Cambridge Healthtech Institute's 7th Annual

SCOPE EUROPE

SUMMIT FOR CLINICAL OPS EXECUTIVES

Optimising Digital and Hybrid Trials in Europe and across the Globe

29-30 October 2024 | InterContinental Barcelona (Fira Center) in Barcelona, Spain

Conference Programs

- Trial Design and Protocol Development
- Feasibility and Study Activation
- Patient Engagement and Recruitment
- Clinical Data and Technology
- Clin Ops in Europe's Emerging Biopharma
- Risk-Based Quality Management

Featured Speakers

Christoph Koenen
Head of Clinical Development & Operations, Pharma Research & Development, Bayer

Shyard Wong
Head, Clinical Quality & Continuous Improvement, Sanofi

Paul Duffy
Head, Global Clinical Site Partnerships, MSD

Jonathan Crowther, PhD
Head, Predictive Analytics, Pfizer R&D

Jacqueline Bowman
Co-Founder, Foundation for the Rights of Citizens with Obesity

Bari Kowal
Senior Vice President & Head, Development Operations & Portfolio Management, Global Development, Regeneron Pharmaceuticals, Inc.

FINAL WEEKS To Register

Event Features

- 3 Plenary keynote sessions
- Senior level executives from pharma, biotech, government, and academia
- Interactive panel discussions
- Exclusive exhibits and networking
- Best of Show Awards

PREMIER SPONSORS

CERTARA Fortrea H1 IQVIA MEDIDATA ThermoFisher SCIENTIFIC

LEAD SPONSORSHIP ORGANISATIONS

BARNETT INTERNATIONAL

ClinEco

ScopeSummitEurope.com

7th Annual SCOPE EUROPE
SUMMIT FOR CLINICAL OPS EXECUTIVES

CONFERENCE-AT-A-GLANCE

29-30 OCTOBER 2024 | PRE-CON WORKSHOPS ON 28 OCTOBER

InterContinental Barcelona (Fira Center) in Barcelona, Spain

Optimising Digital and Hybrid Trials in Europe and across the Globe

Workshops and User Groups on Monday Afternoon | **28 October 2024**

MONDAY

Arrive on Monday in Beautiful Barcelona and Start SCOPE Europe on Monday Afternoon!

ESG (Environmental, Social & Governance) Leaders in Pharma: Sustainable Trials Summit @SCOPE	**(Monday PM)**
Innovation Day at SCOPE Europe with IQVIA Technologies @SCOPE	**(Monday PM)**

Conference on Tuesday and Wednesday | **29-30 October 2024**

TUESDAY

Morning Coffee and Conference Registration | **(Tuesday AM)**

TRIAL DESIGN AND PROTOCOL DEVELOPMENT	FEASIBILITY AND STUDY ACTIVATION	PATIENT ENGAGEMENT AND RECRUITMENT	CLINICAL DATA AND TECHNOLOGY	CLIN OPS IN EUROPE'S EMERGING BIOPHARMA	RISK-BASED QUALITY MANAGEMENT
Novel Approaches to Trial Design and Patient-Centric Protocol Development	Modernising Feasibility, Site Selection, Site Engagement, and Start-Up Practices	Engagement and Recruitment through Communities and Technologies	Clinical Data, Technology, and AI/ML for Digital and Hybrid Trials	Optimising Clinical Programs, Clin Ops Teams, and Outsourcing Partners in Europe's Emerging Biopharma	Risk-Based Quality Management (RBQM) and Monitoring

Grand Opening Coffee Break in the Exhibit Hall

Morning Shared Plenary Keynotes and Panel Discussion

Interactive Discussion with Topic Champion | Join an Interactive and Facilitated Discussion with a Group of Your Peers.

Join Your Peers for a Networking Luncheon in the Exhibit Hall & Join Us for a SCOPE Europe Prize Drawing!

TRIAL DESIGN AND PROTOCOL DEVELOPMENT	FEASIBILITY AND STUDY ACTIVATION	PATIENT ENGAGEMENT AND RECRUITMENT	CLINICAL DATA AND TECHNOLOGY	CLIN OPS IN EUROPE'S EMERGING BIOPHARMA	RISK-BASED QUALITY MANAGEMENT

Welcome Reception in the Exhibit Hall with Beer, Wine, and Tapas

Join our Exhibitors for a Booth Crawl of Specialty Foods and Beverages and a SCOPE Europe Prize Drawing! | **(Tuesday PM)**

WEDNESDAY

Morning Coffee **(Wednesday AM)**

TRIAL DESIGN AND PROTOCOL DEVELOPMENT	FEASIBILITY AND STUDY ACTIVATION	PATIENT ENGAGEMENT AND RECRUITMENT	CLINICAL DATA AND TECHNOLOGY	CLIN OPS IN EUROPE'S EMERGING BIOPHARMA	RISK-BASED QUALITY MANAGEMENT

Coffee Break in the Exhibit Hall and Special Book Signing

Morning Shared Plenary Keynotes and Panel Discussion

Join Your Peers for a Networking Luncheon in the Exhibit Hall & Join Us for a SCOPE Europe Prize Drawing!

TRIAL DESIGN AND PROTOCOL DEVELOPMENT	FEASIBILITY AND STUDY ACTIVATION	PATIENT ENGAGEMENT AND RECRUITMENT	CLINICAL DATA AND TECHNOLOGY	CLIN OPS IN EUROPE'S EMERGING BIOPHARMA	RISK-BASED QUALITY MANAGEMENT

Clinical Research News SCOPE Best of Show Awards 2023 Recognising Exceptional Innovation in Technologies Used by Clinical Research Professionals & Closing Plenary Keynote Panel Discussions

Close of SCOPE Europe **(Wednesday PM)**

PARTNERING ORGANISATIONS

CISCRP, ClinEca, Sustainable Healthcare Coalition, Cure SMA, kits4life, MEDSURPLUS ALLIANCE, The Task Force for Global Health, Leukemia & Lymphoma Society, Pistoia Alliance, SCRS

MEDIA PARTNERS

Official Event Publication

Clinical Research News – Clinical Trials to the Clinic

Lead Media Partner

Bio-IT World

Lead Sponsoring Organisation

Barnett International

Sponsoring Publications

DDN, GEN Genetic Engineering & Biotechnology News, Pharmaceutical Outsourcing

Lead Sponsoring Publications

Applied Clinical Trials, Clinical Leader, The Clinical Trial Vanguard

#SCOPEsummit

Sponsorship & Exhibit Opportunities

CHI offers comprehensive packages that can be customized to your budget and objectives. Sponsorship allows you to achieve your goals before, during, and long after the event. Packages may include presentations, exhibit space, and branding, as well as the use of delegate lists. Signing on early will maximize your exposure to qualified decision-makers and drive traffic to your website in the coming months.

PODIUM PRESENTATIONS — *AVAILABLE WITHIN MAIN AGENDA!*

Showcase your solutions to a guaranteed, targeted audience through a 12- or 25-minute presentation. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. Presentations will sell out quickly! Sign on early to secure your talk.

1:1 MEETINGS/ HOSPITALITY SUITE

- Access to a small meeting room for one-on-one meetings set with table and chairs.
- Your company will select invitees from the conference pre-registration list. CHI will set up 6-8 one-on-one meetings, 15-20 minutes each with your TOP prospects, and confirm appointment.
- CHI will extend invitations, conduct follow-up, and monitor responses.

EXHIBIT

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today!

Additional branding and promotional opportunities are available, including:

- Exhibit Hall Reception
- Exhibit Hall Break Sponsor
- Tote Bags - ***SOLD***
- Lanyards - ***SOLD***
- Booth Crawl
- Patient Lounge Sponsor
- Breakout Discussion Sponsor
- Branded item such pens, lip balms, or other relevant product

Hotel & Travel Information

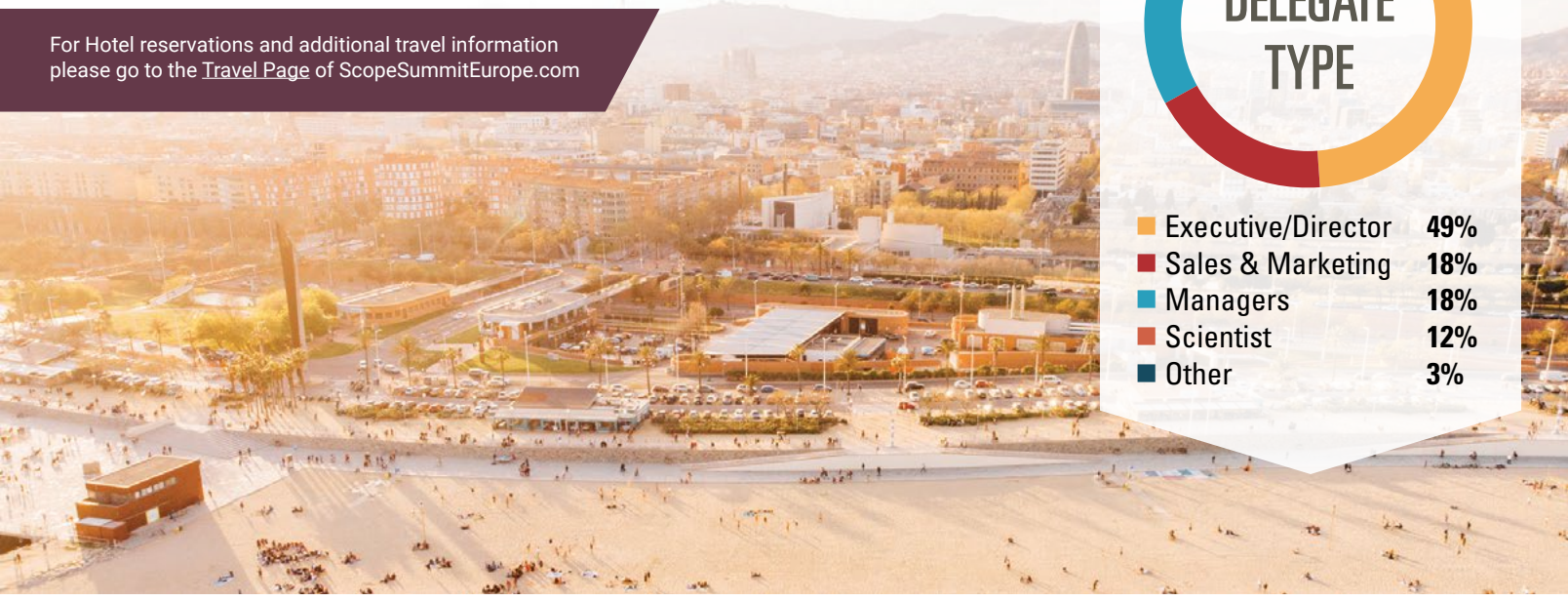
CONFERENCE VENUE AND HOTEL:

InterContinental Barcelona (Fira Center)
Avenida de Rius I Taulet, 1-3
Barcelona, 08004, Spain

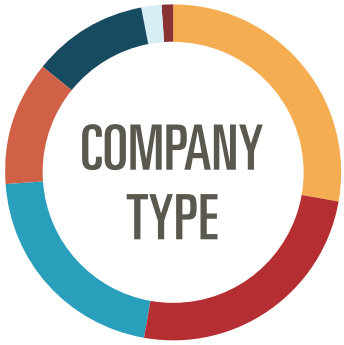
Discounted Room Rate:
€320 Single/€350 Double (includes Wi-Fi)

Discounted Room Rate Cut-off Date:
27 September 2024

For Hotel reservations and additional travel information please go to the Travel Page of ScopeSummitEurope.com



2023 Attendee Demographics



Biotech	28%
Pharma	25%
CRO	21%
Services & Societies	12%
Healthcare/Hospital	11%
Academic	2%
Other	1%

Executive/Director	49%
Sales & Marketing	18%
Managers	18%
Scientist	12%
Other	3%

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

COMPANIES A-E

Ilana Quigley
Director, Sales

(+1) 781-972-5457
iquigley@healthtech.com

COMPANIES F-J

Katelin Fitzgerald
Senior Manager,
Business Development

(+1) 781-247-1824
kfitzgerald@
cambridgeinnovationinstitute.com

COMPANIES K-T

Jon Stroup
Senior Manager,
Business Development

(+1) 781-972-5483
jons@healthtech.com

COMPANIES U-Z

Patty Rose
Senior Director, Sales

(+1) 781-972-1349
prose@healthtech.com

KEYNOTE SPEAKERS & USER GROUP INFO

MONDAY, 28 OCTOBER

MONDAY AFTERNOON: USER GROUP

Arrive on Monday in beautiful Barcelona and start SCOPE Europe on Monday Afternoon! Visit our Travel page. https://www.scopesummiteurope.com/travel

14:30 – 19:00 Innovation Day with IQVIA Technologies at SCOPE Europe

More info and RSVP* Join IQVIA Technologies' digital product leaders and customer success experts for an afternoon of discussions, demos, and networking. We'll share our vision to transform clinical operations, the progress we've made to date, and our roadmap for 2024 and beyond. **Registration is limited to pharmaceutical, biotech companies, and research sites. IQVIA reserves the right to decline any registration.*

MONDAY EVENING IN BARCELONA

Join friends and colleagues for dinner at a spot near the conference hotel, which is in a great location. https://bit.ly/CHI-Barcelona-Restaurants

Main Conference Tuesday and Wednesday, 29-30 October 2024. Join the morning run/walk at 07:00. Registration opens at 07:45 and the opening presentations start at 08:50.

TUESDAY, 29 OCTOBER

07:00 SCOPE Europe Fun Run/Walk Up the Magic Fountain Steps

Join SCOPE Europe's Coordinators for our Fun Walk/Run! All of us at Cambridge Healthtech Institute recognise the importance of integrating well-being and fitness into our work travel routines. This is an easygoing, informal running (or walking) event where we ascend the stairs of the iconic Magic Fountain. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! Meet us in the front lobby at the InterContinental at 7 am sharp!

