patient insights in trial design and conduct
- Engaging multi-media communication that uses all types of media
- Details of study protocols which influence the decision of patients to take part or not to take part in a clinical study
- The use of social listening to build recruitment/retention strategies

Panel Chair:
Marisa Minetti, *Clinical Trial Transparency Manager,*
Chiesi Farmaceutici, Italy

Panellists:
Dr Bettina Bergtholdt, *Managing Partner,*
Emovis GmbH, Germany

Kate O'Brien, *Clinical Study Nurse,* **NHS, UK**

CLOSING PLENARY:

17:30 **Inspirational: From Ice to Dust – taking medicine to extremes**

Dr Mike Stroud OBE

18:00 **Lifetime Achievement Award**

18:15-19:30 **Partnerships Bar and Drinks Reception sponsored by** THEOREM SIMPLIFYING COMPLEX TRIALS™

CONFERENCE DAY ONE: Wednesday 18th November 2015
Stream 4 – Advances in Disruptive Innovation

13:50 **Opening remarks from the Chairperson**

Michael Sauter,
Senior Director Digital Health Technologies,
Biogen, USA

14:00 **Remote monitoring in clinical trials: Getting closer to objective and actionable data**

- Sensor based data collection in clinical trials: The concept and its implementation
- The advantages of continuous remote monitoring: Accuracy, time and cost
- Mining ecologically valid data from everyday life activities
- Behavioural biomarkers: Is my medication really helping?

Judith Kornfeld,
Chief Business and Operations Officer, Orcatech,
Oregon Health & Science University, USA

14:35 **Understanding why we innovate**

Marc Stone,
Executive Vice President, Strategic Innovation,
PRA Health Sciences, USA

15:10 **The Innovation Den: Exploring innovative technologies and processes**

The innovation den will showcase innovations and creative ideas that are changing the way clinical trials are run. Hosts will have 10 minutes to present their innovation / idea to the audience. After all speakers have discussed their innovation the audience will vote for the technology or process that they deem to be most innovative. The winner will be announced during the lunch networking break.

Topics to be covered include:

- Addressing technology platforms and processes that are shaping the clinical trial landscape

Covering the following points:

- What is your invention/ technology/ idea/ innovative process
- How will this change the way we run clinical trials?
- What benefits will this offer
- Case study examples of your idea/ process/ technology in practise

Chairperson:
Gene Odle,
Consultant,
eValueDrugs, Bulgaria

The Innovation Den Finalists Include:
Nhan Ngo Dinh,
R&D Manager,
Linkverse, Italy

Wenke Schult,
Deputy CEO,
Emovis home care visits GmbH, Germany

Dr Susan M. Dallabrida,
Vice President, Clinical Science & Consulting,
ERT, USA

Other Finalists To be Announced
If you want to be shortlisted as a finalist and join this session please contact Sukhvir Hayre. Email: sukhvir.hayre@informa.com Tel +44 (0) 207 017 7131

15:40 **Afternoon Tea and Networking Time sponsored by** MEDPACE

16:20 **How disruptive technology enables companies to possess a differentiating capability with their eTMF**

- The eTMF maturity model: what it is and how to assess your organisation's maturity phase
- Benchmarking: how does your organisation's TMF strategy compare to the industry
- Roadmap: how to reach an optimal state of TMF efficiency and accuracy by applying disruptive technology

Rik van Mol,
Vice President R&D Europe,
Veeva Systems, UK

16:55 **Revolutionising sponsor and site communications through the Shared Investigator Platform**

- Provide an overview of the Shared Investigator Platform
- Present features and benefits for sites and sponsors
- Preview release 2 functionality and roadmap for future releases

John Bots,
Global Head CSMS,
AbbVie, USA

CLOSING PLENARY:

17:30 **Inspirational: From Ice to Dust – taking medicine to extremes**

Dr Mike Stroud OBE

18:00 **Lifetime Achievement Award**

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14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

CONFERENCE DAY TWO: Thursday 19th November 2015

Plenary Sessions

08:15 **Morning coffee**

Plus sign up for Ask the Experts

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

Graham Belgrave,
Senior Vice President, Head Global Clinical Development Operations,
Grünenthal GmbH, UK

09:00 **Partnerships in clinical trials- Question Time**

Delegates will submit their questions on an interactive post-it board throughout the conference on day one. The chairperson will be tasked to pick the most interesting questions and put them to the expert panel for answers.

