

CHI's Second Annual

SCOPE

EUROPE

SUMMIT FOR CLINICAL OPS EXECUTIVES

17-18 September 2019

Barcelona, Spain

CROWNE PLAZA
BARCELONA-FIRA CENTER

Event Features

- » 2 Plenary keynote sessions
- » Senior level executives from pharma, biotech, gov't, and academia
- » Interactive breakout discussion groups & panel discussions
- » Conference-hop between five concurrent meetings
- » Exclusive exhibits and networking
- » Community luncheon on both days

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Conference Programs



**Analytics-Driven
Feasibility, Site Selection
and Study Activation**



**Patient-Centric
Enrollment
Planning and
Engagement**



**Risk-Based
Monitoring
Europe**



**Digitalization
of Clinical
Trials**



**Budgeting, Resource
Management, and
Outsourcing for
Clinical Trials**

Featuring



Bert Hartog, PhD
Senior Director, Clinical
Innovation, Janssen
Pharmaceutica N.V.



Greg Hersch, PhD
Head, Innovation,
Global Development
Operation, Novartis



Caroline Feys, MSc, MBA,
Associate Director,
Janssen Clinical Innovation
Clinical Innovation



Raj Pallapothu
mHealth Global Business
Lead, Bayer Pharmaceuticals;
mHealth Global Advocate



Koen Kas, MD
Founder & CEO,
Healthskouts; Partner,
HealthStartup.eu



Ronald Dorenbos, PhD
Head, Innovation Management &
Scouting, Innovation & Technology
Science, Takeda



Bettina Ryll, MD, PhD
Founder, Melanoma Patient
Network Europe



Klaus Peter Kammerer, MD
Global Head, Vendor &
Quality Management,
Knowledge Management,
Boehringer Ingelheim



Elsbeth Carnan
Vice President, Supplier
Performance Management, Global
Clinical Operations, EMD Serono



Mishal Patel, PhD
Head, Health Informatics,
AstraZeneca

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SUMMIT FOR CLINICAL OPS EXECUTIVES

EUROPE

Conference At-a-Glance
 17-18 September 2019
 Barcelona, Spain

CROWNE PLAZA
 BARCELONA-FIRA CENTER

<p>Analytics-Driven Feasibility, Site Selection and Study Activation</p> <p>Improving Protocol Development, Global Site Selection, Feasibility and Site Management</p>	<p>Patient-Centric Enrollment Planning and Engagement</p> <p>Utilizing New Technology, Analytics and Outreach to Improve Patient Recruitment</p>	<p>Risk-Based Monitoring Europe</p> <p>Integrating Quality into Clinical Trials to Ensure Effective Monitoring</p>	<p>Digitalization of Clinical Trials</p> <p>Digital Technology, AI, Real World Data and Advanced Analytics for Next-Gen Trials</p>	<p>Budgeting, Resource Management, and Outsourcing for Clinical Trials</p> <p>Maximizing Trial Budgets and Resources to Drive Outsourcing Strategy and Quality Clinical Trials</p>
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<p>Shared Opening Plenary Keynote What Does Patient-Centric Drug Development and Trials Mean and How Do We Achieve It?</p>					
TUESDAY	Protocol Development, Global Site Selection, Feasibility and Site Management	Enrollment Planning and Patient Recruitment	Clinical Trial Quality and Risk Management	Clinical IT Strategy and Governance	Functional and Full-Service Outsourcing and Partnerships
	Breakout Discussion Groups				
	Reception				
WEDNESDAY	Improving Site-Study Activation and Performance	Patient Engagement, Enrollment and Retention through Communities and Tech	Implementing Risk-Based Monitoring (RBM)	Clinical Data Technology and Integration	Forecasting and Maximizing Clinical Trial Resources in Each Function and Category
	Breakout Discussion Groups				
	<p>Shared Closing Plenary Keynote & European Innovation Awards Clinical Research News European Innovations Awards & Clinical Trial Technology and Data Utilization: Utilizing Big Data, Artificial Intelligence, and Real-World Data</p>				

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Plenary Keynote Presentations

Tuesday, 17 September

7:30 - 17:00 Registration Open

8:00 - 8:35 Morning Coffee

SHARED OPENING PLENARY KEYNOTE: EVALUATING NEW TECH, CONNECTING DIRECTLY WITH PATIENTS, AND UNDERSTANDING DATA OWNERSHIP

8:35 Organizer's Welcome

Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)



8:40 Chairperson's Opening Remarks: Novel Tech and Data - First and Foremost: Think about the Patient

Bert Hartog, PhD, Senior Director, Clinical Innovation, Janssen Pharmaceutica N.V.

The pace of new technology becoming available is dizzying. How does one minimise risk to trials and select what tech to use and when a supplier is ready for use at scale? What is the impact of using tech on patients' experience participating in a trial, is friction-less tech becoming reality? Tech generates new data, patients have the right to own their data, but where does this leave other stakeholders' interests? Does Pascal's principle from physics apply and can a new equilibrium be established?

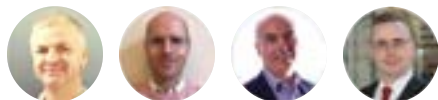


8:50 Customer-Focused Research and Healthcare: A New Breed of Digital Health Tools to Deploy in Tomorrow's Trials

Koen Kas, MD, Founder & CEO, Healthskouts; Partner, HealthStartup.eu

This talk will introduce Real World Data you've never considered of value or that you didn't trust. Emerging digital health tools enable accessing and capturing these data for the first time ever. How can you use them to spice up your clinical trial design in order to obtain unique selling points for emerging drugs? What are ways to really move into Personalised Medicine and get financially rewarded for it? Welcome to a fresh look into clinical trial design and execution with concrete examples of a "TripAdvisor" toolbox to apply immediately.

9:20 INTERACTIVE PANEL DISCUSSION: Patient Data Ownership and Privacy in Clinical Research Today



Moderator: Paul Drake, PhD, Chief Information Security Officer (CISO) & Chief Privacy Officer, Signant Health

Panelists:

Bert Hartog, PhD, Senior Director, Clinical Innovation, Janssen Pharmaceutica N.V.

Koen Kas, MD, Founder & CEO, Healthskouts; Partner, HealthStartup

Greg Hersch, PhD, Head, Innovation, Global Development Operation, Novartis
Pharmaceutical companies are increasingly focused on a direct connection with patients at scale. With the advent of GDPR as well as broad concerns around privacy and data ownership globally, having the voice of the patient is a central theme. Control of the data and ongoing usage of the data becomes an important topic of discussion as companies focus on a more targeted and direct involvement with patients. Topics to be discussed:

- Who owns the patient data in clinical research?
- Do the patients get longitudinal choice and control of ongoing use of their data?
- What are the opportunities in a consented life-long relationship with patients, via a digital twin?

