Clinical Outsourcing Group Europe

Hotel NH Milano Congress Centre, Milan, Italy

10th & 11th October 2023

Philipp Badorrek - Head of Department, Clinical – **Fraunhofer Institute for Toxicology & Experimental Medicine**
Isabelle Naëije - Associate Global Trial Director – **Novartis**
Mariusz Olejniczak – CEO – **WPD Pharmaceuticals**
Helén Johansen Blanco - Vice President, Operations – **Cytovation ASA**
Dalila Nafi – Consultant – **Pistoia Alliance**
Robert Dobosz – Director, Clinical Trial Solutions - **Ryvu Therapeutics**
Tamara Noël – Director, Site Management West & North Europe – **Abbott**
Sonja Simon-Zoula – Head of Clinical Operations – **EarlySight**
Konstantinos Tsekmes – Associate Director, Clinical Operations – **MSD**
Charlotte Mailhat – Director, Clinical Operations – **GETAID**
Hari Radhakrishnan - Precision Medicine Director - **MediCover**
Sam Vakili - CEO – **INVEST.IN.TEK**
Alina Codrescu – Associate Director, Clinical Operations Romania & Turkey – **Bristol Myers Squibb**
José Pablo Werba – Principal Investigator, PREVENT-IAM – **Centro Cardiologico Monzino**
Arto Palmu – Chief Research Officer – **FVR, Finnish Vaccine Research**
Daniëlle van Keulen – Lead Scientist – **SkyLineDX**
Vanessa Dekou - Managing Director - **CSI**
Robert Greene - Founder - **HungerNdThirst Foundation**
Elisabeth (Els) Coart – Principal Biostatistician, Director of Consulting Services & Biomarker Development - **IDDI**
Myrthe Trompert – CEO – **Salvius Legal**
Paula Arranz Gutiérrez - Clinical Operations Lead - **Faes Farma**
Lisa Chamberlain James - Senior Partner - **Trilogy Writing & Consulting**
Ton van Beijsterveldt - Senior Business Development Manager - **EarlyHealth Group**
Quan Doan - VP, Technology Solutions - **SDC (Statistics & Data Corporation)**
Jasmin Hellwig - Associate Director, Relationship Management - **MSD**
Gherardo Sabaini - Senior Clinical Supply Manager - **Catalent**
Pauline Frank - Patient Engagement & Insights Director, Oncology - **Novartis**

Complimentary delegate attendance passes are exclusively reserved for pharma, biotech, and medical device companies who are trial sponsors and not those who offer a service or solution of any kind.

Register for your pass here:
https://www.thepbcgroup.com/registration-page

PBC
GROUP

10th October - Day 1

08:00

Registration & Welcome Refreshments

08:30

Welcome Address

Alexander O'Leary, Director, PBC Group

08:35

Onstage Interview: **Addressing Diversity & Race Inequalities in Clinical Trials**

Patient-centric trial design, and recruitment, enrolment strategy is paramount to attract a diverse group of patients into your clinical trial. Many trial sponsors partner with patient advocacy groups to help reach underrepresented populations.

In this interview Robert will lead the discussion into exploring the current landscape of diversity in clinical trials, exploring methods adopted by trial sponsors to meet regulatory guidelines, explaining the use of patient advocacy organisations, and incorporating the patient's voice.

Robert Greene - Founder - HungerNdThirst Foundation

09:05

Gaining insight into the internal challenges a Sponsor encounters to change suppliers

It's a challenge we've all encountered - dealing with a supplier or vendor that isn't meeting expectations and the frustration of attempting to enhance their service quality. It's a demanding task that can often find its solution in the form of a new partnership. However, embarking on such a change presents its own set of complexities.

Within this presentation, Ton van Beijsterveldt delves into the internal obstacles and barriers that arise when considering a shift to a new supplier - a shift that the company desperately needs. Navigating the landscape of internal hurdles, negotiating contracts, and strategically evaluating the most fitting new supplier all come into play.'

Ton van Beijsterveldt - Senior Business Development Manager - EarlyHealth Group

09:35

Navigating the Financing Landscape in Biotech: Strategies for Securing Investment at Different Stages of Drug Development/ Clinical trials

Private Equity attitudes have shifted since the global COVID pandemic, with institutions asking for a clear go-to-market strategy ahead of investment. Generally, investors are more cautious, the financial landscape sees less liquidity whilst numbers of biotech's seeking investment are at an all time high.