Panel Chair:

Dr Kenneth Getz,
Director of Sponsored Programs,
Tufts CSDD,
Chairman,
CISCRP, USA

Panellists:

Dr Guy Yeoman,
Vice President Patient Centricity, VP Patient Centricity,
AstraZeneca, UK

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

Dr Arun Maseeh,
Vice President, Medical Services,
Cadila Pharmaceuticals, India

Dr Paulo Moreira,
Vice President, GCO Head of External Innovation,
Merck Serono, USA

Dr Jaikrishna Balkissoon,
Senior Medical Director, Oncology, Global Product Development,
PPD, USA

Professor Brendan Buckley,
Chief Medical Officer,
ICON, Ireland

10:00 **Trends and drivers shaping the clinical trial industry: Where will this lead to?**

- The economy and the future of the clinical industry: Who is putting the patients first?
- What is the economy trend and what will this mean for the pharma industry?
- Highlighting problems in Europe with funding: Payers are pushing for heavier discounts, drug funding has just been cut, are we charging too much and are we making the wrong decisions?

Lawrence Klein,
Associate Principal,
Mckinsey & Company, USA

My main objectives in attending are to make more contacts with new, different CROs - I want to see who is on the market and what innovative solutions they can provide

Peter Born, Global Lead Buyer, Clinical Procurement – Sanofi, France

10:30 **Addressing the changing needs of clinical trial development**

- Update on LabCorp and Covance acquisition
- Change management: the challenges faced
- What is the planned benefit to sponsors?
- How does this acquisition address development needs?
- How is Covance addressing changing sponsor needs?
- What role can a CRO play in reducing development time?

Steve Anderson, PhD,
Senior Vice President and Chief Scientific Officer,
Covance, USA

Robert J Davie, PhD,
Vice President & General Manager, Global Phase II-IV, Clinical Development Services,
Covance, USA

11:00 **Morning tea and networking time with partneringONE®**

13:00 – 13:40 **Ask the Experts – Day Two**

Experts are waiting to advise you on burning questions with one-on-one sessions. This is the place to be for ideas, inspiration or ways around a specific problem.

Dramatically improved project management to bring drugs to market?

Dr Pete Harpum,
Client Director,
Mannaz A/S, UK

Integrating patient centricity into recruitment and retention practices

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

Vendor management and oversight: How to ensure oversight of CRO's third party providers and what is required?

Julianne Hull,
Managing Director,
WenStar Enterprises, UK

Best practise for requests for proposals

Paul Bouten,
Consultant Interim Manager,
PharmConMed, The Netherlands

The impact of patient involvement was new for me and I found it fascinating

Past Delegate, PCT 2014

14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

CONFERENCE DAY TWO: Thursday 19th November 2015

Stream 5 – Governance, Oversight and Change Management

11:40 **Opening remarks from the Chairperson**

Ronel Steyn,
Executive Director, Program Delivery, Global Project Management,
inVentiv Health, France

11:50 **How do you govern the relationship management between a CRO and pharma - an operational perspective?**

- Is there a disconnect between a CRO and sponsor in what they expect as a high quality relationship?
- What are the drivers for a successful and sustainable relationship management and how are they linked with performance management?
- The impact of the different outsourcing models - functional service vs. full service and the differences for early exploratory studies vs. late stage studies.
- What metrics are available with respect to the time spent internally on oversight of outsourced studies?

Guido Mathews,
Head of Governance & Support,
Bayer Pharma AG, Germany

12:25 **Development of a high-functioning quality management organisation**

- Industry perspective: Developments in quality management over the past four years and where we are now based on Avoca's qualitative and quantitative data on quality management practices.
- What are the current perceptions of quality in the industry? How have these changed over the past four years?
- Which quality management practices have shown clear improvement and where has there been decline?
- What are the current tools that are being used to measure and manage quality, to assess and manage risk?