10:00 Grand Opening Coffee Break with Exhibit Viewing

Wednesday, 18 September

CLINICAL RESEARCH NEWS EUROPEAN INNOVATIONS AWARDS & SHARED CLOSING PLENARY KEYNOTE: OPERATIONALISING DIGITAL TECH, PATIENT- CENTRIC AND VIRTUAL TRIALS



14:10 Clinical Research News European Innovations Awards

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

The Clinical Research News European Innovation Awards recognizes outstanding examples of applied strategic innovation—partnerships, deployments, and collaborations—that manifestly improve the clinical trial process. Clinical Research News is seeking submissions to its European Innovations Awards. Click below for more information: www.clinicalinformaticsnews.com/BestPracticeAwards/



14:15 Chairperson's Remarks

Denis McMillan, Vice President, Solutions Consulting – CROs, Strategic Feasibility, PAREXEL



14:20 Offering Context: Re-Defining Digital Recruitment and Patient Outreach

Greg Hersch, PhD, Head, Innovation, Global Development Operation, Novartis



14:30 Achieving Next-Gen Consumer Health and Research through Patient Engagement and Digital Tech

Raj Pallapothu, mHealth Global Business Lead, Bayer Pharmaceuticals; mHealth Global Advocate

By facilitating patient recruitment, consent, engagement and involvement in the clinical research process, mHealth technology is disrupting consumer health and clinical trials simultaneously. This presentation will cover 1. Emergence of wearables, sensors, bio-markers in clinical trials, 2. Patient adaptation, challenges at site level, 3. Data transfers, privacy, portability growing need and associated challenges, 4. Operational challenges, 5. Value proposition, and 6. Market trends.



14:45 Virtual Trials: Overcoming the Barriers to Patient Centricity

Caroline Feys, MSc, MBA, Associate Director, Janssen Clinical Innovation

Virtual or site-less trials has become a new buzz-word. Based on the state-of-the-art, we will explore the components of virtual trials that are new and components which have been used for a while but are now embedded in the virtual trial business architecture. Besides highlighting the opportunities and the challenges, we will emphasize the benefits for the different stakeholders in the health ecosystem, based on concrete and already accomplished examples. The two presentation anchor points are how virtual trials can improve patient centricity and the role of real-world data. Given that we continue facing challenges with recruitment, enrollment, site activation, patient retention, etc., discussions around novel trial conduct are essential.

15:20 Closing Remarks

Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)



Analytics-Driven Feasibility, Site Selection and Study Activation

Improving Protocol Development, Global Site Selection, Feasibility and Site Management

Tuesday, 17 September

7:30 - 17:00 Registration Open

8:00 Morning Coffee

8:35 Opening Plenary Keynotes

See page 3 for details.

10:00 Grand Opening Coffee Break in the Exhibit Hall

PATIENT-CENTRIC FEASIBILITY AND EVIDENCE-DRIVEN SITE SELECTION: REAL-WORLD EXAMPLES FOR IMPROVING PROTOCOLS AND DEVELOPMENT PLANS

10:50 Chairperson's Opening Remarks

Marcy Kravet, Head, Operational Design Center (ODC), Global Clinical Operations, Merck KGaA

10:55 OPENING CO-PRESENTATION: Shifting the Paradigm in Building Evidence-Driven Site Profiles for Clinical Trial Participation

Oriol Serra, MBA, Head, Site Intelligence & Site Selection, Study Optimization, Pfizer

Jonathan Crowther, Associate Director, Site Intelligence & Feasibility Lead, Study Optimization, Pfizer

Can we challenge the status quo to effectively develop predictive algorithms to build an ideal site profile based on key indicators on performance, start up, quality and competitive intelligence? This presentation will provide a real-world demonstration on how a new methodology can improve transparency and collaborative efforts to optimize study execution. We have developed an innovative approach that aims to change the paradigm in site selection.

11:20 CASE STUDY CO-PRESENTATION:

Patient-Centric Feasibility: Integrating Patient Insights in Protocol Design, Operational Risk Assessment and Regulatory Discussion

Sponsored by



Daoying Hu, PhD, MBA, Associate Director, Strategic Feasibility, Global Clinical Sciences and Operations, UCB BioSciences, Inc.

Camilla Ramdeen, PhD, Director, Strategic Feasibility, PAREXEL

Data-driven feasibility is a vital component of implementing a successful clinical trial. Whilst much attention is given to big data and the role of RWD in trial planning, we believe strongly that evaluating from a patient perspective is crucial in understanding trial challenges and building a deliverable operational plan. We worked to integrate patient insights upfront and will present a case study to discuss multi-faceted feasibility including a patient-centric approach deployed to support study design, operational risk assessment and influence regulatory decision.

11:45 Forces of Evolution: Can the Industry Change its Approach to Protocol Development?

Sponsored by



Bob Brindle, Venture Lead, Life Sciences, Cognizant

We have seen few meaningful changes in approaches to protocol development in the last 20-30 years, despite huge advances in science and technology. Research demonstrates almost no impact on measurable outcomes, including protocol complexity and avoidable amendments. Join this session for an analysis of current protocol development practices across the industry and a discussion on protocol evolution: Are there constraints that will always hold us back or is there a path to a better future?

12:10 The #1 Way to Make Clinical Trials Patient-Centric: Ask Patients What They Want

Mary Elmer, MSN, Director, Patient, Caregiver and Consumer Experience, Merck

While the clinical trials industry talks more about being patient-centric, the number one way to be truly patient-focused is to listen to what

patients want. At TransCelerate we are providing sponsors with free tools to understand the patient experience during a clinical trial. The Patient Protocol Engagement Toolkit (P-PET) provides a framework for how sponsors can work with patients to design protocols centered around the patient. The Study Participant Feedback Questionnaire (SPFQ) asks participants about their experience at the start, middle, and end of their participation in the trial. The questionnaire was created following the FDA's Clinical Outcomes Assessment development methodology and allows sponsors to take immediate action to update their clinical trial based on participant feedback.

12:35 Lunch in the Exhibit Hall (Community Networking)

EFFICIENT SITE SELECTION & START-UP PROCESS: NEW EU CLINICAL TRIALS DIRECTIVE (EU-CTR), OPERATIONAL DESIGN CENTER (ODC), & EARLY PATIENT INSIGHTS

13:55 Chairperson's Remarks

Mary Elmer, MSN, Director, Patient, Caregiver and Consumer Experience, Merck

14:00 New EU-Clinical Trials Regulation: Industry Preparation via Pilot Procedures

Thorsten Ruppert, MD, Senior Manager, Research, Development and Innovation, Association of Research-Based Pharmaceutical Companies (vfa)

The presentation will provide an overview to the topic and problems with the actual EU Clinical Trials Directive (EU-CTR). The pilots in different European member states enable sponsors of clinical trials to test the status of their preparation for the new authorization system in Europe. The presentation will also show details from the experience of the pharmaceutical industry, share insight into the status of the pilot project in Germany, and will address the status of industry preparation for the new European authorization system for clinical trials. This will enable an in-depth discussion on the overall status in Europe.