In this session Sam will share an overview of the drug/clinical development process, various possible sources of funding BioTech solutions, considerations for the financing at each stage of product development, challenges facing biotech financing from product owners as well as Investor standpoint. Sam will also share some case studies of what INVESTINTEK have done before in the same field, and What is the future outlook of financing Biotech solutions from investors standpoint

Sam Vakili - CEO – INVEST.IN.TEK

10:05

Comparator Sourcing: An Enabling Step in the Process of Successful Clinical Trial Supply

Clinical Trial Supply is an essential and potentially very complex and expensive part in the conduct of a clinical trial. Determining how to manage risk in complex studies, as well as strategies to deliver savings and value.

CSI will discuss requirements, the challenges and risks involved in different phases of drug development, provide tangible ways to identify and manage risks and present strategies for successful conduct for even the most complex adaptive trials.

Vanessa Dekou - Managing Director - CSI

10:35

Morning refreshments and networking break

Track A - Patient Collaboration and Clinical Operations

Track B - Innovation, Technology & Supply

11:05

Panel

Driving Enrolment in Clinical Trials

With the FDA and EMA now providing guidance and legislation on diversity within clinical trial participants, this is now a necessity when designing recruitment strategies, whilst balancing existing challenges of patient enrolment.

This panel will explore themes such as, but not limited to: Strategies adopted to attract and retain patients for studies, partnering with patient advocacy groups, reasons for trial termination and embedding clinical trials into the care environment to reach underrepresented populations.

Tamara Noël – Director, Site Management West & North Europe – Abbott
Isabelle Naëije - Associate Global Trial Director – Novartis
Robert Greene - Founder - HungerNdThirst Foundation

Panel

Impact of Technology on Trials Since the Pandemic

In 2022 there were over 1,300 clinical trials which were either fully decentralised or incorporated a virtual component. Most trials adopt a hybrid structure which would have previously not been possible if it were not for the plethora of technologies available to trials sponsors.

This panel explores the technologies available today (from Biometrics, to Wearables) to incorporate into study design and the key considerations when implementing a DCT or hybrid trial design.

Konstantinos Tsekmes – Associate Director, Clinical Operations - MSD
Quan Doan - VP, Technology Solutions - SDC (Statistics & Data Corporation)

11:35

Is the hype real? Real-life user experience of an AI tool for Clinical Study Report (CSR) production

What a year it's been for artificial intelligence (AI)! The pace at which the conversation around AI has accelerated in 2023 is unprecedented. AI is beginning to affect almost every industry, and medical writing is no different.

Looking back on almost 1 year of using an AI tool in day-to-day CSR production at a medical writing company, this session will report on how using the tool changes the process of planning and writing regulatory documents and will give some ideas about new ways of thinking that medical writers and authoring teams need to be open to as these technologies become common place.

Lisa Chamberlain James - Senior Partner - Trilogy Writing & Consulting

Avoiding Common Pitfalls in Clinical Supply Planning

When developing your clinical supply strategy, it is important to plan for potential supply chain challenges that may arise. The study's protocol requirements, drug characteristics, packaging specifications, as well as identifying any patient compliance concerns are all key factors of which to obtain a strong understanding.

This session will focus in on strategies to build that understanding and delve into ways to help avoid common pitfalls within your clinical supply plan.

Gherardo Sabaini - Senior Clinical Supply Manager - Catalent

12:05

Achieving Patient Centricity through Integrating Strategic Partners

Choosing the right partners in clinical trials can act as a catalyst for patient centricity. Further, integrating partners as part of your clinical team can reap many benefits.

In this session Jasmin will share her thoughts on how the pandemic shaped businesses, as well a framework to govern, and tips on how to integrate strategic partners.

Jasmin Hellwig - Associate Director, Relationship Management - MSD

Utilising Real World Data to Adapt Study Design & Execution

With availability of digital and analogue modes of data collection we need to ensure their appropriate use in real world studies, both within study design and the future execution.

The presentation will share models and examples of RWD collection, and how to design trials to best enable innovative solutions to enhance high-quality evidence to help decision-makers and patients, and to provide further clinical evidence beyond prelicensure trials for commercial launch.

Arto Palmu – Chief Research Officer – FVR, Finnish Vaccine Research

12:35

Lunch and networking break

13:35

What Do Patients Expect From A Clinical Trial?