Panel Chair:
Dr Jennifer Emerson,
Corporate CDMQ Europe,
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Panellists:
Dr Patty Leuchten,
CEO,
Avoca, USA

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

A Representative of World Courier

12:55 **Lunch and networking break in the exhibition hall with partneringONE®**

Plus sign up for "Ask the Experts"

14:25 **Sponsor-CRO relationship: What have we learned from our front line perspective?**

- Case reports and real life scenario from direct CRO-sponsor cooperation.
- How to ensure oversight of CRO's third party providers and what is required?
- Common problems, easy and difficult solutions
- Auditor's perspective and lessons learned from inspection
- How much oversight of CRO is necessary or overkill?

Tomasz Kosieradzki,
Quality Assurance Advisor,
Polpharma Biologics, Poland

Natalia Tomkiewicz,
Clinical Development Manager,
AstraZeneca, Poland

15:00 **Outsourcing data management to a vendor, a strategic partnership**

- Start of the partnership/drivers to outsource
- Plan of action from both sides
- Getting through the first year, positive notes/pitfalls
- Lessons learned from both perspectives
- Take home messages

Marcel Bisschop,
Oversight Clinical Data Manager,
GSK – Vaccines, The Netherlands

What are different companies putting in place with their procurement structures and category management?

Gill Roberts, Strategic Sourcing Manager, Bayer Plc UK

15:35 **The Role of Procurement and Category Management**

- How companies are structured and how is this structure working?
- Procurement or outsourcing: Who drives the outsourcing of clinical trials? Is there a battle between departments?
- Difference between value and process: Quality, cost and timeline - the right balance
- How to reduce costs and run clinical trials more efficiently?
- When we outsource, how can we ensure that we get the quality we expect?

Panel Chair:
Peter Born,
Procurement – Scientific & Clinical, Global Lead Buyer,
Sanofi, France

Panellists:
Patricia Schuckman,
Senior Global Sourcing Manager within the Global Category Clinical CRO & Trial Supplies Services,
Boehringer Ingelheim, Germany

Martin Neumayer,
CRO Manager,
Sandoz Biopharmaceuticals Clinical Development, Germany

Peter Clompen,
Senior Global Strategic Sourcing Manager, PCS Consult,
Consultant for Actelion Pharmaceuticals Ltd, Switzerland

16:05 **Networking break in the Plenary Room**

CLOSING PLENARY:

16:20 **Patient and Doctor: An inspiring story of saving faces through innovative clinical and surgical trials- Exploring a patient's perspective**

- A story of saving faces and improving lives
- Linking surgical trials to pharmaceutical clinical trials: sharing challenges and sharing the goal of helping people
- Transferring knowledge from surgical trials to the clinical trial industry
- Hear from a patient from Saving Faces, discover their inspiring story and their involvement in a surgical clinical trial
- Open discussion between a patient from Saving Faces and Professor Iain Hutchison

Professor Iain Hutchison, *Director,* **The National Facial and Oral Research Centre (NFORC),** *Consultant Oral and Maxillofacial Surgeon* **St Bartholomew's and Royal London Hospitals,** *Honorary Chief Executive,* **Saving Faces-The Facial Surgery Research Foundation** *&* **A Patient from Saving Faces, UK**

16:50 **Closing remarks and end of PCT 2015**

14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

> I'm happy to see Mid-Size Pharmas taken into consideration in the main themes. There will be good discussions in the stream 6.
>
> Merja Mäkitalo, Clinical Study Manager & Outsourcing Specialist, Orion Pharma, Finland

CONFERENCE DAY TWO: Thursday 19th November 2015

Stream 6 – Outsourcing Partnerships and Strategies for Small to Mid-Size Pharma and Biotech

11:40 **Opening remarks from the Chairperson**

Paul Quinn,
Director - Clinical Operations,
Vectura Limited, UK

11:50 **Outsourcing models and Partnering challenges for Biotech and Small-mid-sized Pharma**

- Which outsourcing model best serve the biotech industry?
- How does the different size of the business partners (CRO vs. Biotech or small Pharma) affect the cooperation?
- Which type of CRO serves the biotech industry?
- How to manage the risk in outsourcing?
- What is the difference between a small pharma/biotech , mid-size pharma and large pharma when selecting the right outsourcing strategy?
- Which type of CRO serves the biotech industry? How to manage the risk in outsourcing?