14:25 CO-PRESENTATION: Strengthening Control over Clinical and Financial Outcomes through an Operational Design Center (ODC)

Marcy Kravet, Head, Operational Design Center (ODC), Global Clinical Operations, Merck KGaA

Marc Philipp, MBA, Partner, Managing Director, Pharma & Life Sciences, Accenture GmbH

With its new Operational Design Center (ODC), Merck KGaA found a formula for success in building and embedding new, data-driven capabilities into established ways of working – in a bootstrapped approach enabled by smart external partnerships. The ODC provides clin ops insights to enrich Merck's study designs. In the fully outsourced model, the ODC improves transparency on protocol designs' decisions impacting financial and performance metrics, enabled by application of advanced analytics. The ODC provides data and insights to teams and development leaders, strengthening decision-making on the trade-offs between time, cost and quality of clinical research.

14:50 Starting Off Right: Driving an Efficient Site Selection & Start-Up Process

Sponsored by



Chibby Ebhogiaye, Head, Feasibility Services, Solution Adoption Center, IQVIA

This session will explore how standardized profiles and enrollment forecasts, based on performance metrics, are driving the start-up process from feasibility through to site enrollment, by increasing the accuracy of study planning and drastically reducing start up timelines. This session demonstrates how analytics derived from feasibility assessments and enrollment benchmarks can be used throughout the site start-up process. The unique selling proposition and differentiator is the emphasis (and reliance) on feasibility, enrollment metrics and active site engagement. A comprehensive overview and understanding of the pitfalls and misconceptions that should be avoided in order to enable and implement an efficient site selection and start-up process.

**15:15 Who's Listening to the Patient? Building Insights into Clinical Development Plans and Protocols**

Sharon Allin, Sr Manager, Feasibility, Enrollment & Retention Optimisation, Global Clinical Operations, Biogen

Over the years clinical development programs have been developed with great input and insights from pharma companies, expert medical advisory boards and regulators. However, a key stakeholder is missing from this list: the patient. Over the last few years the tide has changed somewhat and patients are now being asked what is important to them, and the industry is listening. In this session Narinder will review opportunities to gain insights from patients (and their families/caregivers) and share how these have been built into clinical development plans or protocols.

15:30 Refreshment Break in the Exhibit Hall

BREAKOUT DISCUSSION GROUPS

16:10 Find Your Table and Meet Your Moderator

16:15 Interactive Breakout Discussion Groups (Session #1)

See pages 15-17 for details.

17:00 Networking Reception in the Exhibit Hall

18:00 End of Day

Wednesday, 18 September

8:00 Morning Coffee

UTILIZING EHR/RWD TO ENHANCE PROTOCOL FEASIBILITY, SITE SELECTION AND PATIENT RECRUITMENT: HOSPITAL-SPONSOR COLLABORATIONS

8:30 Chairperson's Remarks

Marc Philipp, MBA, Partner, Managing Director, Pharma & Life Sciences, Accenture GmbH

8:35 Federated EHR Platform Technology: Evidence of Enhancing Site Selection and Patient Recruitment

Mats Sundgren, PhD, Director, Health Informatics, Advanced Analytic Center - Global Medicine Development, AstraZeneca

Capabilities of new health data-collection/re-use technologies including EHRs will have a huge impact to support clinical research and trial execution over the next years. The foundation of federated EHR platform technology is here, processes are in place and regulators are supportive. The technology is disruptive to the current Business Models by collaborating directly with HCOs. Results from two service providers and hospital networks will be presented in various impact areas ranging from EHR-enabled study design, site selection and recruitment.

9:00 CO-PRESENTATION: EHR/RWD Platforms Lead to Strategic Data-Driven Partnerships between Hospitals and Sponsors

Danny Hasselbaink, PhD, Associate Director, Global Feasibility Lead, Feasibility Center of Excellence, Janssen Biologics B.V.

Hospital Presenter to be Announced

Secure, GDPR compliant and innovative EHR/RWD platforms, leveraging federated data management, enable the re-use of EHR data for clinical research. During this presentation, a case study will be presented illustrating these new data-driven partnerships for protocol feasibility and recruitment. Benefits for both the sponsor and the hospital partners will be presented. For example: for sponsor companies, these platforms can be complementary to traditional feasibility approaches. At the hospitals,

clinicians can use RWD/EHR platforms to support research studies and re-use the care data for insights into treatments and outcomes for their patient populations.

9:25 Reducing the Administrative Burden on Sites

Larissa Comis, Product Lead, Shared Investigator Platform, Life Sciences Products & Platforms, Cognizant

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Every sponsor wants to make life easier for investigators, but what are the initiatives that are delivering measurable benefits today? This session will share the practices that are truly making a difference. Use cases of solutions that have proven to reduce investigator frustration, burnout, and drop-out will be explored.

9:50 Coffee Break in the Exhibit Hall

DATA MONITORING COMMITTEES, ACCURATE COUNTRY/SITE SELECTION, RELIABLE FEASIBILITY & BIOMARKER-DRIVEN TRIALS

10:35 Keeping Pace: How Data Monitoring Committee Identification Can Evolve to Support Current Clinical Trial Demands

Ana Herradon, Associate Director, Site Monitoring Manager and Regional Clinical Operations, Iberia, Bristol-Myers Squibb

The increasing number and complexity of clinical trials has resulted in an increasing need for independent Data Monitoring Committees (DMC). However, the number and availability of qualified candidates, coupled with a lack of cultivation of new generation DMC candidates has resulted in few available DMC candidates. This presentation will share the results of a TransCelerate initiative which collaborated with and built on existing CTTI DMC assets and expert network recommendations. Specifically discussed will be a future concept for a DMC Registry as well as a proposed DMC apprenticeship model.

11:00 How to Assess: Is Your Clinical Trial Attractive for Patients in this Country

Maya Zlatanova, Co-Founder, FindMeCure Foundation; Partner, International Alliance of Patients' Organizations & ACRES

We often speak about the country as site selection and focus so much on identifying the best set of sites that have both historical data on performing clinical trials and access to patients. Reality shows that where clinical research experience makes the sponsor and CROs work easier with the site, this does not ensure patients are on board in time. Why? Because at the end of the day, it's the patient's decision to participate or not. So how can we leverage data to understand what patients want and need, and improve our decision-making process on-the-go? Tricks and hacks how you can predict whether you might face difficulties with patient recruitment while selecting countries and sites and how to see further opportunities to improve patient engagement and plan better budget allocation (more sites or patient recruitment activities or both?).