07:45 – 09:00 Registration and Morning Coffee

08:50 – 10:50 Join Conference Sessions (6 Tracks)

10:53 Grand Opening Coffee Break in the Exhibit Hall

The SCOPE Europe Exhibit Hall is the best place to fuel up with a mid-morning coffee while visiting with our many exhibitors. Learn about what's new in the industry, connect with colleagues and vendors, and make some new friends.

TUESDAY MORNING PLENARY SESSION: REINVENTING CLINICAL DEVELOPMENT & CONVERGING RESEARCH WITH CLINICAL CARE

11:50 Chairperson's Remarks

Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

11:55 KEYNOTE PRESENTATION: Reinventing Clinical Development and Overcoming Unnecessary Complexity

Christoph Koenen, Head of Clinical Development & Operations, Pharma Research & Development, Bayer

This keynote presentation proposes a paradigm shift in clinical development, advocating for the adoption of a minimal viable product (MVP) approach focused solely on fulfilling regulatory requirements. By streamlining processes and resources to the essentials, this strategy promises significant cost reductions and time efficiencies while maintaining regulatory compliance. Through case studies and implementation strategies, attendees will gain insights into how embracing this innovative approach can revolutionize clinical development, paving the way for greater agility, adaptability, and patient-centricity in the industry.

12:20 ClinEco Commons and the Power of the Clinical Research Community

Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

The Commons is a ClinEco and SCOPE resource. It is a go-to hub for resources, tools, news, regulatory updates, and more, designed to support professionals in the field of clinical research. 'The Commons' serves as a collaborative space where you can access, visit, share valuable content as well as contribute to the wealth of knowledge within the SCOPE and ClinEco community. The "Ask a ClinEco Luminary" feature allows users to connect directly with research leaders to learn from colleagues. One of the Luminary sections is "Ask a Patient" (with Savvy and EUPATI).

12:30 KEYNOTE PANEL DISCUSSION: Converging Clinical Research with Clinical Care: A Multi-Stakeholder Panel on Tackling this Bold Vision

PANEL MODERATOR:

Paul Duffy, Head, Global Clinical Site Partnerships, MSD.

This plenary panel will show how stakeholders across biopharma R&D have come together to develop pragmatic solutions that are foundational to enabling the future of drug development and integrating clinical research as part of the care continuum. This panel will feature biopharma industry leaders, Health Authorities, patient advocates, and other industry consortia candidly discussing why everyone must work together to drive innovation in the R&D ecosystem, shape the future of healthcare, and bridge the gap between clinical research and clinical care.

PANELISTS:

Maria Dutarte, Executive Director, European Patients' Academy on Therapeutic Innovation (EUPATI)

Maria Koutsopoulou, Senior Vice President, Head of Global Development Operations, Merck KGaA

Bari Kowal, Senior Vice President & Head, Development Operations & Portfolio Management, Global Development, Regeneron Pharmaceuticals, Inc.

12:55 SCOPE Europe 2023 Accelerator Project Update and Outcomes: Innovative Outsourcing Process for Biotech

Micah Lieberman, Executive Director, Cambridge Healthtech Institute; Co-Founder, ClinEco

Last year at SCOPE Europe we engaged with sponsor orgs in attendance on a project with ClinEco, our B2B clinical research marketplace and network, to help with scoping, selection, and onboarding of outsourcing partners for a trial. The goal was to challenge the norms of clinical trials outsourcing, improve vendor selection, and speed up the RFI process...and more. We learned a lot with our partner and some of those key learnings apply to us all.

13:00 KEYNOTE PANEL DISCUSSION: Quantifying the Collection of Non-Core and Extraneous Core Protocol Data and its Relationship with Clinical Trial Performance

PANEL MODERATOR:

Emily Botto, Senior Research Assistant, Tufts University

This panel discussion provides perspectives and updates on a collaborative research study looking at optimizing non-core and extraneous clinical research data collection practices, with the aim to reduce patient and site burden. The panel will explore considerations that helped define the study methodology and insights expected from the study findings that will inform new protocol design strategies.

PANELISTS:

Paul Duffy, Head, Global Clinical Site Partnerships, MSD

Joachim Lovin, DCT Specialist, Novo Nordisk

13:35 Join Your Peers for a Networking Luncheon in the Exhibit Hall

Take this opportunity to refresh and refuel with our Exhibit Hall lunch. Enjoy good food and even better conversation during our walk and talk luncheon.

14:35 – 17:00 Join Conference Sessions (6 Tracks)

16:57 Reception in the Exhibit Hall with Beer, Wine, and Tapas

Wind down at the end of a busy session day with colleagues, beer, wine, and tapas. Have a drink with your favorite exhibitor and take a chance at winning a fabulous raffle prize (must be present to win)!

WEDNESDAY, 30 OCTOBER

08:15 Registration and Morning Coffee

08:45 – 10:15 Join Conference Sessions (6 Tracks)

10:17 Coffee Break in the Exhibit Hall and Special Book Signing
More coffee, more exhibitors, more networking, and some delicious snacks. What's not to love?

WEDNESDAY MORNING PLENARY SESSION: INTEGRATING DIGITAL HEALTH TECH IN TRIALS & IMPROVING STUDY DESIGN WITH PATIENTS

11:00 Organiser's Welcome Remarks

Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI); Co-Founder, ClinEco

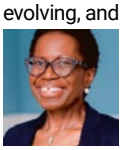
11:05 Presentation to be Announced

11:20 KEYNOTE PANEL DISCUSSION: Integrating Digital Health Technologies in Clinical Trials: A New Era for eCOA and ePRO

PANEL MODERATOR:

Moe Alsumidaie, Chief Editor, Editorials, Clinical Trial Vanguard

This panel will delve into how emerging digital health technologies, including eCOA and ePRO, are transforming patient data collection in clinical trials. It will cover the evolution of digital endpoints, patient-centric approaches, and the integration of these technologies into clinical research frameworks. How are digital health technologies, especially eCOA and ePRO solutions, revolutionizing data collection in clinical trials? Have they led to more patient-centric trials? What are the challenges in integrating these technologies into existing clinical trial frameworks, and how have they been overcome? What considerations should be made when selecting technology partners? Looking towards the future, how do you see digital health technologies evolving, and what implications will this have on clinical research?



PANELISTS:

Jacqueline Bowman, Co-Founder, Foundation for the Rights of Citizens with Obesity

Bernhard Glombitza, Head, Clinical Operations EMEA and APAC, Bayer

Kai Langel, Senior Director, Strategy and Innovation, Global Regulatory Policy and Intelligence, Global Regulatory Affairs, Janssen R&D

11:45 KEYNOTE PANEL DISCUSSION: How to Build Meaningful Relationships and Shift to Patient-Led Conversations for Improved Study Design and Execution

PANEL MODERATOR:

Maria Dutarte, Executive Director, European Patients' Academy on Therapeutic Innovation (EUPATI)

Join us for a critical exploration into the transformative approach of integrating patient insights into clinical trial protocols. This panel will explore how strong relationships and patient-led conversations can improve study design and execution, significantly easing the burden on sites and patients. Learn from experts about common pitfalls and challenges in patient engagement, gaining actionable strategies towards more effective and empathetic trials.

PANELISTS:

Jose Aibar, President, Dravet Syndrome Foundation Spain

Jacqueline Cannon, Chief Executive, The Lewy Body Society

Roger Legtenberg, PhD, Co-Founder, Partners4Patients Foundation UG

12:10 Join Your Peers for a Networking Luncheon in the Exhibit Hall
Join us again for lunch in the Exhibit Hall. Last chance to visit with exhibitors you missed and to enter our final raffle!

13:10 – 14:30 Join Conference Sessions (6 Tracks)

WEDNESDAY AFTERNOON PLENARY SESSION: NEW ERA OF RISK/QUALITY (R3) & LEVERAGING AI TO ACCELERATE TRIALS

14:35 Clinical Research News' Best of Show Award: Recognizing Exceptional Innovation in Technologies Used by Clinical Research Professionals

Allison Proffitt, Editorial Director, Bio-IT World and Clinical Research News

Sponsored by **Clinical Research News & ClinEco**

The 2024 Best of Show Awards offer exhibitors of the SCOPE Summit Europe an exclusive opportunity to distinguish and highlight their products, ranging from an innovative application, technology, tool, or solution. The SCOPE community is invited to identify exceptional innovation in technologies used by life science professionals, voting on the most impactful new products of the year. Submit your entry! https://www.scopesummiteurope.com/sponsor-exhibitor/best-of-show-awards

14:40 FIRESIDE CHAT: Redefining Excellence: The Future of Clinical Trial Quality




Coleen Glessner, Executive Vice President, Quality, Ethics and Compliance, Emergent BioSolutions

Patricia Leuchten, Founder and CEO, Diligent Pharma

Shyard Wong, Head, Clinical Quality & Continuous Improvement, sanofi-aventis

Kristi Koontz, Vice President, Global Clinical Operations, Daiichi Sankyo US

This keynote will explore milestones from the past that have shaped our present approach to clinical trial quality. Delving into the present, we scrutinize the existing paradigms and contemplate the ongoing transformations in our approach to ensuring trial quality. As technological advancements, regulatory shifts, and societal demands continue to reshape the landscape, we confront the imperative of redefining what excellence means in the realm of clinical research. How will emerging methodologies, such as decentralized trials and real-world evidence, redefine our benchmarks for success? What role will artificial intelligence, big data analytics, and patient-centricity play in shaping the future of clinical trial quality?

15:05 USE CASE: From Theory to Therapy: Accelerating Clinical Trials with AI

Jonathan Crowther, PhD, Head, Predictive Analytics, Pfizer R&D

This new story and real-world use case is an exploration of the future potential of GenAI in clinical trials, focusing on optimizing trial efficiency, reducing costs, and the broader business impact. Inspire the audience to think about the long-term benefits of integrating GenAI into their processes.

15:20 KEYNOTE PANEL DISCUSSION: Data to Decisions: GenAI's Role in Transforming Clinical Trials

PANEL MODERATOR:

Allison Proffitt, Editorial Director, Bio-IT World and Clinical Research News

Artificial intelligence, data analytics, automation and technology have the power to connect stakeholders and applications and enhance protocol design, study feasibility, and patient identification and recruitment. The recent explosion of innovation with generative AI is delivering promising advances as we all know. However, this involves constructing a robust data infrastructure, harnessing cutting-edge technologies, adhering to privacy and data security regulations, and enforcing data governance principles.




PANELISTS:

Dorothee Bartels, PhD, Associate Professor (Apl. Professor) for Public Health and Epidemiology, Medizinische Hochschule Hannover

Jonathan Crowther, PhD, Head, Predictive Analytics, Global Product Development, Pfizer

Farrell Healion, Senior Director Emerging Technologies, Global Clinical Solutions, AstraZeneca

Adama Ibrahim, Vice President, Digital Strategy & Change Management, Novo Nordisk

15:45 Close of Conference

SPONSORS

PREMIER SPONSORS

CERTARA · Fortrea · H1 · IQVIA · MEDIDATA · ThermoFisher SCIENTIFIC

CORPORATE SPONSORS

AKRIVIA HEALTH · anju · Care Access · CITELINE a norstella company · Clinical ink · CluePoints · Cyntegrity · Ercules · EXOSTAR We build trust. · greenphire · inato · LANGLAND · mrn · mytomorrows · PREMIER · Science37 · SLOPE · TriNetX · TRI · umotif · VERISTAT · ZS

CORPORATE SUPPORT SPONSORS

baltacon · CLARINESS · CRScube Clinical Research Solutions · florence Healthcare · HCLTech · HERAX Life Science · IAG IMAGE ANALYSIS GROUP · mdgroup · MÜV · PRAXIS · ShareCRF · siron clinical · stefanini GROUP · stitch · SUVODA · TRANSCOM Communicating Health Worldwide · TRANSPERFECT LIFE SCIENCES · Validated Cloud · VCTC · YPrime

Trial Design and Protocol Development

Novel Approaches to Trial Design and Patient-Centric Protocol Development

MONDAY 28 OCTOBER

MONDAY AFTERNOON: USER GROUP & WORKSHOP

14:30 – 19:00 Innovation Day with IQVIA Technologies at SCOPE Europe

CO-SPEAKERS:
Kevin Landells, Vice President Patient Centered Technology Delivery, IQVIA Technologies
Stefan Dürr, Senior Director, Client Delivery, IQVIA Technologies
Petar Genov, Senior Director, Business Operations and Capabilities – Payments, IQVIA Technologies
Tim Reily, Vice President, Clinical Data Analytics, IQVIA Technologies
Alison Liddy, Senior Vice President, Patient and Site Centric Solutions, IQVIA
Clinical trial sponsors are invited to join IQVIA Technologies' digital product leaders and industry representatives for an afternoon of discussions, demos, and networking. IQVIA will share our vision to transform clinical operations, demonstrate our technologies that improve the patient, site, and sponsor journeys, and ask for your input on our roadmap for future product development. Innovation Day is complimentary and will be of interest to pharmaceutical executives or sites with roles in clinical operations, innovation, technology, finance, budgeting, data analytics, patient or site engagement, or strategic sourcing. IQVIA reserves the right to decline registrations for those not in these categories. For more information or to register **click here**.