Panel Chair:
Natalie Morrison,
Senior Reporter,
Biopharm Insight, UK

Panellists:
Warda Allaoua,
Associate Director, Global Strategic Outsourcing,
Celgene International, Switzerland

Mike Sitton,
Chief Executive Officer,
Haoma Medica, UK

Jessica Lee,
Vice President, Clinical Operations and Compliance,
Inovio Pharmaceuticals, USA

Dr Udo Breyer,
Partner and Managing Director,
OutsourcingTriologie GmbH & Co., Germany

Fernando Martinez, PhD, MBA,
Executive Director,
Covance, Spain

Angelika Riedl,
Senior Vice President, Regional Sales,
Quintiles, UK

12:25 **Precision medicine for biotech and small to mid-sized pharma, success for any size trial**

- Simplify your clinical trial set-up, for any size trial, in any geography
- Make data-driven decisions for your clinical trials and drug development
- Design cost-efficient studies that are effective and risk-averse
- Develop a biomarker strategy for clinical drug development for any size trial
- Enable consistent, deep data cleansing with consolidation of data sources
- Deliver validated data faster and easier

Dr MaryAnne Rizk,
Global Head – CRO Strategy and Partnerships,
Oracle Health Sciences, USA

Josh Rose,
Vice President of Strategic Planning Services Strategy,
Quintiles, USA

Solomon Babani,
Global Vice President, Alliance Management
Covance Inc, USA

12:55 **Lunch and networking break in the exhibition hall with partneringONE®**

Plus sign up for "Ask the Experts"

14:25 **Keynote: Consolidation in the CRO industry**

- Recent transactions made by strategic and financial buyers
- New industry participants and new types of partnerships
- Financing your company: The availability and cost of growth capital
- Anticipated M&A activity in 2016 for large, mid-sized, and smaller players

Michael A Martorelli,
CFA Director,
Fairmount Partners, USA

15:00 **Outsourcing of early phase oncology trials from a biotech company perspective**

- Experience with different outsourcing models, pros and cons
- What is required of you as sponsor of a trial?
- Can one person run the trial via a CRO or what internal competence is required?
- Challenges in relationship management
- How to establish a good working relationship?
- Preferred partner, pros and cons
- What can you do when your partner is not performing to your expectation?

Dr Eva Järlid Westerberg,
Vice President, Clinical Operations,
Genmab A/S, Denmark

15:35 **Update on Celgene's partnership model that includes clarification of local country office role in outsourced studies, as well as established local sponsor/CRO interaction**

- Moving from a tactical sourcing approach into a strategic partnership
- Exploring the integration of affiliate organisations (local country offices across the world) into the model
- Opportunity to provide insight into what value has been created as well as challenges faced

Antje Hindahl,
Director Portfolio Sourcing and Relationship Management,
Celgene International, Switzerland

16:05 **Networking break in the Plenary Room**

CLOSING PLENARY:

16:20 **Patient and Doctor: An inspiring story of saving faces through innovative clinical and surgical trials- Exploring a patients perspective**

Professor Iain Hutchison, *Director,* **The National Facial and Oral Research Centre (NFORC),** *Consultant Oral and Maxillofacial Surgeon* **St Bartholomew's and Royal London Hospitals,** *Honorary Chief Executive,* **Saving Faces-The Facial Surgery Research Foundation** *&* **A Patient from Saving Faces, UK**