11:25 CO-PRESENTATION: It Shouldn't Be This Hard: Overcoming Barriers of Delivering Reliable Feasibility and Commercial Research

Tanya Turgoose, Industry Operations Manager, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre

Matt Cooper, PhD, Director, Business Operations, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre

Efficient and effective delivery of research is imperative for all stakeholders, especially patients. During setup and delivery, issues are often encountered; we discuss how we overcame these using existing resources and infrastructure, to deliver the trial successfully.



11:50 SOPHiA Trial Match: Leverage SOPHiA's Clinical Research Community to Improve Trial Performance

Esteban Czwan, Senior Vice President, Clinical Trials Business Area, SOPHiA GENETICS

Of the challenges faced in trial planning and execution, accurate sites selection and enrollment are still major bottlenecks for the industry. SOPHiA, the AI empowering Data-Driven Medicine, has analyzed over 330,000 genomic profiles to date ... one every four minutes! SOPHiA's Clinical Research Community includes institutions that analyze a patient's genomic profiles and can now match them to ongoing biomarker-driven clinical trials.

12:15 Lunch in the Exhibit Hall (*Community Networking*)

13:25 Transition to Breakouts & Keynotes

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BREAKOUT DISCUSSION GROUPS

13:35 Find Your Table and Meet Your Moderator

13:40 Interactive Breakout Discussion Groups (Session #2)

See pages 15-17 for details.

14:10 Clinical Research News' European Innovations Awards & Closing Plenary Keynotes

See page 3 for details.

15:25 Close of Conference



Patient-Centric Enrollment Planning and Engagement

Utilizing New Technology, Analytics and Outreach to Improve Patient Recruitment

Tuesday, 17 September

7:30 - 17:00 Registration Open

8:00 Morning Coffee

8:35 Opening Plenary Keynotes

See page 3 for details.

10:00 Grand Opening Coffee Break in the Exhibit Hall

ACHIEVING PATIENT-CENTRIC TRIALS: PATIENT INSIGHTS, INTERACTIVE TECH & BROADER COMMUNITY ENGAGEMENT

10:50 Chairperson's Opening Remarks

Mark Summers, President, Patient Engagement, WCG

10:55 CASE STUDY: Look Who's Talking – Patients!

Bert Hartog, PhD, Senior Director, Clinical Innovation, Janssen Pharmaceutica N.V.

It's not just a trend, it's a paradigm shift. It's made its way across nearly every industry and into millions of homes. We're talking Voice-Enabled Technology. VET holds the power to reshape business and can redefine the clinical trial experience. Results from a pioneering study evaluating a voice-activated application in a real-life clinical setting will be presented. These will help researchers understand how patients with rheumatic diseases interact with VET and their preferences for using it.

11:20 CASE STUDY: Share4Rare: Digital Innovative Platform for Citizen Science in Rare Diseases

Begonya Nafria Escalera, Patient Engagement in Research Coordinator, Clinical Research Unit, Sant Joan de Deu Barcelona Children's Hospital, Research Foundation Barcelona Children's Hospital

Share4Rare (S4R) is a collective online platform with the ambition to make a difference for rare disease patients and their families. In the enabling S4R environment, patients and families are in direct contact with researchers and clinicians to become researchers of their own disease. Interactive platforms will break isolation and allow learning across rare conditions, so that being rare no longer means being alone.

11:45 CO-PRESENTATION: Patient Centricity: Translating Intention into Action

Sophie Evett, Feasibility Lead, Study Optimization, Global Product Development, Pfizer

Gareth Powell, Business Operations, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre
Meaningful patient and public involvement and engagement in clinical research design and delivery has been taking place across England for the decade, but it has often been regional or localised to specific institutions or disease areas. The UK is now realising the ambition of implementing a national framework for patient involvement with a clear route for life science companies to engage with relevant patients who can help shape clinical trial design and delivery at the earliest possible opportunity. This requires meaningful involvement at the protocol design stage, not just at the patient information leaflet stage. This presentation will describe a collaboration to design, develop and pilot a network approach to connecting companies and patients who are willing and able to contribute at the protocol design stage.

12:10 Patient Centric Supply Models – How to Successfully Implement Direct to Patient Services

Kim Finn, Vice President, Global Patient Centric Services, Commercial Operations, Marken

Topics to be discussed include: 1) Industry update 2) How Direct to Patient can support Enrollment and Engagement 3) Challenges, Lessons learned, How to Ensure Success 4) What to consider when thinking about Direct to Patient.

12:35 Lunch in the Exhibit Hall (Community Networking)



INTEGRATING PATIENT INSIGHTS IN PROTOCOL DESIGN & BETTER PREDICTING/DELIVERING RECRUITMENT

13:55 Chairperson's Remarks

Sophie Evett, Feasibility Lead, Study Optimization, Global Product Development, Pfizer

14:00 CASE STUDY: Simulation in Paediatric Clinical Trials

Joana Claverol Torres, Clinical Trials Unit Coordinator, Sant Joan de Deu Barcelona Children's Hospital, Research Foundation Barcelona Children's Hospital

Simulation of the different activities to be performed during a trial with patients is a good opportunity to anticipate risks and to make adjustments in order to perform patient-centered projects. Sant Joan de Déu Children's Hospital has a dedicated unit for simulation activities. We will explain our experience in the administration of a trial with a radioactive medication, in order to anticipate security, logistic and quality of the clinical trial service. There is a lack of expertise in the implementation of simulation in the field of paediatric clinical trials. In the most complex situation it helps a lot to save time, resources and offer better quality for patient experience.

14:25 CASE STUDY: Tool and Method for Tracking Site and Patient Recruitment Performance and ROI Across All Vendors

Brendan O'Neill, Senior Director, Patient Recruitment Programs, Clinical Development & Operations, Global Product Development, Pfizer

Pfizer has pioneered a technology and methodology to track site and patient recruitment performance and ROI across all vendors while leveraging the largest online destination for patient recruitment. We will share a streamlined solution that manages the internal ROI dynamics of the sponsor/site patient recruitment needs while leveraging the leading online patient ecosystem for clinical research to efficiently connect patients into appropriate clinical trials. This is a new and transformational solution to the challenges patient recruitment has faced for decades.

14:50 Flipping the Funnel in Patient Recruitment to Accelerate Enrollment Timelines

Mark Summers, President, Patient Engagement, WCG

15:15 Overcoming Logistical Challenges to Participation in Global Clinical Trials

Jim Murphy, CEO, Greenphire

15:30 Refreshment Break in the Exhibit Hall

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BREAKOUT DISCUSSION GROUPS

16:10 Find Your Table and Meet Your Moderator

16:15 Interactive Breakout Discussion Groups (Session #1)

See pages 15-17 for details.