Once a patient is recruited for a study, they would typically attend appointments at sites within the study network. On-site experience can vastly differ depending on the trial commitments as well as burden of drug delivery.

This session will delve into what patients expect from the entirety of a clinical trial, including methods to develop trust, pre-study collaboration, & communication.

Pauline Frank – Patient Engagement & Insights Director, Oncology - Novartis

14:05

Sites as Partners: The Question of Feasibility

The feasibility questionnaire is prepared by a study sponsor or CRO to engage and identify the most suitable sites to run your study successfully.

In this session Philipp will share the current model for assessing feasibility through questionnaires, discussing the common mistakes made and how best to evaluate sites for studies through meaningful partnerships.

Philipp Badorrek - Head of Department, Clinical Airway Research – Fraunhofer Institute for Toxicology & Experimental Medicine

14:35

Clinical Trials In The Era of Precision Medicine for Rare Diseases

Advances in molecular diagnostics, multiomics, and cell and gene therapies are driving the growth of precision medicine and companion diagnostics for rare diseases. The needs of the clinical trial industry are evolving with these new developments.

In this session, we will share our insight into the needs of this new era,the challenges facing the CT industry, and the actions needed to adapt to them.

Hari Radhakrishnan - Precision Medicine Director - MediCover

15:05

Eastern European Advantage: Comparing CEE countries Romania & Turkey to Western Europe

It is reported that the recruitment rate in CEE is 10.3 patients per site, compared to 7.5 in Western Europe. Combined with the adoption of CTIS, Romania now has the capacity to accelerate study start up timelines, with a transparent ethics committee and capacity for more trials.

In this session Alina will share insight into the trial environment in Romania & Turkey including patient recruitment, regulatory/ ethical environment as well as expected timelines for trial start up.

Alina Codrescu – Associate Director, Clinical Operations Romania & Turkey – Bristol Myers Squibb

15:35

Unlocking Success: Navigating Clinical Research Contracts With Sites & Vendors

When engaging vendors & sites, successful planning and contract management can vastly improve your negotiation position and benefit your study timelines, which will drive positive management throughout the duration of clinical studies. Studies are often carried across a vast network of sites, which adds to their complexities.

In this keynote, Myrthe will share key insights into how trial sponsors can position themselves through planning, negotiation, and contract execution to reduce costs, gain leverage, and protection against overruns.

Myrthe Trompert – CEO – Salvius Legal

16:05

Afternoon coffee and networking break

16:35

Panel

Harnessing Non-Profit Organisations: From Academic to Patient Advocacy How This Benefits Trial Sponsors

Europe is home to some of the world's leading institutions for research, many of which initiate trials and conduct globally recognised medical research. Patients are supported by an extensive network of patient advocacy groups which lead the discussion on developing new treatments. Connecting with these organisations provides access to patient populations as well as the opportunity to benefit from the wealth of knowledge held by industry and medical experts.

This panel shares the opportunity and benefits for trial sponsors when collaborating with not for profit organisations – including funding, understanding and access to patient populations, driving trial recruitment as well as generation of RWE.

Philipp Badorrek - Head of Department, Clinical Airway Research – Fraunhofer Institute for Toxicology & Experimental Medicine
Mariusz Olejniczak – CEO – WPD Pharmaceuticals

16:55

Randomization: Handle with Care – One Chance, No Regrets

In contrast to analysis of randomized clinical trials (RCT) data, the treatment allocation cannot be redone, hence the importance of selecting the most appropriate procedure AND implementing it correctly. When many prognostic factors need to be balanced, minimization is probably the method of choice.

Elisabeth will expand upon the controversies around this method and its characteristics will be illustrated based on a study of 50 clinical trials that have used minimization for treatment allocation.

Elisabeth (Els) Coart – Principal Biostatistician, Director of Consulting Services and Biomarker Development - IDDI

17:25

Quality Data: Risk Based Monitoring vs Source Data Verification

With many CROs now offering risk-based monitoring at no additional cost this is now becoming the industry standard, ensuring data quality.

This session will highlight the key differentials between RBM and SDV and how they can work hand in hand to maintain and ensure viable accurate data.

Sonja Simon-Zoula – Head of Clinical Operations - EarlySight

17:55

Drinks and Canapés Reception (complementary admission to all conference participants)

11th October - Day 2

09:00

Registration & Morning Refreshments

09:20

How to Best Equip Sites to Improve Study Start-Up Schedules

In the midst of a worldwide site staff shortage trial sponsors are experiencing heavily delayed study start-up, due to training and staff retention issues at site level. Due to personnel constraints its key to plan, reduce burden and train site staff efficiently to best enable them to carry out your study.