16:50 **Closing remarks and end of PCT 2015**

An opportunity to understand trends in the industry and how to apply the learnings and innovation from different sponsors, CROs and consortiums

Jonathan Zung, Vice President, Global Clinical Sciences & Operations, UCB, USA

CONFERENCE DAY TWO: Thursday 19th November 2015

Stream 7 – Changes in Clinical Trials Regulation and Compliance

11:40 **Opening remarks from the Chairperson**

Isabella Salerio,
Clinical Operations, R&D and Open Innovation,
Zambon S.p.A, Italy

11:50 **The New EU Clinical Trials Regulation: What does it change and what will the impact be to drug development in the EU?**

- Investigating the rationale behind the changes in the previous clinical trials directive
- Reviewing needs for EU trials and how these have evolved recently
- Forecasting timelines and meeting the preconditions for the new EU Regulation to go into effect
- Pinpointing core components and country-specific aspects of the regulation
- Highlighting advantages of the New EU CT Regulation and the impact that this will have on sponsors
- Will the changes be positive for Europe and how does the US view it?

Dr Martine Dehlinger-Kremer,
Global Vice President Medical and Regulatory Affairs,
SynteractHCR, USA

12:25 **Corporate Social Responsibility (CSR) in Pharma – a case story**

- What impact does CSR have for pharma and how are compliance policies executed in practice
- Supplier evaluation – CSR principles and case story on how a pharma company has established the role in R&D
- What defines a HCP/HCO
- Example of a pharma compliance processes relating to transparency and reporting requirements
- Examples of compliance audits

Rikke Winther,
Senior Director, Outsourcing Management R&D,
Lundbeck, Denmark, USA

12:55 **Lunch and networking break in the exhibition hall with partneringONE®**

Plus sign up for "Ask the Experts"

14:25 **Some policy and legal comments on the new EU Clinical Trials Regulation**

- The necessary division of responsibilities between EU and Member States
- Realising the ambitions of the new Regulation
- The broader background and legal context of the transparency provisions

Peter Bogaert,
Partner,
Covington & Burling LLP, Belgium

15:00 **Clinical Trial Regulation: What major changes will be relevant to your role?**

- What is the impact of the European Federation of Pharmaceutical Industries and Associations (EFPIA) responsible transparency principles for clinical trial data and for the clinical trial approval process?
- Transparency provision: What will be made public?
- There are exceptions- e.g. protecting personal data, commercial- What do the EMA accept as confidential?
- What are the lessons learnt from the sunshine act?
- Explaining the key points and practical implications of the new regulations

Panel Chair:
Dr Antonio Ferrari,
Global Cardiac Leader,
Chiesi Farmaceutici, Italy

Panellists:
Andy Powrie-Smith,
Communications Director,
EFPIA (European Federation of Pharmaceutical Industries and Associations), Belgium

Dr Maurizio Salvi,
Principal Administrator, Ethics of science and new technologies,
European Commission, Belgium

Dr Ryan Burger,
Director, Transparency Reporting,
AstraZeneca, USA

16:05 **Networking break in the plenary room**

CLOSING PLENARY:

16:20 **Patient and Doctor: An inspiring story of saving faces through innovative clinical and surgical trials- Exploring a patients perspective**

Professor Iain Hutchison, *Director,* **The National Facial and Oral Research Centre (NFORC),** *Consultant Oral and Maxillofacial Surgeon* **St Bartholomew's and Royal London Hospitals,** *Honorary Chief Executive,* **Saving Faces-The Facial Surgery Research Foundation** *&* **A Patient from Saving Faces, UK**

16:50 **Closing remarks and end of PCT 2015**

14th Annual PCT PARTNERSHIPS IN CLINICAL TRIALS

CONFERENCE DAY TWO: Thursday 19th November 2015

Stream 8 – The Collaboration Zone: Interactive Sessions

This day will feature various interactive panels and round table sessions to encourage group interaction. Round table sessions will take place in parallel. Select the round table you wish to join and take part in open discussion with the group. This session is designed to be highly interactive and is an effective way of gaining new knowledge that you can implement within you day-to-day role.