17:00 Networking Reception in the Exhibit Hall

18:00 End of Day

Wednesday, 18 September

8:00 Morning Coffee

OPERATIONALISING PATIENT-CENTRIC ENROLLMENT WITH DIGITAL OUTREACH, DIRECT-TO-PATIENT MODELS & REAL-WORLD PATIENT DATA

8:30 Chairperson's Remarks

Gareth Powell, Business Operations, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre



8:35 SPECIAL CASE STUDY: Operationalizing Patient-Centric Enrollment Using Digital Tech and Direct-to-Patient Models

Greg Hersch, Head, Innovation, Global Development Operation, Novartis Medicines can spend years in the development pipeline held back by a lack of suitable patients at clinical sites, yet we know the patients exist and are desperately waiting for the right medicines. Digital approaches can transform recruiting by adopting direct-to-patient models with these approaches enabling access to a wider pool of potential patients and the ability to explore new responses to diseases. We will share our vision for an end-to-end clinical trial recruitment capability based on a modular and partnership approach and also highlight the problems and pitfalls that that can be encountered when developing Outreach Electronica.

9:20 Patient Centricity on Trial

Mark Evans, Managing Director, Havas Lynx Faze

Clinical trials are broken and only patients can help us fix them. If we let them. We will explore how some of the world's most innovative companies are bringing the patient experience front and centre in clinical trials, and reaping the benefits of doing so.

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9:35 Efficient Patient Recruitment Strategies - Using Real World Patient Data for Successful Enrollment

Andree Beckerling, PhD, CEO, Clariness

The use of high quality real-world patient data is a powerful tool to better understand patient profiles, patient location, availability and specific indication insights. Presentation key takeaways will be a deeper understanding about the efficient use of real-world patient data for successful patient enrollment and learnings on timelines, challenges and success factors for planning recruitment and retention across multiple countries. A case study will be shared to demonstrate how this has been implemented.

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9:50 Coffee Break in the Exhibit Hall

IMPROVING CLINICAL TRIAL INFORMATION ACCESSIBILITY, TRANSPARENCY AND COMMUNICATION VIA DIGITAL TOOLS: GIVING PATIENTS WHAT THEY WANT AND NEED

10:35 Clinical Trial Information Accessibility: Improving the Quality and Utility of Clinical Trial Registration Data for Patients

Keir Hodge, Global Studies Leader, Global Clinical Operations, Hoffman La Roche

The Common Registry Data Packet (CRDP) is a TransCelerate initiative whose goal is to develop a catalog of the quality of existing registration data fields accompanied by guidance that will enable clinical trial sponsors to submit quality registration data that is both compliant to registry standards and presents high utility for patients. To ensure data quality is improved in a way that is beneficial to patients, CRDP's scope is limited to the registration data fields patients find most useful and informative on government-owned clinical trial registries. This session will share the key components of the CRDP catalog and how the initiative will ultimately improve the accessibility and value of clinical trial registries.

11:00 The Trials We Want: Clinical Trial Design from the Cancer Patient Perspective

Bettina Ryll, MD, PhD, Founder, Melanoma Patient Network Europe

Clinical trials in oncology provide treatment opportunities for patients with no other options. With stakes as high as survival, patients optimise their treatment strategies, with direct impact on trial recruitment and retention. MPNE, the Melanoma Patient Network Europe, has been educating Melanoma patients about scientific developments, clinical trials and innovative trial designs for more than 5 years and will share some of its learnings.

11:25 CASE STUDY CO-PRESENTATION: Digital Engagement to Better Reach and Retain Under-Represented Patients

Narinder Chopra, Director, Feasibility, Enrollment & Retention Optimisation, Global Clinical Operations, Biogen

Speaker to be Announced, Biogen

Incorporating digital tools to improve clinical trial infrastructure, participant outreach, enrollment, retention, and ultimately, outcomes, is a path the industry has been on for some time now. However, beyond the hype are some operational challenges that must be understood before investing in new tech or altering budgets/timelines with overly-optimistic expectations. This talk will share a specific application of digital engagement for under-represented patients.

11:50 Patient Centered Technology in the Age of Virtualization - Focusing on the Patient and Technology Design

Anthony Costello, Vice President, Mobile Health, Medidata

Virtual Trials provide many benefits to patients including lowering patient burden, increased patient engagement, and lower out-of-pocket costs. A critical component of virtual trials is the patient experience when using digital tools during the conduct of a trial. This session reviews the use of virtualization technologies and the process by which the patient perspective is infused into the software development life cycle to create technical solutions that improve the overall patient experience.

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12:15 Lunch in the Exhibit Hall (Community Networking)

13:25 Transition to Breakouts & Keynotes

BREAKOUT DISCUSSION GROUPS

13:35 Find Your Table and Meet Your Moderator

13:40 Interactive Breakout Discussion Groups (Session #2)

See pages 15-17 for details.

14:10 Clinical Research News' European Innovations Awards & Closing Plenary Keynotes

See page 3 for details.

15:25 Close of Conference



Tuesday at 12:35 & Wednesday at 12:15

COMMUNITY LUNCHEON AND NETWORKING IN THE EXHIBIT HALL

Join your new and established friends, colleagues and partners for a pleasant group luncheon in the exhibit hall. We will be enjoying lunch and networking in a casual setting. After the luncheon you will still have time for a break before the afternoon sessions begin.



Risk-Based Monitoring Europe

Integrating Quality Into Clinical Trials To Ensure Effective Monitoring

Tuesday, 17 September

7:30 - 17:00 Registration Open

8:00 Morning Coffee

8:35 Opening Plenary Keynotes

See page 3 for details.

ACHIEVING HIGHER QUALITY: PROTOCOL DEVIATIONS & RBM ISSUES

10:00 Grand Opening Coffee Break in the Exhibit Hall

10:50 Chairperson's Opening Remarks

Andy Lawton, Director & Consultant, Risk Based Approach Ltd.

10:55 Solving Key Protocol Deviation Challenges to Improve Data Quality

Catherine Stewart, PhD, PMP, Executive Director, Clinical Sciences, Protocol Deviations, Pfizer

Currently, clinical research sponsors and sites are working to interpret potentially confusing or misunderstood elements of the ICH E3 and the associated guidelines related to protocol deviations (PD). Based on input from sites, IRBs, as well as research sponsors themselves, the Transcelerate Protocol Deviations Initiative is creating a Protocol Deviation Management Toolkit and engaging health authorities on this topic with a goal of ultimately improving patient safety, reliability of study data, and data quality.

11:20 Protocol Deviations: The Issues that Matter

Paul Michael Johnson, MSHS, Director, Global Clinical Operations, Kiniksa

The discussion will be focused on a practical guide to implementing protocol deviation planning oversight and proactive management from protocol development to CSR and includes notes on pitfalls and resource burden of overzealous protocol deviation capture.

11:45 Risk-Based Everything?

Adam Baumgart, Head, Risk-Based Quality Management, AstraZeneca

AstraZeneca like many companies has been through a series of incarnations of RBM and this presentation will cover a short history of why and where we are. RBM has spilled into adjoining areas such as quality assurance and site selection, so where does it begin and end? How is Risk Based Quality Management impacting planning of programs and protocols? What are some of the risk trends AZ have observed and how is this changing the way we work?