17:30 – 19:00 The Path towards Sustainable Clinical Trials: How to Minimise Environmental Impact and Stay Ahead of Future Regulatory Requirements

INSTRUCTORS:
Fiona Adshead, Chair, Sustainable Healthcare Coalition
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Marisa Minetti, Patient Research Partner, Chiesi Group
Keith Moore, Programme Coordinator, Sustainable Healthcare Coalition
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond benefiting the environment, adopting sustainable practices is increasingly demanded by stakeholders and can significantly influence customer choices and talent acquisition. Perhaps more compelling are the growing regulatory pressures and expectations, including the Corporate Sustainability Reporting Directive (CSRD) and Task Force on Climate-related Financial Disclosures (TCFD) among others. This workshop will discuss the current hotspots of carbon emissions in clinical research, introduce a new clinical trial carbon footprint calculator for assessing current state, and suggest introductory reduction strategies. Whether you are in clinical trial design clin ops, procurement, innovation, sustainability, or resource management, this workshop is for you.

TUESDAY 29 OCTOBER

7:00 SCOPE Europe Fun Run/Walk Up the Magic Fountain Steps

Join SCOPE Europe's Coordinators for our Fun Run/Walk! All of us at Cambridge Healthtech Institute recognise the importance of integrating well-being and fitness into our work travel routines. This is an easygoing, informal running (or walking) event where we ascend the stairs of the iconic Magic Fountain. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! *Meet us in the front lobby at the InterContinental at 7 sharp!*

7:45 Registration and Morning Coffee

8:50 Organiser's Welcome Remarks

INTEGRATING PATIENT VOICE IN EARLY-STAGE DEVELOPMENT

8:55 Chairperson's Remarks *(Sponsorship Opportunity Available)*

9:00 Unleashing Valuable Patient Insights: The Transformative Power of Patient Perspective in Operationalising Decentralised Clinical Trials

Marisa Minetti, Patient Research Partner, Chiesi Group
Ylenia Paleari, PhD, Patient Engagement Manager, Global Rare Diseases R&D Clinical Development, Chiesi Group

How insights from collaborative studies with patients and health care professionals in the USA and Europe, revealing perspectives on the benefits and challenges of DCTs, can help shape the future of patient-centric research in advancing DCTs in respiratory and rare diseases. This session discusses the implications of these results and explores actionable insights on modifying DCTs to better address the needs and preferences of both patients and HCPs.

9:25 Integrating Patient Perspective in Early-Stage Development: Actions Outweigh Words

Dominik Kraus, PhD, Principal Clinical Scientist, Roche
Léa Proulx, Patient Voice Partner, Strategy, Portfolio & Operations, Roche

Integrating patient insights into early protocol development is paramount in making key patient-inclusive development decisions in determining target patient population, endpoint selection, eligibility criteria, and schedule of assessment. Roche will share their approach to assess a patient-inclusive mindset, addressing gaps from both strategic and tactical perspectives and providing concrete examples on how to integrate patient insights in an early, systematic, and timely manner to design and implement patient-inclusive trials.

9:50 Assumptions Are the Root of Mistakes: Designing Studies Whilst Avoiding 'Unicorn' Protocols

Melissa Harris, Global Head, Fortrea

Assumptions in trial design impacts everything. Headways been made with patient-centric design philosophy but ultimately its sites who must execute the study. Listening to and incorporating input from sites and patients concurrently drives new treatments to the right patients, faster. A duel-centric approach is a potent model for achieving efficiency whilst meeting demands of sponsors and patients, beyond simply listening for intelligent, and compassionate protocol measures.

10:15 Overcoming Access Barriers for the Sexual and Gender Minority (SGM) Community: Actionable Measures from Protocol Design through Recruitment & Retention

Garo Kiledjian, Founder & CEO, SGM Alliance
Kamil Kuhr, Director of R&D GxP Learning Operations, AstraZeneca
Binita Patel, MSc, Diversity Strategy Lead, Bayer

This thought-provoking session kicks off with the introduction of SGM Alliance who's paving the way in addressing health inequities faced by the SGM community who are often overlooked in clinical research. It then digs into actionable measures you can take to include SGM in clinical study design, spanning from protocol design through recruitment and retention. Together, let's drive meaningful change for a more inclusive and accessible landscape in clinical research.

10:40 Embracing a Patient-First Approach in Clinical Trial Design: Leveraging Granular Data for Precision Planning

Elke Ydens, Associate Director, Business Solutions, Anju Software

With trials increasingly targeting more specific patient sub-populations, identifying and incorporating granular, high-quality, historical datasets is crucial to match expectation and reality in trial design and planning. This presentation addresses the complexities of sourcing and utilizing patient subset data while showcasing how our new strategic feasibility application is revolutionizing the process by delivering more precise, data-driven insights that will keep improving trial planning.

10:53 Grand Opening Coffee Break in the Exhibit Hall

The SCOPE Europe Exhibit Hall is the best place to fuel up with a mid-morning coffee while visiting with our many exhibitors. Learn about what's new in the industry, connect with colleagues and vendors, and make some new friends.

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

13:35 Join Your Peers for a Networking Lunch in the Exhibit Hall

Take this opportunity to refresh and refuel with our Exhibit Hall lunch. Enjoy good food and even better conversation during our walk and talk luncheon.

EVOLVING DCT APPROACHES: INNOVATION IN TRIAL DESIGN AND OPERATIONS

14:35 Chairperson's Remarks

Matthew Bonam, Head BioPharmaceuticals R&D, Digital Patient Health & Innovation, AstraZeneca R&D

14:40 Sponsor Experience Implementing Decentralised Clinical Trial (DCT) Elements: DCT Implementation Survey Results & Lessons Learned

Joachim Lovin, DCT Specialist, Novo Nordisk

To understand the current state and future direction of decentralized clinical trials post-COVID-19, a survey was conducted across 14 sponsor companies to assess implementation experiences, success factors, and challenges. This presentation will focus on key trends and insights across survey respondents, including lessons learned. While implementation challenges remain, ongoing collaboration among industry, regulatory authorities, and patients will play a pivotal role in shaping the future landscape of decentralized clinical trials.

15:05 Presentation to be Announced

VERISTAT

15:30 Inconvenient Truths of Decentralised Clinical Trials (DCT)

Reamonn Madden, Innovation Capability Director, Global Clinical Operations Innovation, Novartis Pharmaceuticals

The experiences of COVID-19 restrictions and a return to a "new normal" permit a fairer perspective on opportunities and realities for decentralized clinical trials. This talk will provide reflections on the challenges for DCT implementation and what these mean for its use in the near future.

15:55 Bringing Clinical Trials to Everyone's Backyard

Stuart Redding, CEO, Medical Research Network Ltd.

16:07 Unlocking the Power of Decentralised Clinical Trial (DCT): Navigating Trial Design Considerations in Modern Models

Science 37

Ali Wherry, Director, Science37

Explore the future of clinical research through a new lens on Decentralized Clinical Trial (DCT) components. Often overlooked, the full potential of DCTs can be unlocked by prioritizing intentional planning from the outset. Join this session to discuss innovative trial design considerations that enhance operational feasibility and ease patient burden. Get set for a journey towards more efficient, patient-centric clinical trials!

16:32 Enhancing Patient Engagement and Satisfaction: Are Decentralised Trials Delivering on This Promise?

Stefania Collamati, DCT Operations Manager, Clinical Operations, Bayer SPA

Bayer has successfully implemented innovative trial designs that aim to fit the lifestyle of patients in both hybrid and fully decentralized clinical trials. With this presentation we take a deep dive into the DCT strategies Bayer has adopted and their impact on patient satisfaction, experience, and willingness to participate in future clinical trials which are offering more modern and flexible approaches.

16:57 Reception in the Exhibit Hall with Beer, Wine, and Tapas

Wind down at the end of a busy session day with colleagues, beer, wine, and tapas. Have a drink with your favorite exhibitor and take a chance at winning a fabulous raffle prize (must be present to win)!

18:00 Close of Day

WEDNESDAY 30 OCTOBER

8:15 Registration and Morning Coffee

NEW TRENDS IN PROTOCOL DESIGN: REDUCING SITE AND PATIENT BURDEN

8:45 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:50 The Benefits of Building the Use of Digital Technologies into Clinical Program Design by First Intent

Matthew Bonam, Head BioPharmaceuticals R&D, Digital Patient Health & Innovation, AstraZeneca R&D

Digital technologies have the potential to accelerate the clinical development of new medicines and improve the patient and site experience of participating in a trial. If applied poorly, these same technologies can have the opposite effect. Case studies and patient testimonials will be used to describe the benefits of using digital technologies in clinical programs. Actionable insights will aid clinical teams in the design of digital-first clinical development programs.

9:15 Integrated Trail Optimization: An Innovative Approach to Study Design Including Both the Patient and Site Voices

ThermoFisher SCIENTIFIC

Jenna McDonnell, Senior Director Strategy & Innovation, Thermo Fisher Scientific

Caitlin Thomas, Research Scientist, Thermo Fisher Scientific

There are often challenges when designing clinical trials with tension between scientific and operational considerations, patient burden and site burden. The PPD clinical research business of Thermo Fisher Scientific offers Integrated Trial Optimization solutions that have been built to overcome these obstacles. Join us to learn how we use proprietary tools, data sources and capabilities together to deliver the optimal plan for program delivery, regulatory success and market access.

9:40 Optimisation of Protocol Design: A Path To Efficient, Lower Cost Clinical Trial Execution

Marina Malikova, PhD, Executive Director, Surgical Translational Research, Operations and Compliance, Boston University School of Medicine

Explore the challenges clinical teams face in developing protocols to ensure that the right patients are enrolled and the right data are collected to demonstrate that a drug is safe and efficacious, while managing study costs and study complexity based on proposed comprehensive scoring model. A methodology to identify processes at planning phase, approaches to increase fiscal return and mitigate fiscal compliance risk for clinical trials will be addressed.

10:05 Sponsored Presentation *(Opportunity Available)*

10:17 Coffee Break in the Exhibit Hall with Special Book Signing

More coffee, more exhibitors, more networking, and some delicious snacks. What's not to love?

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

12:10 Join Your Peers for a Networking Luncheon in the Exhibit Hall

Join us again for lunch in the Exhibit Hall. Last chance to visit with exhibitors you missed and to enter our final raffle!

ENGAGING PATIENTS AND SITES FOR BETTER TRIAL DESIGN

13:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

13:15 Researcher Training to Elevate Patient Engagement as the Standard for Clinical Development

Maria Dutarte, Executive Director, European Patients' Academy on Therapeutic Innovation (EUPATI)

Patient engagement is transforming clinical development as expert patients increasingly delve into its complexities. Ready for substantive dialogues, these informed patients often find researchers unprepared for effective engagement. Our session highlights the critical benefits and strategies of training researchers to optimise interactions with patient experts, ensuring both sides can fully leverage these valuable exchanges.

13:40 FIRESIDE CHAT: Protocol Design Trends—Opportunities to Lower Site and Patient Burden and Optimise Trial Execution

Frank Berger, MD, Expert Data & Analytics Solutions, Clinical Development & Operations, Boehringer Ingelheim

Carme Esteve, EU Clinical Trial Submission Strategy Manager, Sanofi

Zachary Smith, Senior Data Scientist, Tufts Center for the Study of Drug Development

Tufts CSDD has developed assessments for the burden experienced by both participants and trial sites when participating in clinical trials. These assessments (and other similar assessments) can identify sources of elevated burden and be used to identify ways to reduce the burden of participation and improve trial performance. They also highlight similarities and differences in the sources of burden experienced by trial participants and sites.

14:05 Sponsored Presentation *(Opportunity Available)*

14:30 Session Break

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

15:45 Close of Summit

Feasibility and Study Activation

Modernizing Feasibility, Site Selection, Site Engagement, and Start-Up Practices

MONDAY 28 OCTOBER

MONDAY AFTERNOON: USER GROUP & WORKSHOP

14:30 – 19:00 Innovation Day with IQVIA Technologies at SCOPE Europe

CO-SPEAKERS:
Kevin Landells, Vice President Patient Centered Technology Delivery, IQVIA Technologies
Stefan Dürr, Senior Director, Client Delivery, IQVIA Technologies
Petar Genov, Senior Director, Business Operations and Capabilities – Payments, IQVIA Technologies
Tim Reily, Vice President, Clinical Data Analytics, IQVIA Technologies
Alison Liddy, Senior Vice President, Patient and Site Centric Solutions, IQVIA

Clinical trial sponsors are invited to join IQVIA Technologies' digital product leaders and industry representatives for an afternoon of discussions, demos, and networking. IQVIA will share our vision to transform clinical operations, demonstrate our technologies that improve the patient, site, and sponsor journeys, and ask for your input on our roadmap for future product development. Innovation Day is complimentary and will be of interest to pharmaceutical executives or sites with roles in clinical operations, innovation, technology, finance, budgeting, data analytics, patient or site engagement, or strategic sourcing. IQVIA reserves the right to decline registrations for those not in these categories. For more information or to register **click here**.

17:30 – 19:00 The Path towards Sustainable Clinical Trials: How to Minimise Environmental Impact and Stay Ahead of Future Regulatory Requirements

INSTRUCTORS:
Fiona Adshead, Chair, Sustainable Healthcare Coalition
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Marisa Minetti, Patient Research Partner, Chiesi Group
Keith Moore, Programme Coordinator, Sustainable Healthcare Coalition

Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond benefiting the environment, adopting sustainable practices is increasingly demanded by stakeholders and can significantly influence customer choices and talent acquisition. Perhaps more compelling are the growing regulatory pressures and expectations, including the Corporate Sustainability Reporting Directive (CSRD) and Task Force on Climate-related Financial Disclosures (TCFD) among others. This workshop will discuss the current hotspots of carbon emissions in clinical research, introduce a new clinical trial carbon footprint calculator for assessing current state, and suggest introductory reduction strategies. Whether you are in clinical trial design clin ops, procurement, innovation, sustainability, or resource management, this workshop is for you.