In this session Konstantinos will share steps taken to champion the clinical trial ecosystem in Greece. Including, the steps a trial sponsor can take to streamline site staff training, site technology applications, site level recruitment planning, and patient assistance services.

Konstantinos Tsekmes – Associate Director, Clinical Operations - MSD

09:50

Study Design: Investigating Through Web-Based Empowerment Program, PREVENT-IAM

In collaboration with the Ministry of Health Italy, the PREVENT-IAM web-based empowerment program is designed to educate patients after being discharged to improve Cardiovascular health and adherence to therapy. The study is hosted using ProSALUTE 4.0, a custom-built digital platform to communicate and engage patients.

In this session José will provide an overview of the ongoing study, including methods of profiling patients, the study design, anticipated outcomes as well as personalised care for participants.

José Pablo Werba – Principal Investigator, PREVENT-IAM – Centro Cardiologico Monzino

10:30

Achieving Sustainability for DCT Operations & Supply

As Clinical trials are a key milestone in the drug life cycle development , delivering clinical trials on time, within budget and quality standards, is of high importance. Today there is an increasing awareness from many Pharma stakeholders to consider another pillar to those standards, namely the carbon footprint impacts and environmental sustainability of clinical trials and DCTs in particular.

In this session the need for industry collaboration is confirmed, along with the creation of standards and measures for assessing and improving the sustainability of DCT operations and supply.

Dalila Nafi – Consultant – Pistoia Alliance

11:00

Morning refreshments and networking break

11:30

Creating a Culture of Creativity in Clinical Development

Clinical research is often bound by strict protocols, and more often than not, a culture of doing things in a tried and tested way. However this does not mean the traditional methods of clinical development can not be improved.

In this session Mariusz will share insights into WPD Pharmaceuticals' research and discovery methods and processes, and how they have allowed for increased productivity between CRO and Pharma.

Mariusz Olejniczak – CEO – WPD Pharmaceuticals

12:00

How to Drive CRO Accountability

With sites across the world stretched to capacity, and an increasing number of trials in recruitment it is paramount to work with partners to enable your study's success.

This presentation will harness the methods used from a procurement perspective to drive desire and motivation from your suppliers, as well as initially identifying and contracting the right supplier for you.

Paula Arranz Gutiérrez - Clinical Operations Lead - Faes Farma

12:30

Outsourcing Clinical Trials: Small Biotech Perspective

When considering clinical operations of your study it is key to engage and work with the right partners, sites and patients to enable success.

Robert will provide insights into methods used to engage with suppliers, identify and engage the right sites, as well as enrol patients.

Robert Dobosz – Director, Clinical Trial Solutions - Ryvu Therapeutics

13:00

Lunch and networking break

14:00

Paediatric Trials: Kawasaki Disease Diagnostic Test Development

Engaging paediatric patients into studies is essential when tracking the progress of a disease from birth to adult years. Paediatric means that typical routes of recruitment and engagement are redundant.

This session highlights the Kawasaki Disease biomarker test development at SkyLineDx, highlighting the challenges faced when initiating a study involving paediatric patients and how it was accelerated through partnerships with universities, and development partners.

Daniëlle van Keulen – Lead Scientist – SkyLineDX

14:30

Financial Oversight of Clinical Studies

The management and monitoring of financial resources allocated to a clinical study is paramount to ensure they are used appropriately and in accordance with the study's protocol, applicable regulations, and sponsor requirements.

In this session Helen will share insight into effective financial oversight methods adopted throughout her career, to ensure vendor compliance, effective cost monitoring and planning for unforeseen expenses.

Helén Johansen Blanco - Vice President, Operations – Cytovation ASA

15:00

9 Months On: CTIS In Action

CTIS was introduced on 31st January 2023 with the aim to harmonise the processes for assessment and supervision of clinical trials across the European Union. With the evaluation, authorisation and supervision responsibilities lying with individual member states.

This session will assess the successes and pitfalls from the introduction of CTIS across, to determine how the regulatory landscape has changed, which member states have the fastest approval times, how trials are allocated and whether safety has been positively impacted.

Charlotte Mailhat – Director, Clinical Operations - GETAID

15:30

Conference Close