12:10 What the FDA Pushing RBQM and E8 (R1) Means for Your Studies

Sponsored by

Tammy Finnigan, COO, Operations, TRI

The FDA want us to "stop calling it Risk-Based Monitoring and call it Risk-Based Quality Management, it's not just about monitoring, it is an end-to-end process". Recent E8(R1) guidance greatly reinforces this approach. In this session Tammy will share what RBQM and E8(R1) means for your studies, how to become a champion for driving reform of risk management and how to use RBQM to deliver better clinical trials.



12:35 Lunch in the Exhibit Hall (Community Networking)

13:55 Chairperson's Remarks

Andy Lawton, Director & Consultant, Risk Based Approach Ltd.

14:00 Quality Tolerance Limits: Achieving High Quality with a Tolerance for Imperfection

Lukasz Bojarski, Associate Director, Central Monitoring, AstraZeneca Pharmaceuticals, Inc.

ICH GCP R2 and Transcelerate definitions of Quality Tolerance Limits (QTLs) will be discussed and key differences between QTLs, risk indicators and

action thresholds will be presented. An approach to QTL set-up, both in terms of selection of a parameter and identification of a tolerance limit, will be proposed. Challenges to QTL implementation at scale and speed in AstraZeneca will also be discussed.

14:25 CO-PRESENTATION: The Quality Journey - A Small Company's Approach to the Implementation of ICH E6 and RBM

Andy Lawton, Director & Consultant, Risk Based Approach Ltd.

Yiwen Sun, Associate Manager, Clinical Risk Management at Samumed, LLC

This presentation will be in two parts, firstly examining the overall quality imperative within the clinical trial arena and the second part will focus on Samumed's ICH E6 and RBM journey to current status and future direction. Key points: 1. Understand the quality requirement expected of sponsors, 2. What can be achieved by a small company – current status, 3. Future direction.

15:15 Sponsored Presentation (Opportunity Available)

15:30 Refreshment Break in the Exhibit Hall

BREAKOUT DISCUSSION GROUPS

16:10 Find Your Table and Meet Your Moderator

16:15 Interactive Breakout Discussion Groups (Session #1)

See pages 15-17 for details.

17:00 Networking Reception in the Exhibit Hall

18:00 End of Day

Wednesday, 18 September

8:00 Morning Coffee

HARNESSING RBM & CENTRALIZED MONITORING DATA FOR INSIGHTS

8:30 Chairperson's Remarks

Andy Lawton, Director & Consultant, Risk Based Approach Ltd.

8:35 Leveraging RBM & Centralized Monitoring Data for Site Insights

Nurcan Coskun, PhD, Global Risk Based Monitoring Program and Technology Solutions Manager, Medtronic

This presentation will discuss the methodically and process that we are using for analyzing the RBM and centralized monitoring data we have collected as well as provide examples of how we are leveraging the data to enhance our decision making around site selection and other site insights.

9:00 INTERACTIVE PANEL DISCUSSION: Measuring the Effectiveness of RBM

Moderator: Marion Wolfs, Director, Risk Management-Central Monitoring, Janssen

Panelists: Michael Walega, MS, Head, Centralized Monitoring, Global Data Management and Centralized Monitoring, Bristol-Myers Squibb

Marcin Makowski, Head, Risk Based Monitoring & Standards, UCB

Adam Baumgart, Head, Risk-Based Quality Management, AstraZeneca

- How should we define effective RBM? The definition of effective RBM should be linked to the purpose of RBM -> improve quality and create efficiencies
- How do you measure improvement of quality due to implementation of RBM? (KRIs, QTLs, audit and inspection findings)
- How do you measure efficiencies gained?
- How do you deal with noise in measurements, created by other process improvements/changes to processes?
- Who do you measure when RBM is considered business as usual?

9:25 Sponsored Presentation (Opportunity Available)

9:50 Coffee Break in the Exhibit Hall



RBM CASE STUDIES

10:35 How Alkermes Created a Risk-Based Data Quality Oversight Framework

Amy Neubauer, Director, Data Quality Oversight, Alkermes, Inc.

Many CROs are offering RBM capabilities but how should sponsors provide oversight for outsourced studies? This session will take a look at the roles, tools, partnership model, internal framework, high level results, lessons learned, and future plans that Alkermes' Clinical Data Sciences team is taking to lead the clinical study teams in an effective risk-based data quality oversight approach as the company transitions from small pharma to mid-sized.

11:00 Fit for Purpose RBM for Novel Study Types

Ryanne van Huijkelom, Manager, Risk Management-Central Monitoring, Janssen

Risk-Based Monitoring is commonly applied to later phase pharmaceutical studies with the goals of attaining subject safety, data quality, and operational efficiencies. However, the risk management requirements described in ICH-GCP E6 (R2) also apply to other types of clinical studies. Since Risk-Based Monitoring is flexible by design, it can be made fit for purpose and applied to all study types. We'll explore how using the different steps of Risk-Based Monitoring in a flexible way at J&J, Risk-Based Monitoring has been implemented not only in later phase but also in novel study types.

11:25 Risk-Based Monitoring of Virtual Trials

Marcin Makowski, Head, Risk Based Monitoring & Standards, UCB

Decentralized Trial (DCT) Model utilizes telemedicine to reach patients.

The model creates many opportunities and a few specific challenges.

The presentation will concentrate on the challenges around monitoring of such trials. Traditional on-site monitoring brings limited value. Moreover, classical risk-based monitoring concentrated on between-site differences also doesn't fit as often there is just one site. A new model of monitoring implemented on one of UCB DCT's based on cooperation and division of responsibilities between the site, CRO, and the sponsor will be presented.

11:50 Sponsored Presentation (Opportunity Available)

12:15 Lunch in the Exhibit Hall (Community Networking)

13:25 Transition to Breakouts & Keynotes

BREAKOUT DISCUSSION GROUPS

13:35 Find Your Table and Meet Your Moderator

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See pages 15-17 for details.

14:10 Clinical Research News' European Innovations Awards & Closing Plenary Keynotes

See page 3 for details.

15:25 Close of Conference

EUROPEAN INNOVATIONS AWARDS

CLINICAL RESEARCH NEWS 2019

Advanced Deadline (no fee): June 7, 2019 | Final Deadline: July 12, 2019

Clinical Research News is seeking submissions to its European Innovations Awards. This awards program recognizes outstanding examples of applied strategic innovation—partnerships, deployments, and collaborations that manifestly improve the clinical trial process. Judges are looking for thoughtful approaches to tough industry problems, approaches that have been used and proven. Quantify ROI and explain how the solution could be deployed by others. Project results are more important than product feature lists.

Find out more at ClinicalResearchNews.com

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Digitalization of Clinical Trials

Digital Technology, AI, Real World Data and Advanced Analytics for Next-Gen Trials

Tuesday, 17 September

7:30 - 17:00 Registration Open

8:00 Morning Coffee

8:35 Opening Plenary Keynotes

See page 3 for details.