TUESDAY 29 OCTOBER

7:00 SCOPE Europe Fun Run/Walk Up the Magic Fountain Steps

Join SCOPE Europe's Coordinators for our Fun Run/Walk! All of us at Cambridge Healthtech Institute recognise the importance of integrating well-being and fitness into our work travel routines. This is an easygoing, informal running (or walking) event where we ascend the stairs of the iconic Magic Fountain. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! *Meet us in the front lobby at the InterContinental at 7 sharp!*

7:45 Registration and Morning Coffee

8:50 Organiser's Welcome Remarks

DATA ANALYTICS & GEN AI: NEW APPROACHES TO IMPROVE SITE SELECTION & ACTIVATION

8:55 Chairperson's Remarks *(Sponsorship Opportunity Available)*

9:00 Feasibility and Site Identification Powered by Data and Gen AI

Carole Ackermann, EEA Cluster Portfolio Head, Novartis
Abhishek Chatterjee, Head, Health Data Insights and Design a.i., Novartis
Tony Yordanov, Clinical Operations Program Director, Novartis

Despite significant advancements in clinical trial processes and technology, industry faces challenges in delivering medicines efficiently and cost-effectively. An AI-driven feasibility approach, combining human insights, process, and technology can bring patients into focus. Let's explore how AI can enhance clinical trial feasibility and review the challenges of integrating AI into the development process.

9:25 Embedding Digital Tools and Data-Driven Approaches for Site Selection: Change Management, Training Needs, and Implementation Strategy

Susannah Finney, Clinical Operations Lead, Product Development Global, Roche

Effective site-selection is key for a study's speed and success. Shifting the foundation of this decision from a basis of personal experience to objective data requires strategic rollout and a long-term organisation mindset shift. Roche has embedded Sitescape: an objective data-driven site-selection tool. Join us to learn how we navigated this change in both process and behaviour.

9:50 Unlocking AI-Enriched EHR Data for Precision Psychiatry through the Akrivia Health Research Platform

Benjamin Fell, PhD, Head of Research, Akrivia Health

The drive for precision psychiatry has increased the availability of high-dimensionality molecular data, rich real world phenotypic data remains difficult to access. Akrivia Health has addressed this challenge through a 15-year programme creating digital research infrastructure and data enrichment pipelines for NHS psychiatric electronic health records. The result is a research-ready dataset of 5 million+ patients' full EHR histories, enriched through an AI-driven NLP pipeline, providing the scale and depth of information needed to realise precision psychiatry's promise.

10:15 Bridging the Gap: Integrating Data Science and Gen AI in Feasibility

Nadia Lim, Head, Feasibility Strategy & Analytics, Pfizer Inc.
Joao Goncalo Nascimento, Performance Analyst, Predictive Analytics – PRD (OARS), Pfizer Inc.

In this talk, we share new ways of working in feasibility to optimise clinical trial execution. We address operational challenges in integrating new technologies in feasibility, such as data science and Gen AI. We discuss how we optimise feasibility planning while also considering the risks, alongside user adherence, and the necessity of explainability. These considerations are crucial for the successful application of these innovations to improve site selection.

10:40 Streamlining Study Start-Up: Unlocking Results & Benefits for Sponsors and Sites

Tom Johnson, Senior Director, Life Sciences & Health IT, Exostar

We hear you. Sponsors are challenged with lengthy study start-up processes and ongoing monitoring, while the clinical trial sites are burdened with technology redundancy and sign-on silos obstacles. In this talk, we will give the sponsor's and site's perspective on the progress made to overcome these issues and share real examples of how sponsors and sites are collaborating and streamlining the user's experience.

10:53 Grand Opening Coffee Break in the Exhibit Hall

The SCOPE Europe Exhibit Hall is the best place to fuel up with a mid-morning coffee while visiting with our many exhibitors. Learn about what's new in the industry, connect with colleagues and vendors, and make some new friends.

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

13:35 Join Your Peers for a Networking Lunch in the Exhibit Hall

Take this opportunity to refresh and refuel with our Exhibit Hall lunch. Enjoy good food and even better conversation during our walk and talk luncheon.

SPONSOR/SITE COLLABORATION: SUPPORTING SITES TO IMPROVE RECRUITMENT, RETENTION, AND PERFORMANCE

14:35 Chairperson's Remarks

Paul Duffy, Head, Global Clinical Site Partnerships, MSD

14:40 PANEL DISCUSSION: Increasing Trust & Transparency to Accelerate Site Selection and Start-Up

Moderator: Marcy Kravet, Vice President, Strategic Operations, Inato

In a recent global survey, 72% of sites think sponsors trust their feasibility data while only 13% of sponsor/CROs report trusting site responses. In addition, 92% of sponsor/CROs and 70% of site respondents reported feeling stressed during site selection. This sponsor and site panel will share insights from the survey and discuss opportunities to fix feasibility by leveraging data and technology to accelerate timelines and reduce sponsor and site burden.

Panelists:
Rosia Shah, MD, Medical Lead, VCTC

Thomas Westgate, Director, Strategic Feasibility, Clinical Research, PPD, part of Thermo Fisher Scientific

15:05 Clinical Trial Diversity: Expanding Past the FDA to the Rest of the Globe

Robert Consalvo, Director, Strategic Commercial Engagement, H1

This presentation will discuss, best practices for measuring diversity, equity, and inclusion in a clinical trial. Also included will be practical guidance for understanding diversity outside of the United States and innovative measures for strategically infusing generative AI into clinical operations.

15:30 Long-Term Relationship Development with Clinical Research Sites

Paul Duffy, Head, Global Clinical Site Partnerships, MSD

Overview of our company's approach to building long-term relationships with our high-performing clinical research institutions in order to ensure development of our clinical research pipeline. Which approach we took to identify engagement for the long term and ensure that these sites were given appropriate access to our clinical research pipeline in order to optimise planning, engage with investigators to match studies, and ensure delivery of high-quality data.

15:55 The Impact of Site Tech Overload on Feasibility and Study Start-Up

Speaker to be Announced, IQVIA

Alison Liddy, Senior Vice President, Patient & Site Centric Solutions, IQVIA

Lorenzo Parma, Director, Solution Engineering, IQVIA Technologies

Raphaelle Gilg, SSO Strategy and Operations, EMEA, Novartis

Facing staffing shortages, clinical research sites are taking longer to activate and even turning down the studies they find unworkable. How can we make life easier for sites so that everyone benefits, most importantly the patients being served? In this panel discussion, leaders across the clinical trial ecosystem will discuss viable strategies to reduce the overload of technology that is contributing to site burden and staff burn-out. Can an industry approach deliver a truly vendor-agnostic, single sign-on solution?
Moderator: Lorenzo Parma, IQVIA Technologies
Panelists
Raphaelle Gilg, Novartis
Chloe Rose, Pratia
Alison Liddy, IQVIA

16:20 AI-Enabled Forecasting: Increase Confidence in Study Feasibility and Execution

Rachel Horovitz, Vice President, Product Strategy, Medidata AI

16:32 Sponsored Presentation *(Opportunity Available)*

16:57 Reception in the Exhibit Hall with Beer, Wine, and Tapas

Wind down at the end of a busy session day with colleagues, beer, wine, and tapas. Have a drink with your favorite exhibitor and take a chance at winning a fabulous raffle prize (must be present to win)!

18:00 Close of Day

WEDNESDAY 30 OCTOBER

8:15 Registration and Morning Coffee

TECHNOLOGIES AND PROCESSES TO IMPROVE FEASIBILITY, ACTIVATION, AND OPERATIONS

8:45 Chairperson's Remarks

Alison Foster, Vice President, Strategic Delivery & Growth, Fortrea

8:50 Acceleration of Interactive Response Technology: Innovative Methods to Enhance Efficiency

Cezary Bregier Director, Global Clinical Solutions, AstraZeneca

Hubert Filipczak, Director, Global Clinical Solutions, AstraZeneca Pharma Poland Sp zoo

This session offers an in-depth exploration of the Interactive Response Technology (IRT) setup process for clinical studies, from early engagement to system activation. Participants will learn about the roles of both sponsors and IRT providers and discover strategies to enhance efficiency, including process waste identification, standardisation, and ways to improve specification document quality to reduce lead times.

9:15 Talk Title to be Announced

Ben Carmel, Chief Revenue Officer, Slope

9:40 Towards an Automated Site Feasibility with Use of Ontologies

Aditya Tyagi, Project Manager, Pistoia Alliance

The Pistoia Alliance offers a pre-competitive platform for collaboration among pharmaceutical members and R&D service providers. The Clinical Operations Ontology project aims to automate clinical trial processes through machine-readable data via ontologies. Site feasibility ensures protocol-site alignment for study viability. Our focus is on enhancing trial planning efficiency by automating processes, leveraging linked data, and standard methodologies. This approach promises expedited decision-making and reduced redundant efforts.

9:58 Feasibility: Process Update to Ensure Active Site Engagement

Heidi Egsgaard Frandsen, Director, Indication/Program Lead, AstraZeneca

Karin Schiene, Director, Indication Program Lead, AstraZeneca

During this discussion, you will learn how AstraZeneca has made process changes and shifted the mindset of the feasibility process. We will share the process and template changes we have implemented to ensure we are actively engaged from our first interaction through site selection.

10:17 Coffee Break in the Exhibit Hall with Special Book Signing

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

12:10 Join Your Peers for a Networking Luncheon in the Exhibit Hall

Join us again for lunch in the Exhibit Hall. Last chance to visit with exhibitors you missed and to enter our final raffle!

REDUCING SITE BURDEN TO OPTIMISE OPERATIONS

13:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

13:15 How CSLs Improved Feasibility Process Helps Study Teams Improve Their Robustness in Operational Planning

Mireille Ermens, Senior Director, Clinical Development Operations—Global Feasibility and Start-Up Support, CSL Behring

Mary Smith, Senior Director, Clinical Portfolio Execution, Seqirus A CSL Co.

Early planning and study start-up challenges are common across the industry and may cause additional burden to study teams and sites with downstream impact on recruitment, timelines, and cost. Organisational focus is required to address these challenges. During this session you will learn how CSL has improved the feasibility process to help study teams improve their robustness in operational planning.

13:40 Optimizing our Focus on Site Facing Training

Mette Flindt Heisterberg, PhD, Competency Development Specialist, Clinical Operations Office, Global Trial Portfolio, Novo Nordisk AS

In the past year, Novo Nordisk has meticulously optimised site-facing training, emphasising user-centric learning journeys. By establishing a dedicated site learning unit and refining processes, we can deliver best-in-class learning experiences. Shifting our focus, we aim to explore optimal training delivery and foster flexible, engaging experiences for our site staff. We invite you to join us in exploring our challenges, solutions, and reflections, as we embark on this transformative journey.

14:05 AI-Driven Augmentation for Global Strategic Clinical Trial Delivery

Lee Coram, Senior Director Business Insights, Thermo Fisher Scientific

Dave Hiltbrand, Associate Director Data Science, Thermo Fisher Scientific

Jeffrey Zimmerman, Senior Director Data Science, PPD Clinical Research, Thermo Fisher Scientific

Optimizing clinical trial study delivery by reducing timelines and mitigating risk in best-fit global selection strategy and patient enrollment is a long-standing challenge of CROs and Pharma. The PPD Clinical Research Business of Thermo Fisher Scientific has nearly a decade of experience using AI and data science to meet this need. Join us to learn how we use feasibility, start-up, enrollment, and AI to empower our partners to deliver faster, higher quality, and more affordable medicine.

14:30 Session Break

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

15:45 Close of Summit

MONDAY 28 OCTOBER

MONDAY AFTERNOON: USER GROUP & WORKSHOP

14:30 – 19:00 Innovation Day with IQVIA Technologies at SCOPE Europe

CO-SPEAKERS:
Kevin Landells, Vice President Patient Centered Technology Delivery, IQVIA Technologies
Stefan Dürr, Senior Director, Client Delivery, IQVIA Technologies
Petar Genov, Senior Director, Business Operations and Capabilities – Payments, IQVIA Technologies
Tim Reily, Vice President, Clinical Data Analytics, IQVIA Technologies
Alison Liddy, Senior Vice President, Patient and Site Centric Solutions, IQVIA

Clinical trial sponsors are invited to join IQVIA Technologies' digital product leaders and industry representatives for an afternoon of discussions, demos, and networking. IQVIA will share our vision to transform clinical operations, demonstrate our technologies that improve the patient, site, and sponsor journeys, and ask for your input on our roadmap for future product development. Innovation Day is complimentary and will be of interest to pharmaceutical executives or sites with roles in clinical operations, innovation, technology, finance, budgeting, data analytics, patient or site engagement, or strategic sourcing. IQVIA reserves the right to decline registrations for those not in these categories. For more information or to register **click here**.

17:30 – 19:00 The Path towards Sustainable Clinical Trials: How to Minimise Environmental Impact and Stay Ahead of Future Regulatory Requirements

INSTRUCTORS:
Fiona Adshead, Chair, Sustainable Healthcare Coalition
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Marisa Minetti, Patient Research Partner, Chiesi Group
Keith Moore, Programme Coordinator, Sustainable Healthcare Coalition

Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond benefiting the environment, adopting sustainable practices is increasingly demanded by stakeholders and can significantly influence customer choices and talent acquisition. Perhaps more compelling are the growing regulatory pressures and expectations, including the Corporate Sustainability Reporting Directive (CSRD) and Task Force on Climate-related Financial Disclosures (TCFD) among others. This workshop will discuss the current hotspots of carbon emissions in clinical research, introduce a new clinical trial carbon footprint calculator for assessing current state, and suggest introductory reduction strategies. Whether you are in clinical trial design clin ops, procurement, innovation, sustainability, or resource management, this workshop is for you.