11:40 Achieving a standard level of service excellence – persistent challenges in a mature industry

- In an industry considered as mature, why does the level of service excellence often depend on the individual CRO project team rather than the choice of CRO?
- How and why do other service industries achieve a higher level of standardization with respect to service excellence?
- To what extent may competitive pricing be jeopardising quality of service?
- Are Sponsors and CROs "satisficing" with respect to service excellence and quality?
- What can CROs and Sponsors do to improve?

Dr Elizabeth Baldauf, *Consultant & Trainer,* **Baldauf Training & Consulting, Germany**

11:40 Sponsors, CRO's and sites: How to improve the site selection process

- What can be done to sharpen the feasibility and increase accuracy of results?
- Non-enrolling sites: did the industry improve of the last years? What are companies doing with non-enrolling sites?
- Ideal cooperation Sponsor/CRO in the feasibility process
- Sharing current best practices and ideas among the panelists
- Exploring new ways to work with sites: ideas and suggestions
- Examining better opportunities to improve site selection process

Dr Michael Zörer, *Senior Group Leader, Clinical Operations,* **AOP Orphan Pharmaceuticals AG, Austria**

Annika Ekelöw, *Senior Clinical Outsourcing Manager, Clinical Operations,* **Swedish Orphan Biovitrum, Sweden**

12:55 **Lunch and networking break in the exhibition hall with partneringONE®** Plus sign up for "Ask the Experts"

14:25 The role of academic research sites and clinical research units in clinical trials

- How could an ARO and CRO collaborate to improve clinical trials process?
- Are they set up to move at the same speed that industry wants and do they have the resources to do it?
- Do AROs have the new technologies and the knowledge that CROs have?
- Discussing the advantages they have over CROs for rarer disease areas

Dr Chris Keep, *Global Category Leader, Academic & HCP Services, GMD Procurement,* **AstraZeneca, UK**

Graeme Boyle, *Senior R&D Manager,* **Tayside Medical Science Centre (TASC), UK**

Professor Diederick E. Grobbee, *Professor of Clinical Epidemiology,* **University Medical Center Utrecht, The Netherland**

Ruth Ladenstein, *Managing Director,* **OKIDs GmbH, Austria**

14:25 Current initiatives to ensure the quality of clinical trial data

- Transparency of data
- Processes to ensure data accuracy
- Ensuring integrity of conclusions re benefit/risks of products
- Effective quality management

David Morgan, *Vice President Senior Statistical Adviser,* **Ipsen, UK**

Patricia Hall, *Director,* **Deighton Hall Associates Ltd, UK**

Alec Deighton, *Director,* **Deighton Hall Associates Ltd, UK**

15:35 The increasing demand of non-interventional late phase studies - How to manage non interventional studies

- What are the different types of non-interventional studies? Identify appropriate study types/designs
- How to manage non-interventional studies with CROs more effectively
- Providing continued assessment of safety and more details of patent populations

Viola Bonness, *Associate Director VOM NIR,* **Bristol Myers Squibb - Swords Laboratories, Switzerland**

15:35 Innovative thinking on how clinical hypnosis can add value to the clinical trial process and enhance patient centricity

- Clinical hypnosis and common misconceptions: what it is and what is it not
- Understanding how other clinical and medical industries implement clinical hypnosis for patient engagement and to improve the overall patient experience – case study examples
- How can clinical hypnosis techniques be used by site investigators and study nurses?

Gavin Emerson, *CEO,* **Emerson Strategies & Brief Clinical Hypnosis Ltd, UK**

16:05 **Networking break in the plenary room**

CLOSING PLENARY:

16:20 Patient and Doctor: An inspiring story of saving faces through innovative clinical and surgical trials- Exploring a patients perspective

Professor Iain Hutchison, *Consultant Oral and Maxillofacial Surgeon* **St Bartholomew's and Royal London Hospitals, UK** *&* **A Patient from Saving Faces, UK**

16:50 **Closing remarks and end of PCT 2015**

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