10:00 Grand Opening Coffee Break in the Exhibit Hall

SMART TECHNOLOGIES FOR NEXT-GENERATION TRIALS

10:50 Chairperson's Opening Remarks

10:55 Digital Technologies and AI to Re-Shape Clinical Trials

Mishal Patel, PhD, Head, Health Informatics, AstraZeneca

Clinical development organizations are changing how they collect, manage and analyze clinical data and new measures of clinical outcomes are being adopted. Data will be the fuel that powers machine learning and AI. As a result we must re-imagine what is required to create a data powered organization that unlocks value and insights. We will explore how information supply chains, elastic infrastructure, tools for data science, and automation enable a 21st century data backbone accelerating the delivery of new medicines to patients.

11:20 CO-PRESENTATION: EHR2EDC – Pioneering Greenfields to Optimize Clinical Research Data Management

Agustín Gómez de la Cámara, MD, PhD, Senior Scientist & Head of the Central Unit of Clinical Research and Clinical Trials, Biomedical Research Institute, Hospital 12 de Octubre

Marija Todorovic, Bridges Associate, Hospital Engagement Lead/Data Sciences, Janssen R&D, Clinical Innovation

EHR2EDC is a public-private eIT funded project which aims at developing processes, procedures and technology for automatic transfer of data elements from the electronic health records (EHRs) into the electronic data capture (EDC) environment. This novel technology solution can improve the efficiency of clinical research in a GDPR compliant manner. A RWD/EHR platform, built according to the principles of federated data management, provides real world data and insights for protocol design, feasibility and recruitment and allows for a streamlined communication path between a sponsor and the participating sites. In 2018-2019, the existing RWD/EHR platform services are being extended to demonstrate the possibility of EHR data extraction that will be automatically uploaded in the EDC during trial execution. Several pilots will validate the technical capabilities paying attention to appropriate process optimization and regulatory requirements for future operational EHR2EDC solutions. Presenters will share overall project experiences and lessons learned, advantages for all participants in the ecosystem, especially speaking from the hospital and sponsor perspective.

11:45 Trends, Insights, and Strategies to Improve Study Execution

Rik Van Mol, Vice President, Development Cloud Strategy, Europe, Veeva

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During this presentation you will: 1) Hear new results from one of the industry's largest, global clinical operations surveys 2) Examine the drivers and barriers to unifying clinical systems and processes 3) Learn about trends in data sharing and collaboration 4) Discover innovative approaches for streamlining study execution 5) Hear about the steps the industry is taking to improve study quality and speed.

12:10 Exploring eConsent Options: Self-Authoring vs Vendor-Managed Models

Mika Lindroos, Director, Product Management, Signant Health

In this session, discover the difference between vendor-managed and self-authoring eConsent models and how to choose the right one for your study. Learn the ideal features that support self-authoring and ways to manage implementation within your teams.

12:35 Lunch in the Exhibit Hall (Community Networking)

Sponsored by



DIGITAL ENDPOINTS AND BIOMARKERS

13:55 Chairperson's Remarks

Marija Todorovic, Bridges Associate, Hospital Engagement Lead/Data Sciences, Janssen R&D, Clinical Innovation

14:00 Digital Endpoints: Insights into Performance, Behaviour and Beyond
Ieuan Clay, PhD, Head, Digital Data Science, Translational Medicine, Novartis Institutes for Biomedical Research

As the field of digital endpoints matures, as well as more readouts progressing towards acceptance, we are also seeing new domains of readouts emerging. Focusing on our work on mobility, we will discuss how emerging capabilities in analytics and technology have allowed us to move from gait performance measures into studying mobility behavior and bridging into subjective perceptions of independence.

14:25 Smartphone-Based Objective Assessments of Physical Function in Rheumatoid Arthritis Patients

Valentin Hamy, PhD, Data Analytics Leader, Digital Biomarkers, GSK Associate Fellow, Biostatistics, R&D, GlaxoSmithKline

Analysis of iPhone sensor data collected by means of a mobile software application. Objective tasks were deployed during which gyroscope and accelerometer time-series data were captured. The tasks were performed remotely and without any medical supervision. Machine learning-based processing schemes enabled the extraction of motion-specific features for comparison with subjective pain and mobility parameters collected from Rheumatoid Arthritis patients, which highlighted links between reduced mobility and increased symptoms severity.

14:50 INTERACTIVE PANEL DISCUSSION: Moving Towards Virtual Trials

15:30 Refreshment Break in the Exhibit Hall

BREAKOUT DISCUSSION GROUPS

16:10 Find Your Table and Meet Your Moderator

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17:00 Networking Reception in the Exhibit Hall

18:00 End of Day



Wednesday, 18 September

8:00 Morning Coffee

AI: HOPE OR HYPE

8:30 Chairperson's Remarks

Ronald Dorenbos, PhD, Head, Innovation Management & Scouting, Innovation & Technology Science, Takeda

8:40 AI in Pharma & Clinical Trials

Ronald Dorenbos, PhD, Head, Innovation Management & Scouting, Innovation & Technology Science, Takeda

The presentation will discuss how AI-related approaches are changing the way clinical trials are executed. The patient's perspective on implementation of AI in clinical trials will briefly be reviewed and the presentation will highlight implementation of AI in a variety of areas within the pharma value chain. The presentation will be concluded with a brief look into the future.

9:10 Tangible Applications of Advanced Analytics

Venkat Sethuraman, Associate Principal, ZS

Machine Learning & AI have a variety of clinical research applications such as protocol digitization, anomaly detection, disease identification and safety prediction. In this session, we will share how companies are building capabilities and processes that harness ML & AI to solve complex problems and optimize operations.

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9:25 Enabling Intelligent Operations: Embracing Emerging Technology in Drug Development

Jennifer Duff, Global Life Sciences Operations Lead, Accenture

Sponsored by
accenture

9:50 Coffee Break in the Exhibit Hall

IMPLEMENTATION CHALLENGES AND SOLUTIONS

10:35 Janssen's Suite of Smart Technologies to Transform Clinical Trials: From Concept to Implementation

Bert Hartog, PhD, Senior Director, Clinical Innovation, Janssen Pharmaceutica N.V

Transforming clinical trials by disruptive partnerships with technology, software, mobile and package vendors. More specifically:

- Impact of personalized patient engagement and automated real-time data collection on patients, sites and companies via smart phones, smart blisters and scanning devices
- Ensuring the "right" kit and "right" pill is given to the "right" patient at all times
- Improving a patient's understanding of drug information and all-in-one digital drug labels
- Value of engaging patients, sites, health authorities and ethics committees directly during the development of smart technologies
- The learnings of a first Phase II study with Alzheimer patients and the first feedback of the ongoing studies

11:00 New Clinical Research Technologies: The Perspective of the Clinical Research Site

Teresa Hines, Associate Director, Clinical Management, Otsuka Pharmaceutical Development & Commercialization

In today's clinical research environment there is a steady progression toward the use of a fully paperless environment including technologies like electronic source and electronic consent. These technologies have significant operational impacts on sponsors and CROs but also, importantly, clinical research sites. Having deployed several trials now with a suite of technologies that are virtually paperless, we have obtained comprehensive feedback from clinical research sites as to what they see as the advantages and challenges of the new technological environment. We will summarize the key finding of this data and speak to the implications for industry as we continue to deploy new technologies in clinical research.