TUESDAY 29 OCTOBER

7:00 SCOPE Europe Fun Run/Walk Up the Magic Fountain Steps

Join SCOPE Europe's Coordinators for our Fun Run/Walk! All of us at Cambridge Healthtech Institute recognise the importance of integrating well-being and fitness into our work travel routines. This is an easygoing, informal running (or walking) event where we ascend the stairs of the iconic Magic Fountain. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! *Meet us in the front lobby at the InterContinental at 7 sharp!*

7:45 Registration and Morning Coffee

8:50 Organiser's Welcome Remarks

GLOBAL APPROACHES TO RECRUITING DIVERSE POPULATIONS: UNIQUE COUNTRY & REGIONAL CHALLENGES

8:55 Chairperson's Remarks

Robert Loll, Senior Vice President, Praxis

9:00 A Global Approach to DEI in Clinical Trials

Estelle Jobson, EUPATI Fellow and Patient Expert
Robina Weermeijer, Global Clinical Trials Diversity & Inclusion Lead, Boehringer Ingelheim

As the world is becoming more and more diverse there is a big need to consider a wide audience when conducting clinical trials. In this presentation, you'll get insights into why it's important to look at diversity, equity, and inclusion on a global level and which efforts are being made by Boehringer Ingelheim in this space through collaboration with diverse stakeholders.

9:25 Diversity in Clinical Trials (DICT) EMEA—A Multiple-Country Approach

Paul Duffy, Head, Global Clinical Site Partnerships, MSD
Laurence Garret, Therapeutic Area Lead, Clinical Operations, MSD

Diversity in Clinical Trials (DICT) a global approach for one company to ensure access for all in their clinical research studies. Hear how our team has taken a practical approach in different countries to identify barriers, build new communication pathways, and to support access for patients through healthcare providers and their teams. Learn how different requirements and opportunities in countries ex USA have driven our approach to equity.

9:50 Talk Title to be Announced

Dan Shannon, Chief Experience Officer, Greenphire

10:15 Recruitment & Retention of Diverse Participants across the Globe

Jameka Hill, Senior Director, Clinical Trial Health Equity, Moderna, Inc.
Katherine Norton,Senior Director, Patient Experience & Operational Feasibility, Moderna, Inc.

Inspired by its success in the US, Moderna is forging ahead with its commitment to inclusive healthcare research in the UK and Europe. The company has made significant strides in patient recruitment and retention, ensuring that clinical trials are a mirror of those most impacted and likely to benefit from new therapies. Moderna's approach cultivates trust and engagement, paving the way for equitable access to future medical advancements.

10:40 What It Takes to Successfully Recruit Patients: An Integrated Platform Approach

Jytte van Huijstee, Director Clinical Trial, myTomorrows

This engaging session will cover the following topics, recognize recruitment challenges related to patient and physician awareness, multilingual support, cross-border referrals, and regulatory compliance, and learn strategies to navigate these. Also, an integrated platform approach to clinical trial recruitment should be developed by combining patient, physician, and site flows to streamline the recruitment funnel from awareness to enrollment. We will discover tactics for engaging with different stakeholders through real-world success stories from treating physicians, patient advocacy groups, and clinical research sites. Join us as we discuss these topics and more.

10:53 Grand Opening Coffee Break in the Exhibit Hall

The SCOPE Europe Exhibit Hall is the best place to fuel up with a mid-morning coffee while visiting with our many exhibitors. Learn about what's new in the industry, connect with colleagues and vendors, and make some new friends.

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

13:35 Join Your Peers for a Networking Lunch in the Exhibit Hall

Take this opportunity to refresh and refuel with our Exhibit Hall lunch. Enjoy good food and even better conversation during our walk and talk luncheon.

ADVANCING INCLUSIVE RESEARCH: DIVERSITY PLANNING, COMMUNITY ENGAGEMENT & SITE ENABLEMENT

14:35 Chairperson's Remarks

Jodie Allen, PhD, Senior Director, Clinical Trial Diversity, AstraZeneca

14:40 FIRESIDE CHAT: The FDA's Revised Draft Guidance on Clinical Trial Diversity

Alberto Fernandez, Senior Vice President, Global Clinical Operations, GSK
Edward Ramos, PhD, Senior Director, Digital Clinical Trials, Scripps Research

We will delve into the latest insights on the FDA's requirements for Diversity Action Plans. We'll discuss the implications for sponsors and explore effective strategies to ensure diverse populations are recruited for clinical trials. Gain an understanding of the process for creating and submitting a plan to the FDA, while navigating the uncertainties surrounding FDA expectations. Explore strategies for involving individuals impacted by the disease in clinical trials.

15:05 Presentation to be Announced

15:30 Breaking Down Boundaries and Rethinking Recruitment with Agile Research Delivery

Alex Hammond, Business Development Manager, National Institute of Health and Care Research (NIHR)
Joanne Henry, Matron, NIHR Clinical Research Network Greater Manchester

Patient Engagement and Recruitment

Engagement and Recruitment through Communities and Technology

This session will take you on a research road trip—not to different locations, but instead to different settings beyond the hospital clinic. Hear how new, flexible ways of working and adaptable research delivery models are breaking down boundaries, increasing accessibility, and creating opportunities to generate real-world evidence. From places of worship to prisons, supermarkets, care homes, schools, hospices, and festivals—direct delivery transforms research delivery by taking research to the people.

15:55 Presentation to be Announced

16:20 Presentation to be Announced

16:32 Addressing Clinical Trial Diversity in a Global Context: Challenges, Opportunities, and Critical Capabilities

Jodie Allen, PhD, Senior Director, Clinical Trial Diversity, AstraZeneca

Elizabeth Bristow, Director, Patient Recruitment & Retention, AstraZeneca

The FDA has led the charge with its recently updated draft guidance. As sponsors of global studies, ensuring that patients in our studies reflect those who may use the medicine requires capabilities that go beyond the U.S. FDA requirements. We will share our experience in building enterprise-level capabilities to improve diversity through design, planning, execution, and monitoring, in line with AstraZeneca's global diversity ambition.

16:57 Reception in the Exhibit Hall with Beer, Wine, and Tapas

Wind down at the end of a busy session day with colleagues, beer, wine, and tapas. Have a drink with your favorite exhibitor and take a chance at winning a fabulous raffle prize (must be present to win)!

18:00 Close of Day

WEDNESDAY 30 OCTOBER

8:15 Registration and Morning Coffee

INNOVATION IN PATIENT ENGAGEMENT

8:45 Chairperson's Remarks

Speaker to be Announced, mdgroup

8:50 Operationalising Participant Data Return—A Step Closer to Personalised Clinical Drug Development

Nadir Ammour, DDS, MBA, Global Lead Clinical Innovation & External Partnership, Sanofi

Johanna Blom, PhD, Associate Professor, Behavioral Neuroscience; Chair, Ethical Committee for Research, University of Modena and Reggio Emilia

Swapna Pothula, Associate Director, Data Strategy & Management, Global Clinical Operations, GSK

Discover insights into current initiatives driving change and explore available solutions for securing leadership endorsement, integrating participant data return into operational processes, defining the details of the data to be returned based on organisational parameters, and acknowledging and addressing the potential concerns or challenges with operationalising the participant data return.

9:15 Empowering Participants: How Compassionate Protocol Design Utilizing Study Support Delivers a Patient-First Experience

Alison Liddy, Senior Vice President, Patient & Site Centric Solutions, IQVIA

We will explore the need for an intersection of compassionate care and cutting-edge technology in all trials while walking through an oncology case study that embraced decentralized study elements, empowered patients, and enhanced trial design. Discover how IQVIA's innovative approaches improved enrollment and shortened recruitment timelines by understanding patient needs, reducing burden, and extending study site boundaries.

9:40 Mapping Site Recruitment Strategies for Engaging Socioeconomically Disadvantaged Populations in Clinical Research

Maria Florez, Research Consultant, Tufts Center for the Study of Drug Development

Learn about strategies that have been shown to improve the recruitment of socioeconomically disadvantaged populations into clinical trials. See recent data on current levels of implementation of such strategies among clinical trial sites. Discuss perceived challenges associated with the implementation of these strategies and how to better support sites in their ability to support prospective and current clinical trial participants.

10:05 Putting Patients at the Center of Their Clinical Trial Journey: Supporting Engagement, Driving ePRO Compliance

Bruce Hellman, Co-Founder & Chief Patient Officer, uMotif Ltd.

How robust, globally-deployable solutions can be designed from a 'patient-first' perspective—sharing learning on achieving meaningful engagement throughout the study—exploring how modern technology both retains patients and drives high eCOA/ePRO compliance—case studies on embedding human-centred design to deliver faster, more flexible outcomes for sponsors.

10:17 Coffee Break in the Exhibit Hall with Special Book Signing

More coffee, more exhibitors, more networking, and some delicious snacks. What's not to love?

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

12:10 Join Your Peers for a Networking Luncheon in the Exhibit Hall

Join us again for lunch in the Exhibit Hall. Last chance to visit with exhibitors you missed and to enter our final raffle!

LEVERAGING DATA AND TECHNOLOGY TO MODERNISE FORECASTING AND RECRUITMENT

13:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

13:15 Optimising Enrollment Forecasting: A Bayesian Approach

Xinyang Li, Senior Data Scientist, Johnson & Johnson

Mohammad Umarfaruque, Data Science Consultant, ZS Associates

A reliable enrollment forecast is key in clinical trials for resource optimisation and clinical supply planning. This proposal introduces a Bayesian methodology for optimising enrollment forecasting in clinical trials. By incorporating real-time data updates, such as one-month actual enrollment data and latest thinking from sites, the proposal ensures that forecasts remain dynamic and reflective of current trends, improving overall forecasting reliability and decision-making capabilities.

13:40 Digital as a Bridge (Not a Divide): Advancements in RWD Collection

Katie Baca-Motes, Chief Strategy Officer, CareEvolution / Scripps Research Digital Trials Center

Bart Lagerwaard, PhD, Assistant Professor, University Medical Centre Utrecht

Cristina Duran, President, Evinova

As new technologies emerge that prove useful tools in collecting data in real-world settings, it is important to evaluate whether they bring with them the unintended consequence of leaving some populations behind. This panel will discuss the importance of identifying and recognising the use of technologies that have the potential to serve as a bridge and improve clinical trial accessibility and participation by populations historically left out of biomedical research.

14:05 Effective Tailored Strategies for Special Patient Populations: Lessons from Global Studies

Lucina Tabasso, Senior Project Manager, ERCULES

Recruiting and retaining special populations, such as pediatric, rare disease, and elderly patients, in clinical trials presents unique challenges. This presentation will showcase the strategies we employed to significantly empower, educate and inform patients, their family members and caregivers. We will discuss methods that improved engagement and enhanced compliance in both decentralized (DCT) and traditional clinical trial settings, drawing from our experiences in international trials.

14:30 Session Break

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

15:45 Close of Summit

MONDAY 28 OCTOBER

MONDAY AFTERNOON: USER GROUP & WORKSHOP

14:30 – 19:00 Innovation Day with IQVIA Technologies at SCOPE Europe

CO-SPEAKERS:
Kevin Landells, Vice President Patient Centered Technology Delivery, IQVIA Technologies
Stefan Dürr, Senior Director, Client Delivery, IQVIA Technologies
Petar Genov, Senior Director, Business Operations and Capabilities – Payments, IQVIA Technologies
Tim Reily, Vice President, Clinical Data Analytics, IQVIA Technologies
Alison Liddy, Senior Vice President, Patient and Site Centric Solutions, IQVIA
Clinical trial sponsors are invited to join IQVIA Technologies' digital product leaders and industry representatives for an afternoon of discussions, demos, and networking. IQVIA will share our vision to transform clinical operations, demonstrate our technologies that improve the patient, site, and sponsor journeys, and ask for your input on our roadmap for future product development. Innovation Day is complimentary and will be of interest to pharmaceutical executives or sites with roles in clinical operations, innovation, technology, finance, budgeting, data analytics, patient or site engagement, or strategic sourcing. IQVIA reserves the right to decline registrations for those not in these categories. For more information or to register **click here**.

17:30 – 19:00 The Path towards Sustainable Clinical Trials: How to Minimise Environmental Impact and Stay Ahead of Future Regulatory Requirements

INSTRUCTORS:
Fiona Adshead, Chair, Sustainable Healthcare Coalition
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Marisa Minetti, Patient Research Partner, Chiesi Group
Keith Moore, Programme Coordinator, Sustainable Healthcare Coalition
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond benefiting the environment, adopting sustainable practices is increasingly demanded by stakeholders and can significantly influence customer choices and talent acquisition. Perhaps more compelling are the growing regulatory pressures and expectations, including the Corporate Sustainability Reporting Directive (CSRD) and Task Force on Climate-related Financial Disclosures (TCFD) among others. This workshop will discuss the current hotspots of carbon emissions in clinical research, introduce a new clinical trial carbon footprint calculator for assessing current state, and suggest introductory reduction strategies. Whether you are in clinical trial design clin ops, procurement, innovation, sustainability, or resource management, this workshop is for you.

TUESDAY 29 OCTOBER

7:00 SCOPE Europe Fun Run/Walk Up the Magic Fountain Steps

Join SCOPE Europe's Coordinators for our Fun Run/Walk! All of us at Cambridge Healthtech Institute recognise the importance of integrating well-being and fitness into our work-travel routines. This is an easygoing, informal running (or walking) event where we ascend the stairs of the iconic Magic Fountain. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! *Meet us in the front lobby at the InterContinental at 7 sharp!*

7:45 Registration and Morning Coffee

8:30 Organiser's Welcome Remarks

DRIVING SCALABLE INNOVATION

8:35 Chairperson's Remarks

Brenda Yanak, Former Vice President, Bristol Myers Squibb Co.; Founder, Clinical Transformation Partners LLC

8:40 Test-Start-Scale: The Data-Driven Technology Maturity Approach

Farrell Healion, Senior Director Emerging Technologies, Global Clinical Solutions, AstraZeneca

Test-Start-Scale is a methodology that takes digital innovation on a journey from idea through refinement, all the way to wider-scale use and BAU. The focus is on taking a data-driven approach which proves the value of the technology in a controlled fashion which can, in turn, help with promoting adoption leaving study teams satisfied and confident in new digital capabilities.

9:00 Digital Data Flow: Digitalising Clinical Protocol Information to Accelerate Clinical Research and Enable Healthcare Interoperability

William Illis, Global Head, Collaboration & Technology Strategy Clinical Development, Novartis Pharmaceuticals

Digitising clinical protocol information can streamline study start-up, enable analytics-assisted study design, and support more routine use of point-of-care data. TransCelerate's Digital Data Flow (DDF) initiative, in collaboration with CDISC, has delivered a data model, exchange standard, and open-source reference implementation aimed at the use of digital protocols. This presentation will highlight current DDF capabilities, use cases, and roadmap for stakeholder collaboration to achieve interoperability across research and care settings.

9:20 Integrating Clinical and Real-World Evidence for AI Augmented Clinical Trial Design

Amhar Jabeer, Computational Scientist, Integrated Clinical Data, Digital R&D, Sanofi Group

Maksim Kriukov, Computational Scientist Lead, Integrative Clinical Data Digital R&D, Sanofi Group

The challenge of integrating real-world data with clinical trials hinders large-scale analysis and modeling of patient treatment journeys. Combining both data types would enable AI applications focused on optimizing trial patient recruitment, predicting treatment outcomes, and stratifying patient populations. We leverage AI and machine learning algorithms to enhance clinical trial design, repurpose treatments, and identify safety risks.

9:40 The Right Patient Technology At the Right Time: Improve Your Clinical Trial Implementation Strategy

Melissa Mooney, Director, eCOA Solutions Engineering, IQVIA

Today's clinical trial landscape requires the use of various technology solutions to support patient enrollment and the collection, management, and review of clinical data which ultimately informs clinical decisions and trial results. In order to improve data quality, optimize workflows, and create a seamless end-user experience, it's important to leverage the appropriate clinical technology strategy. In this session, IQVIA patient suite expert Melissa Mooney will explore how best-in-class clinical technology solutions can be used independently to optimize trial conduct and when/how these technologies can work together to create further workflow benefits. In this session, she will discuss how to design and execute a patient technology strategy that fits study needs. How to reduce clinical site burden by streamlining processes across eConsent, IRT, and eCOA. Finally, how to quickly leverage insights collected from patient data to improve compliance, study optimization, and decision-making.

10:05 Help is Here! Interpreting the ICH E6 R3 Data Governance Requirements

Hasnaa Likaoui, Director, Vendor and Digital Health Quality, Bristol Myers Squibb

Matt Thompson, Executive Director, Corporate Quality, Parexel International

The upcoming ICH E6 R3 (GCP) guideline introduces a brand-new section related to Data Governance in clinical trials. Given the critical nature of data in clinical research, proper governance is essential to maintain the reliability of the trial results. ACRO and TransCelerate collaborated to deliver a Data Governance framework and diverse solutions to support the understanding and interpretation of these new requirements.

10:25 Presentation to be Announced

10:40 Talk Title to be Announced TriNetX

Justin North, Director, TriNetX

10:53 Grand Opening Coffee Break in the Exhibit Hall

The SCOPE Europe Exhibit Hall is the best place to fuel up with a mid-morning coffee while visiting with our many exhibitors. Learn about what's new in the industry, connect with colleagues and vendors, and make some new friends.

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

13:35 Join Your Peers for a Networking Lunch in the Exhibit Hall

Take this opportunity to refresh and refuel with our Exhibit Hall lunch. Enjoy good food and even better conversation during our walk and talk luncheon.

RWD, SYNTHETIC DATA, AND BEYOND

14:35 Chairperson Remarks

Dorothee B. Bartels, PhD, Associate Professor (Apl. Professor) for Public Health and Epidemiology, Medizinische Hochschule Hannover; Founder, HealthData-Advisors

14:40 Navigating Data Quality in Clinical Trials: Innovations and Challenges in Audit Trail Analysis MEDIDATA

Olgica Klindworth, Vice President, Medidata, Dassault Systemes

Amid increasing complexities in data acquisition, data managers and operational users must adapt their approach to data quality oversight, utilizing a wider range of data sources, including audit trails. Audit trail data is immense, and users often struggle to identify key insights or effectively analyze this data, even with regulatory guidance. Consequently, the industry must innovate to find more efficient ways to scrutinize audit trail data and ensure robust data integrity controls. Key challenges with audit trail data include difficulties in gathering and processing massive audit data, pinpointing relevant information (asking right questions), and scalable methods for wider audit data interrogation.

However, audits offer valuable learning opportunities. This session will share real-world examples that showcase novel tools and methodologies for effective audit trail interrogation, and the potential for Generative AI to democratize audit trail review that opens new avenues for more accessible and comprehensive data oversight.

15:05 An Overview of High-Fidelity Synthetic Data Applications

Puja Myles, Director, Clinical Practice Research Datalink, CPRD

An overview of high-fidelity synthetic data applications. Outline of talk: this presentation will provide an overview of synthetic data and applications of high-fidelity synthetic data, including the use of synthetic data for sample size boosting (data augmentation) and as synthetic control arms, in the context of clinical trials. The talk will reference related concepts like *in silico* trial approaches and digital twins, with concluding comments on regulatory considerations.

15:20 The Use of Routinely Collected Electronic Healthcare Records (EHRs) for Clinical Trials Research: Opportunities and Challenges

Nada Khan, Clinical Data Quality Lead, CPRD

This talk will summarise the context for clinical trials research using routinely collected electronic health records (EHRs), including an overview of EHRs, commonly used databases, and data quality considerations. We will discuss advantages and limitations of using these data for clinical trials research with real-world examples.

15:30 How the German HDL is Enabling Health Data Research

Steffen Hess, Head of Health Data Lab, BfarM

Research with claims data and AI isn't just the future, it's the now. The Health Data Lab at the Federal Institute for Drugs and Medical Devices aims to make a significant improvement to healthcare by providing EHR and claims data of all persons insured in statutory health care for research. Sensitive health data will be processed in a secure processing environment to ensure the highest level of cybersecurity and privacy.

15:45 Building the First Large-Scale, Structured, Patient-Centric Real-World Evidence The Waze-Way

Yael Elish, Founder & CEO, StuffThatWorks

StuffThatWorks (STW), rooted in WAZE's excellence, is a patient-focused RWE platform, scaling data collection. It harnesses crowd-sourced health data, mirroring WAZE's disruption in transportation, to remove treatment barriers and boost research. With consent from three million users across 1250 conditions STW is already the largest structured patient-level real-world evidence data set consisting of self-reported, geospatial, and recently added EMR data.

15:55 Moving from Hype to Reality in Pharmaceutical AI Applications CERTARA

Ian Kerman, Data Science & AI Client Solutions Architect, Certara

Life science companies continue to struggle to leverage new AI technologies to enhance the safety and efficacy of therapeutics. The key is identifying clear use cases where AI can maximize impact by supporting bench scientists, data scientists, and medical writers. This presentation will cover three such use cases:

1. Utilizing GPTs for structured content authoring
2. Automating data transformation for eCTD standardization
3. QSP model creation to improve target ID, PK/PD, and clinical trial design

16:20 PANEL DISCUSSION: Triple the Evidence: Real-World Evidence, Synthetic Evidence, and Patient Reported Evidence

Moderator: Dorothee B. Bartels, PhD, Associate Professor (Apl. Professor) for Public Health and Epidemiology, Medizinische Hochschule Hannover; Founder, HealthData-Advisors

Can Synthetic Data and Patient Reported Data complement RWE generation: The Why and the How?

Panelists:

Yael Elish, Founder & CEO, StuffThatWorks

Steffen Hess, Head of Health Data Lab, BfarM

Nada Khan, Clinical Data Quality Lead, CPRD

Puja Myles, Director, Clinical Practice Research Datalink, CPRD

16:57 Reception in the Exhibit Hall with Beer, Wine, and Tapas

Wind down at the end of a busy session day with colleagues, beer, wine, and tapas. Have a drink with your favorite exhibitor and take a chance at winning a fabulous raffle prize (must be present to win)!

18:00 Close of Day

WEDNESDAY 30 OCTOBER

8:15 Registration and Morning Coffee

DATA TECHNOLOGIES TO ADVANCE ACADEMIC AND INDUSTRY RESEARCH

8:45 Chairperson's Remarks

Maria Veleva, Founder & Managing Director, Velev Consulting Ltd.; Individual Consultant

8:50 HIRO: Transforming Clinical Research at Mass General Brigham and Beyond

Merranda Logan, MD, MPH, FACP, Associate Chief Academic Officer, Mass General Brigham

Shawn Murphy, MD, PhD, Chief Research Information Officer, Mass General Brigham

Mass General Brigham's HIRO revolutionises clinical research with a data-driven approach. Our platform integrates hospital-based data for robust analytics, enhancing feasibility assessments, study design, and patient recruitment. With over 3,700 clinical trials supported, we empower industry sponsors, sites, and clinicians to accelerate research globally. Collaborating with pharmaceutical companies, we offer innovative solutions for effective research at the point-of-care, leveraging a network of providers.

9:15 Next-Generation Research: Utilizing Technology and Data to Transform Trial Execution

Myla Maloney, Chief Growth Officer, Premier, Inc.

Hadrian Green, Patient Champion & Leading NLP Expert, Premier, Inc.

This panel will explore how research-driven advancements are transforming clinical trials. Key topics include integrating AI and digital tools for enhanced data capture, improving clinical decision support through NLP, utilizing patient tokenization for secure data management, and leveraging the PINC AI Healthcare Database for forward-tracking patient histories. Experts will also provide insights into optimizing trial design and protocol development for more efficient and precise execution.

9:40 PANEL DISCUSSION: Advancing Clinical Trials through Scalable eSource Integration: The eSource Scale Up Task Force

Moderator: Peter Casteleyn, MSc, Clinical Data Strategy Advisor, i~HD

- Challenges & Opportunities in Clinical Trial Data Collection
- Introduction to the eSource Scale Up Task Force
- Collaborative Model & Stakeholder Engagement
- Future Directions & Deliverables
- Q&A and Closure

Panelists:

Lars Fransson, Strategy Lead for CVGI Account Team, R&D Information, AstraZeneca R&D

Paul Jacobs, Associate Director, Development Innovation, Regeneron Pharmaceuticals, Inc.

Joe Lengfellner, Senior Director, Clinical Research Informatics, Memorial Sloan Kettering Cancer Center

Felix Nensa, Essen University Hospital

10:05 Real-World Data and Digital Measurements in Women's Health: What Is the State-of-the-Art?

Bola Grace, PhD, MBA, Professor, University College London

The lack of attention to women's health means that it has traditionally experienced less innovation compared to other therapeutic areas. More recently, as the digital health landscape rapidly evolves, there has been a concerted effort from several stakeholders to improve application to women's health. This presentation delves into the latest advancements in real-world evidence, digital health technologies, and the application of AI in women's health, addressing current challenges.

10:15 Coffee Break in the Exhibit Hall with Special Book Signing

More coffee, more exhibitors, more networking, and some delicious snacks. What's not to love?

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

12:10 Join Your Peers for a Networking Luncheon in the Exhibit Hall

Join us again for lunch in the Exhibit Hall. Last chance to visit with exhibitors you missed and to enter our final raffle!

ADAPTING NEW TECHNOLOGIES: AZ CASE STUDIES

13:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

13:15 eCOA Delivery Optimisation from Sponsor's Perspective

Sylwia Kondratiuk, Director, Digital Patient Solutions, Global Clinical Solutions, AstraZeneca Pharma Poland Sp zoo

How can we optimise operational delivery of eCOA? We have reshaped the sponsor support model—maximising potential of early engagement—introducing the business analyst role with internal client specification and utilising IT tools like JIRA for design, library-of-standards, and client testing. New support structure is of value to speed up delivery and avoid unnecessary rework.

13:35 Simplicity in Technology Delivery for Clinical Trials

Sylwia Rumniak, Director GCS Study & Digital Solutions, Global Clinical Solutions, AstraZeneca Pharma Poland Sp zoo

Technology is playing a greater role in clinical trials. This presentation explores the role of the AZ Solution Implementation Lead who: drives technology solutions implementation in the most patient- and site-centric way to drive simplicity and choice for patients; reduces patient burden from a technology perspective, utilising early design planning approach; and contributes to streamlined processes, improved data quality, and ultimately, successful trial outcomes.

13:50 Adapting Spirometry—Decentralised Trials and AI Integration

Patrycja Wasikiewicz, Director Global Clinical Solutions, AstraZeneca

I will delve into the evolving landscape of spirometry in clinical trials, emphasising the shift towards decentralised trials and implementation of remote-coached spirometry. I will explore the necessary adjustments for sponsors to stay ahead, addressing the associated risks and benefits while highlighting the potential opportunities for improved patient engagement and data quality. I will discuss the utilisation of AI in spirometry, contributing to efficient and accurate clinical trial outcomes.

14:05 GlucoseReady: A Digital Platform to Integrate Connected Device Data, ePRO, and Adherence Support in Clinical Trials

Nicholas Alp, Chief Medical Officer, Clinical ink

Clinical ink's GlucoseReady™

GCP-compliant digital platform integrates high velocity data from multiple connected devices including GCM and BGM with dynamic ePRO triggering. Validated personality profiling is incorporated to predict adherence and provide personalized support and lifestyle standardization. Integrated tools allow real-time aggregate data visualization and monitoring to drive insights and actions focused on adherence and safety, thus accelerating clinical development.

14:30 Session Break

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

15:45 Close of Summit

MONDAY 28 OCTOBER

MONDAY AFTERNOON: USER GROUP & WORKSHOP

14:30 – 19:00 Innovation Day with IQVIA Technologies at SCOPE Europe

CO-SPEAKERS:
Kevin Landells, Vice President Patient Centered Technology Delivery, IQVIA Technologies
Stefan Dürr, Senior Director, Client Delivery, IQVIA Technologies
Petar Genov, Senior Director, Business Operations and Capabilities – Payments, IQVIA Technologies
Tim Reily, Vice President, Clinical Data Analytics, IQVIA Technologies
Alison Liddy, Senior Vice President, Patient and Site Centric Solutions, IQVIA
Clinical trial sponsors are invited to join IQVIA Technologies' digital product leaders and industry representatives for an afternoon of discussions, demos, and networking. IQVIA will share our vision to transform clinical operations, demonstrate our technologies that improve the patient, site, and sponsor journeys, and ask for your input on our roadmap for future product development. Innovation Day is complimentary and will be of interest to pharmaceutical executives or sites with roles in clinical operations, innovation, technology, finance, budgeting, data analytics, patient or site engagement, or strategic sourcing. IQVIA reserves the right to decline registrations for those not in these categories. For more information or to register **click here**.

17:30 – 19:00 The Path towards Sustainable Clinical Trials: How to Minimise Environmental Impact and Stay Ahead of Future Regulatory Requirements

INSTRUCTORS:
Fiona Adshead, Chair, Sustainable Healthcare Coalition
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Marisa Minetti, Patient Research Partner, Chiesi Group
Keith Moore, Programme Coordinator, Sustainable Healthcare Coalition
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond benefiting the environment, adopting sustainable practices is increasingly demanded by stakeholders and can significantly influence customer choices and talent acquisition. Perhaps more compelling are the growing regulatory pressures and expectations, including the Corporate Sustainability Reporting Directive (CSRD) and Task Force on Climate-related Financial Disclosures (TCFD) among others. This workshop will discuss the current hotspots of carbon emissions in clinical research, introduce a new clinical trial carbon footprint calculator for assessing current state, and suggest introductory reduction strategies. Whether you are in clinical trial design clin ops, procurement, innovation, sustainability, or resource management, this workshop is for you.

TUESDAY 29 OCTOBER

7:00 SCOPE Europe Fun Run/Walk Up the Magic Fountain Steps

Join SCOPE Europe's Coordinators for our Fun Run/Walk! All of us at Cambridge Healthtech Institute recognise the importance of integrating well-being and fitness into our work travel routines. This is an easygoing, informal running (or walking) event where we ascend the stairs of the iconic Magic Fountain. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! *Meet us in the front lobby at the InterContinental at 7 sharp!*

7:45 Registration and Morning Coffee

8:50 Organiser's Welcome Remarks

MASTERING PROVIDER SELECTION & VENDOR OVERSIGHT

8:55 Chairperson's Remarks

Tina Karunaratne, Founder and CEO, Karuna Integrated Clinical Services

9:00 Strategic Navigation for Clinical Trials in Mid-Size Biopharma—Insights from an Executive Director's Perspective

Estrella Garcia Alvarez, PhD, Director, Global Clinical Operations, R&D, Almirall SA
Complex trials strain mid-size pharma. Careful design involving all stakeholders is key to minimise risk and ensure study success.

9:25 Identifying Efficiencies and Improvement Opportunities in the Vendor Qualification Process

Zachary Smith, Senior Data Scientist, Tufts Center for the Study of Drug Development
Tufts CSDD convened a working group of sponsor and CRO companies to update and expand on previous benchmarks in the vendor qualification assessment process. Three separate surveys were used to collect data from sponsors and CROs, vendors, and clinical trial sites. Analysis of the survey results provides insights into the time and personnel investments required, as well as trends in how new technologies are being used in the VQA process.

9:50 Optimizing Clinical Operations: A Small Biotechnology 'Fit for Growth" Strategic Insourcing and Outsourcing Adaptive Framework

Oscar Alcantar, Director, Clinical Operations, Maze Therapeutics
A look into a small biotechnology "fit for growth" framework designed to optimize efficiency and scalability. We will explore how small biotech organizations can strategically balance functional insourcing and outsourcing to meet evolving needs across different stages of growth and clinical trial activities. The adaptive model addresses key considerations in personnel hiring, vendor selection and management to ensure seamless operations and maintain quality standards.

10:15 PANEL DISCUSSION: Choosing & Managing Your Partners and Vendors: Open Forum Discussion

Moderator: Liz Emmerson, Director of Clinical Operations, Clinical Operations, Blue Earth Therapeutics Ltd.
Hear from Expert Leaders and Seize the Opportunity to Ask Questions: A Panel Discussion and Town Hall Discussion on Choosing & Managing Partners and Vendors for Small & Mid-Sized Biopharma

10:53 Grand Opening Coffee Break in the Exhibit Hall

The SCOPE Europe Exhibit Hall is the best place to fuel up with a mid-morning coffee while visiting with our many exhibitors. Learn about what's new in the industry, connect with colleagues and vendors, and make some new friends.

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

13:35 Join Your Peers for a Networking Lunch in the Exhibit Hall

Take this opportunity to refresh and refuel with our Exhibit Hall lunch. Enjoy good food and even better conversation during our walk and talk luncheon.

14:35 Chairperson's Remarks

Tina Karunaratne, Founder and CEO, Karuna Integrated Clinical Services

14:40 Pioneering Trial Designs

Tina Karunaratne, Founder and CEO, Karuna Integrated Clinical Services
Clinical trials constitute the backbone of research and development for evaluating the safety and efficacy of novel interventions. Traditional trial designs have contributed to medical advancements; however, they often encounter challenges such as prolonged timelines, high costs, and limited generalisability. In response, researchers embrace trial designs that offer enhanced efficiency, flexibility, and patient-centricity. This presentation will review some innovative trial designs shaping the research landscape.

15:05 Strategies to Mitigate Vendor-Related Risks in Your First-in-Human Clinical Trials—Real Cases with Vendors Contracting

Dawid Lyzwa, Head of Clinical Development, JJP Biologics
Joanna Mysiak, Senior Project Manager, JJP Biologics
JJP Biologics, a small biopharma company focused on monoclonal antibodies research, emphasises mitigating vendor-related risks in clinical trials. We'll share best practices in vendor qualification, including due diligence, clear contracts, and

robust quality management systems. Additionally, we'll discuss risk-based vendor oversight and offer advice on preparing and comparing Requests for Proposals to ensure comprehensive and effective supplier bids.

15:35 How to Efficiently Work with Vendors—Now the Large Pharma Perspective—What Should You Take into Consideration While Growing with the Number of Trials and Vendors?

Natalia Tomkiewicz, Head of Study Delivery Management Global Clinical Operations, GSK

This presentation offers insights for clinical trial operations executives on efficiently managing vendors from a large pharma perspective. As the number of trials and vendors grows, key considerations include strategic vendor selection, scalable processes, and comprehensive risk management. Emphasising clear communication, robust contracts, and continuous monitoring, these strategies ensure operational efficiency, regulatory compliance, and sustained trial success.

16:00 PANEL DISCUSSION: Take-Home Strategies for Vendor Management

Moderator: Tomasz Kosieradzki, Owner & Principal Auditor, Kosieradzki.com; Individual Consultant

Speakers from this session will share lessons learned.

Panelists:

Dawid Lyzwa, Head of Clinical Development, JJP Biologics

Joanna Mysiak, Senior Project Manager, JJP Biologics

Natalia Tomkiewicz, Head of Study Delivery Management Global Clinical Operations, GSK

16:57 Reception in the Exhibit Hall with Beer, Wine, and Tapas

Wind down at the end of a busy session day with colleagues, beer, wine, and tapas. Have a drink with your favorite exhibitor and take a chance at winning a fabulous raffle prize (must be present to win)!

18:00 Close of Day

WEDNESDAY 30 OCTOBER

8:15 Registration and Morning Coffee

CASE STUDY: THE IMPORTANCE OF ALIGNMENT IN CLINICAL TRIAL DESIGN

8:45 Chairperson's Remarks

Lori Ellis, Head of Insights, BioSpace

8:50 Case Studies: Fast-Track Approaches to Accelerated Patient Care with the Anti-CRO

Meri Beckwith, Co-Founder, Lindus Health Ltd.

Fernando Osorio, Associate Vice President of Medical Affairs, Pharmanovia

In 2024, clinical research faces ongoing challenges despite scientific and technological progress. Misaligned incentives persist among sponsors and contract research organisations (CROs). This presentation explores innovative business models and trial designs that lead to stronger collaborations between sponsors and CROs, and ultimately, to better research outcomes.

9:15 Redefining eConsent: From Misconceptions to Clarity

Hilde Vanaken, Head EFGCP eConsent Initiative, EFGCP - European Forum for Good Clinical Practice

The non-profit European Forum GCP eConsent Initiative, comprised of 50 companies, has released a suite of global tools to address the misconceptions and lack of harmonization and insight about eConsent. Harmonized terminologies and study documents' requirements, insight in stakeholders' benefits and challenges, and a 5-step framework to design the right eConsent for a particular study and generate effective eConsent study data are some topics covered in this session.

UNDERSTANDING THE EU AI ACT: INSIGHTS FROM ALL STAKEHOLDERS IN CLINICAL TRIALS, FROM EMERGING TO LARGE PHARMA

9:40 PANEL DISCUSSION: The EU AI Act: Death Knell or Chance to Prove Value?

Moderator: Barnaby Pickering, Managing Editor, Citeline

The EU AI Act is poised to disrupt the European tech sector, raising compliance concerns for biotechs. Opinions are divided: some fear it will stifle innovation, while others believe it doesn't go far enough. This discussion will explore compliance steps, operational changes, long-term impacts, and strategies for de-risking the process, featuring insights from biotech industry leaders.

Panelists:

Ricardo Gaminha Pacheco, Strategic Partnering, Business Development & Licensing Director, Insilico Medicine

Firas Abdessalem, Head of GPV Signal, Risk & Oversight Digital Service Line, Sanofi

Christopher Hart, Partner, Co-Chair, Privacy and Data Security Group, Foley Hoag LLP

Gandolf Finke, PhD, Founder & Managing Director, Mika Health by Fosanis GmbH

Artemy Shumskiy, Investor, LongeVC

10:17 Coffee Break in the Exhibit Hall with Special Book Signing

More coffee, more exhibitors, more networking, and some delicious snacks. What's not to love?

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

12:10 Join Your Peers for a Networking Luncheon in the Exhibit Hall

Join us again for lunch in the Exhibit Hall. Last chance to visit with exhibitors you missed and to enter our final raffle!

NAVIGATE AND ENSURE SUCCESS IN YOUR CLINICAL TRIALS AS A SMALL BIOPHARMA COMPANY

13:10 Talk Title to be Announced

Lori Ellis, Head of Insights, BioSpace

13:15 Navigating the Complexities of Early-Phase Radiopharmaceutical Therapy (RPT) Clinical Trials

Nathaniel Scott, MPhys, MSc, MPE, Medical Physicist, Blue Earth Therapeutics

Radiopharmaceutical Therapy (RPT) is a rapidly expanding area of interest and its future success is highly dependent on the quality of clinical trials in this space. Early-phase RPT clinical trials require multifaceted site qualification as well as highly technical data collection for dosimetry analysis, involving complex imaging techniques. We propose a presentation on the complexities (and opportunities) that these types of study present from a sponsor's perspective.

13:40 Are You Prepared for a Regulatory Inspection from a Health Authority?

Sheri Lee, CEO, Principal Consultant, Premier Regulatory Consulting (PRC); Former National Program Expert, FDA

Sapna Shah, Head of Global Clinical Operations Americas, Telix Pharmaceuticals

The audience will be able to identify barriers to being inspection-ready, (i.e., staff not understanding regulatory requirements, not conducting a Gap assessment). The audience will understand strategies to implement to become inspection-ready. The audience will know how to use various tools to become inspection-ready.

14:05 Sponsored Presentation *(Opportunity Available)*

14:30 Session Break

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

15:45 Close of Summit

MONDAY 28 OCTOBER

MONDAY AFTERNOON: USER GROUP & WORKSHOP

14:30 – 19:00 Innovation Day with IQVIA Technologies at SCOPE Europe

CO-SPEAKERS:
Kevin Landells, Vice President Patient Centered Technology Delivery, IQVIA Technologies
Stefan Dürr, Senior Director, Client Delivery, IQVIA Technologies
Petar Genov, Senior Director, Business Operations and Capabilities – Payments, IQVIA Technologies
Tim Reily, Vice President, Clinical Data Analytics, IQVIA Technologies
Alison Liddy, Senior Vice President, Patient and Site Centric Solutions, IQVIA
Clinical trial sponsors are invited to join IQVIA Technologies' digital product leaders and industry representatives for an afternoon of discussions, demos, and networking. IQVIA will share our vision to transform clinical operations and ask for your input on our roadmap for future product development. Innovation Day will be of interest to pharmaceutical executives or sites with roles in clinical operations, innovation, technology, finance, budgeting, data analytics, patient or site engagement, or strategic sourcing. IQVIA reserves the right to decline registrations for those not in these categories. For more information or to register **click here**.

17:30 – 19:00 The Path towards Sustainable Clinical Trials: How to Minimise Environmental Impact and Stay Ahead of Future Regulatory Requirements

INSTRUCTORS:
Fiona Adshead, Chair, Sustainable Healthcare Coalition
Thierry Escudier, Portfolio Lead, Pistoia Alliance
Marisa Minetti, Patient Research Partner, Chiesi Group
Keith Moore, Programme Coordinator, Sustainable Healthcare Coalition
Developing frameworks to define and manage sustainability risks, and effective guidelines to reduce the carbon footprint of clinical trial operations is a collaborative effort. Beyond benefiting the environment, adopting sustainable practices is increasingly demanded by stakeholders and can significantly influence customer choices and talent acquisition. Perhaps more compelling are the growing regulatory pressures and expectations, including the Corporate Sustainability Reporting Directive (CSRD) and Task Force on Climate-related Financial Disclosures (TCFD) among others. This workshop will discuss the current hotspots of carbon emissions in clinical research, introduce a new clinical trial carbon footprint calculator for assessing current state, and suggest introductory reduction strategies. Whether you are in clinical trial design clin ops, procurement, innovation, sustainability, or resource management, this workshop is for you.

TUESDAY 29 OCTOBER

7:00 SCOPE Europe Fun Run/Walk Up the Magic Fountain Steps

Join SCOPE Europe's Coordinators for our Fun Run/Walk! All of us at Cambridge Healthtech Institute recognise the importance of integrating well-being and fitness into our work travel routines. This is an easygoing, informal running (or walking) event where we ascend the stairs of the iconic Magic Fountain. No time chips, running bibs, or energy bars—just a laid-back opportunity for a small group to start the day on a positive note. You can sprint, run, jog, walk, jog-and-talk, or walk-and-talk—the goal is to get up and get moving! *Meet us in the front lobby at the InterContinental at 7 sharp!*

7:45 Registration and Morning Coffee

8:50 Organiser's Welcome Remarks

LEVERAGING QTLs AND KRIs FOR CLINICAL RISK DETECTION

8:55 Chairperson's Remarks *(Sponsorship Opportunity Available)*

9:00 Are Your KRIs Detecting Issues Early Enough? How Simple Definition Changes Can Impact Whether Your KRIs Are Leading or Lagging

Keith Dorricott, Director, Dorricott Metrics & Process Improvement Ltd.

Monitoring of risks/issues using metrics (KRIs/QTLs) in RBQM is fundamental to the approach and expectations of regulators, but without critical thinking, signals may be detected too late to change the course of the study. We will explore the definitions of leading and lagging indicators, look at how the KRI/QTL metric definition impacts how early signals are detected, and why it is important to have the end in mind.

9:25 Applying Critical Thinking to QTL and KRI Definitions: Lagging QTLs and Composite KRIs

Jenny Christal, PhD, Associate Director, Risk Based Quality Management, Jazz Pharmaceuticals

We will build on the concepts of lagging and leading indicators, and consider how each can add value to a cohesive approach to QTL management. With practical worked examples, we aim to illustrate how careful and holistic QTL/KRI definition can help to protect the most critical aspects of your study.

9:50 How RBQM Creates Trust between Sponsors and CROs

Duncan Hall, CEO, Triumph Research Intelligence Ltd.

We'll be tackling some of your most-asked questions and concerns including the big communication and trust challenges we see from hundreds of projects; what do the ultimate customers (regulatory authorities) want to see; what is RBQM, what are its challenges, and how can it help; and how technology makes all the difference.

10:15 PANEL DISCUSSION: The Opportunities and Challenges of Outsourcing RBQM

Moderator: Keith Dorricott, Director, Dorricott Metrics & Process Improvement Ltd.

Many organisations choose to outsource all or part of their RBQM to a CRO or vendor. How do you decide what to outsource? How do you know if the CRO/vendor will meet your requirements? How much input should the sponsor have? What are the best practices for oversight? This discussion will outline a variety of perspectives on the subject.

Panelists:
Natalia Buchneva, Risk Management Lead, Clinical Data & Innovation, UCB
Amy Kroeplin, MPH, Senior Director, Centralized Monitoring, PPD
Linda White, Associate Director, Risk-Based Quality Management, Jazz Pharmaceuticals
Rachel Oakley, Associate Director, GD Quality (GCP), Global Development Quality Governance & Oversight (GDQGO), Regeneron Pharmaceuticals

10:40 The Real Cost of Delays in Drug Development and the Role of RBQM and QbD

Johann Proeve, PhD, Chief Scientific Officer, Cyntegrity

Discover how the recent Tufts CSDD study aligns with the approach Cyntegrity embedded in their Clinical Monitoring Cost Savings Calculator, launched earlier this year. The study challenges the outdated $4 million/day delay cost, validating how integrated RBQM and QbD strategies can save up to $2.8 million per study. These strategies improve trial efficiency and ensure more effective cost management, making them essential tools in today's clinical research landscape.

10:53 Grand Opening Coffee Break in the Exhibit Hall

The SCOPE Europe Exhibit Hall is the best place to fuel up with a mid-morning coffee while visiting with our many exhibitors. Learn about what's new in the industry, connect with colleagues and vendors, and make some new friends.

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

13:35 Join Your Peers for a Networking Lunch in the Exhibit Hall

Take this opportunity to refresh and refuel with our Exhibit Hall lunch. Enjoy good food and even better conversation during our walk and talk luncheon.

RBQM IN A CHANGING REGULATORY LANDSCAPE

14:35 Chairperson's Remarks

Marcin Makowski, PhD, Head, Centralized Monitoring & Data Analytics, GlaxoSmithKline

14:40 In Pursuit of Adoption: Risk-Based Quality Management and ICH E6 R3

Arlene Lee, Director, Product Management, Data Quality and Risk Management Solutions, Medidata
Nicole Stansbury, Senior Vice President, Global Clinical Operations, Premier Research; Co-Lead, Risk-Based Monitoring Working Group, Association of Clinical Research Organizations (ACRO)
Madeleine Whitehead, Process Excellence Leader, Product Development Quality Solutions, Roche Products Ltd.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH) renovation of Good Clinical Practice

(GCP) represents a shift in the conduct of clinical research from a one-size-fits-all approach to a more pro-active, risk-based approach. After soliciting direct feedback from our respective member companies, ACRO and TransCelerate have developed a set of tools to support the implementation of a strong foundation for quality in clinical development.

15:05 Harnessing ML and Statistics for Smarter Risk-Based Quality Management

Laura Trotta, Vice President, Research Operations and Statistical Innovation, CluePoints SA

This session illustrates the value of Machine Learning and advanced statistics in enabling a more efficient detection and mitigation of risks in clinical trials. Models, along with the assessment of their value benefits, are discussed. Experience in developing and applying those models in more than 1600 trials is shared with the community.

15:30 New GCP: What to Prepare For

Natalia Buchneva, Risk Management Lead, Clinical Data & Innovation, UCB

Revision 3 of ICH E6 R3 is an important change for the clinical trial industry, and it is important to highlight the changes and upcoming new ways of working. Sponsors, investigators, CRO representatives, and clinical vendors will gain an understanding of the new regulatory landscape for clinical trial conduct, as well as calibrate processes to align with the release of ICH E6 R3.

15:55 Challenges in SDV & SDR Methodology: Introducing a Technical Solution for Flexible Sampling of SDV & SDR Activity

Amy Kroeplin, Senior Director Centralized Monitoring, Thermo Fisher Scientific

Reduced source document verification (SDV) and review (SDR) approaches differ widely across the industry. Despite reduced methods being recognized as an acceptable approach, there are still challenges with adoption. As a result, there is a high degree of variation between sponsors, and CROs. This presentation will consider the complementary processes of SDV and SDR and introduce a technical solution for providing flexibility, traceability and sampling for management of SDV & SDR activity.

16:32 PANEL DISCUSSION: Senior Clinical Trial Leaders Discuss and Debate the Impact of ICH E6 R3, the Expected Challenges, and the Opportunities

Moderator: Patricia Leuchten, Founder & CEO, Diligent Pharma

After much anticipation, ICH E6 R3 will be released in the fall of 2024. In this panel, quantitative and qualitative data (gathered in an industry research study by WCG Avoca) on ICH E6 R3 implementation will serve as a catalyst for discussion among senior leaders. The panel will cover key proposed changes and how they will impact clinical trial execution in terms of challenges with implementation and opportunities for success.

Panelists:
Solomon Babani, CEO, Crovelis
Sandy Smith, Senior Vice President, Clinical Solutions & Strategic Partnering, WCG Clinical

16:57 Reception in the Exhibit Hall with Beer, Wine, and Tapas

Wind down at the end of a busy session day with colleagues, beer, wine, and tapas. Have a drink with your favorite exhibitor and take a chance at winning a fabulous raffle prize (must be present to win)!

18:00 Close of Day

WEDNESDAY 30 OCTOBER

8:15 Registration and Morning Coffee

INTEGRATING RISK-BASED DATA MANAGEMENT (RBDM)

8:45 Chairperson's Remarks *(Sponsorship Opportunity Available)*

8:50 Accelerating Open Source Initiatives in Clinical Trials: 30k Insights

Pooja Chavan, Clinical Program Manager, Oncology, Gilead

In recent years, collaboration within the biotech and pharma sectors has significantly surged. In this presentation, we'll examine the role of open-source tools in fostering collaboration, transparency, and standardisation across industry. We'll also provide an overview of current open-source initiatives in the clinical trial domain, including safety monitoring, data standardisation, and a newly-released open source framework—containing 30k lines of code—for Risk-Based Quality Management (RBQM).

9:15 Achieving the Promise of RBQM

Sharma Ramanathan Deva Devesa, Principal, ZS Associates, Inc.

In the evolving field of clinical trials, Risk-Based Quality Management (RBQM) is transforming drug development. This presentation highlights Roche's creation and implementation of an RBQM Center of Excellence (CoE) with a robust analytical and technology ecosystem. RBQM enhances speed, quality, and cost-efficiency. The industry has seen a 28% drop in protocol deviations, a 38% reduction in monitoring time, and 15-25% cost savings. Discover Roche's journey with RBQM and its impact on clinical trials.

9:40 Using Audit Trail Analytics as a Tool to Evaluate and Optimize Query Management

Kris Lauwers, Manager, Data Science, Advanced Insights, Business Growth, Innovation & Advocacy, Janssen Research & Development

Ensuring accuracy, completeness, and reliability of clinical data is integral to the success of clinical trials. In this session we present insights on the query activities happening on the critical path prior to database lock. Delving into audit trail information unveiled patterns of queries on ageing data with insights into various user roles. We discuss these insights in light of the risk based approach to quality management described in ICH_E6.

10:05 Sponsored Presentation *(Opportunity Available)*

10:17 Coffee Break in the Exhibit Hall with Special Book Signing

More coffee, more exhibitors, more networking, and some delicious snacks. What's not to love?

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

12:10 Join Your Peers for a Networking Luncheon in the Exhibit Hall

Join us again for lunch in the Exhibit Hall. Last chance to visit with exhibitors you missed and to enter our final raffle!

RBQM ADOPTION AND OPERATIONALISATION

13:10 Chairperson's Remarks *(Sponsorship Opportunity Available)*

13:15 Assessment of Risk-Based Quality Management Adoption in Clinical Trials

Maria Florez, Research Consultant, Tufts Center for the Study of Drug Development

This talk will focus on a new comprehensive approach to assessing RBQM adoption; recent data on current levels of RBQM adoption among industry sponsors and CROs; recent data on expected future levels of use of RBQM components; perceived challenges associated with the implementation of RBQM components; and opportunities and benefits of RBQM implementation. We will discuss implications of these findings for the future of RBQM.

13:40 Case Study: Non-Interventional Dry-Run Study Implementing Full-Scope RBQM Methodology for Risk Mitigation

Magda Piskorska, Central Monitoring Lead, GlaxoSmithKline

The dry-run study serves as a preparatory phase for high-risk projects. This non-interventional case study, enrolling 1% of the target population for the efficacy study, aimed to test processes such as eCOA and sample collection. A comprehensive RBQM methodology was implemented. This approach not only enhanced control over critical data collection but also facilitated swift identification and management of both predefined and newly emerging risks.

14:05 Sponsored Presentation *(Opportunity Available)*

14:30 Session Break

PLENARY KEYNOTE SESSION

For a detailed agenda, please visit pages 4-5.

15:45 Close of Summit

CONFERENCE PRICING INDIVIDUAL REGISTRATION	Pharma-Biotech, Medical Device Company	CRO-Vendor, Tech-Consultancy, Service Provider	Government, Academic, Site-Hospital
Includes access to all conferences			
Early Bird Registration until 12 July 2024	€1799	€1999	€999
Standard Registration and Onsite	€2199	€2499	€1299

GROUP REGISTRATION	Pharma-Biotech, Medical Device Company	CRO-Vendor, Tech-Consultancy, Service Provider	Government, Academic, Site-Hospital
Includes access to all conferences.			
Early Bird Registration until 12 July 2024	€1349	€1499	€749
Standard Registration and Onsite	€1649	€1849	€949

GROUP DISCOUNTS

HAVE YOUR COLLEAGUES OR ENTIRE TEAM ATTEND!

Purchase a full-price registration and participants from the same organisation will receive a 25% discount when registering.

For more information on group discounts contact: Melissa Dolen (mdolen@healthtech.com) at +1 781-972-5418

21% VAT will be added to each registration

FOR ADDITIONAL REGISTRATION OPTIONS, VISIT OUR EVENT WEBSITE:

ScopeSummitEurope.com

Use Keycode SCOE PDF when registering!

NETWORKING

Join the conversation before, during, and after SCOPE Europe

Join SCOPE LinkedIn Group »

Join ClinEco, our Global Clinical Trials Ecosystem and Marketplace »

Subscribe to SCOPE of Things Podcast »

For group discount information, please contact

Melissa Dolen | Sr. Account Manager | +1 781-972-5418 | mdolen@healthtech.com

Please refer to the Registration Code below:

Cambridge HEALTHTECH Institute
A Division of Cambridge Innovation Institute

250 First Avenue, Suite 300
Needham, MA 02494
Healthtech.com
Fax: 781-972-5425