11:25 CO-PRESENTATION: Cross-Industry Collaboration: Evaluating How Blockchain Can Transform the Pharmaceutical and Healthcare Industry, Part of Emerging Trends & Technology PhUSE Workgroup

Adama Ibrahim, Associate Director, Clinical Operations, Biogen

Aji Barot, Vice President, Pharma (EMEA), Medisafe® Medication Management Platform

Describing the landscape in the pharma and healthcare settings, exploring the areas where blockchain could be used and presenting two detailed use cases (a. Drug Supply Chain using Smart Contracts; b. Patient Data Access/Transparency) and demo several functionalities around Patient ID, eConsent and Data Sharing.

11:50 Automated Patient-Recruitment System Based on RWD and Natural Language Processing

Javier de Oca, CEO, IOMED

Patient Recruitment is a major issue in Clinical Trials (CT). Increasingly complex and time-consuming CT are a challenge for sponsors and CROs. IOMED offers a system to accelerate patient recruitment, using electronic health records (EHR), routinely collected in hospitals, and processing them with Natural Language Processing. The outcome is a structured database, containing all patient's clinical variables. As a result, we are able to find 3 times more patients in a 10% of the time.

Sponsored by
IOMED

12:15 Lunch in the Exhibit Hall (Community Networking)

13:25 Transition to Breakouts & Keynotes

BREAKOUT DISCUSSION GROUPS

13:35 Find Your Table and Meet Your Moderator

13:40 Interactive Breakout Discussion Groups (Session #2)

See pages 15-17 for details.

14:10 Clinical Research News' European Innovations Awards & Closing Plenary Keynotes

See page 3 for details.

15:25 Close of Conference

HOTEL & TRAVEL INFORMATION

Crowne Plaza Barcelona-Fira Center

Av. Riusi I Taulet, 1-3

E-08004 Barcelona, SPAIN

Phone: +34 934 26 22 23

Discounted Room Rate: €210/single, €230/double

Discounted Room Rate Cut-off Date: August 19, 2019

For more information: ScopeSummitEurope.com/travel



Budgeting, Resource Management, and Outsourcing for Clinical Trials

Maximizing Trial Budgets and Resources to Drive Outsourcing Strategy and Quality Clinical Trials

Tuesday, 17 September

7:30 - 17:00 Registration Open

8:00 Morning Coffee

8:35 Opening Plenary Keynotes

See page 3 for details.

10:00 Grand Opening Coffee Break in the Exhibit Hall

IMPACT OF OUTSOURCING MODELS ON CONTRACTS, RESOURCES, AND QUALITY

10:50 Chairperson's Opening Remarks

10:55 Clinical Outsourcing Contracts: Impact of Sourcing Models, Digital Technologies, and GDPR

Rikke Winther, Independent Outsourcing Professional

This presentation will highlight selected sourcing models within Pharma-CRO contracts for clinical trials and analyze the impact on communication and management for the sourcing teams and study teams. The presenter will also address the impact of the increasing new digital technologies introduced in clinical trials and any GDPR considerations related hereto. The topics will be illustrated by using practical case studies examples.

11:20 Fully Outsourced vs. Hybrid Clinical Trials: Impact on Negotiations and Cycle Times

Kelly Loughner, Senior Associate Director, Site Enablement, Boehringer Ingelheim

This talk will discuss the highs and lows of fully outsourcing global trials. We'll examine alternative methods for negotiation of global trials with hybrid and in-house negotiations and ways to reduce cycle times in all structures.

11:45 CRO Oversight – How We Can Do It Better!

Andy Lawton, Director & Consultant, Risk Based Approach Ltd.

CRO oversight was not specified as a responsibility for sponsors in the original version of ICH E6, but this did not prevent inspection findings from Regulatory bodies. The FDA document (2013) and revision of ICH E6 (2016) have brought an increased focus on oversight. This presentation examines: What you should do to demonstrate oversight, including The Good, the Bad and the Ugly; expectations and findings from Regulatory Inspections, including an assessment of what they really want; and how to simplify the process

12:10 Sponsored Presentation (*Opportunity Available*)

12:35 Lunch in the Exhibit Hall (*Community Networking*)

OPTIMIZING RESOURCES FOR EFFECTIVE PLANNING AND EXECUTION

13:55 Chairperson's Remarks

Bella Sessoms, MPH, Director, Portfolio Sourcing Management, Portfolio Sourcing and Relationship Management, Astellas Pharma Global Development

14:00 Resource Estimation Driving Resource Planning, Allocation, and Related Finance Processes at Bayer Pharma

Anja Pietsch-Ottinger, Resource Manager, Clinical Operations - Resource Management, Bayer AG

This talk will discuss resource management for internal resources of clinical operations at Bayer, as well as provide an introduction of our Resource Estimation Tool (RE Tool) with its general functionality, advantages and caveats. We'll also have a discussion of specific use cases for the resource estimation results.

14:25 CO-PRESENTATION: Optimizing Resources and Maximizing Collaborations Across Your Legal and Outsourcing Teams

Bella Sessoms, MPH, Director, Portfolio Sourcing Management, Portfolio Sourcing and Relationship Management, Astellas Pharma Global Development
Mariya Pinskaya, Principal Consultant, Areva Consulting

Many organizations are faced with increasingly limited resources within their corporate legal teams and as such rely on other departments to support contracting activities. During this presentation, we will review models for optimizing resources and discuss ways to maximize cross functional collaborations.

15:15 Sponsored Presentation (*Opportunity Available*)

15:30 Refreshment Break in the Exhibit Hall

BREAKOUT DISCUSSION GROUPS

16:10 Find Your Table and Meet Your Moderator

16:15 Interactive Breakout Discussion Groups (Session #1)

See pages 15-17 for details.

17:00 Networking Reception in the Exhibit Hall

18:00 End of Day



GROUP DISCOUNT INFORMATION

Special rates are available for multiple attendees from the same organization.

For more information on group discounts contact **Melissa Dolen** at +1 781-972-5418.





Wednesday, 18 September

8:00 Morning Coffee

INNOVATIONS AND NEW REGULATIONS IN CONTRACTING

8:30 Chairperson's Remarks

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

8:35 Quicker, Consistent and More Cost Effective: The UK's New Unified Approach to Costing and Contracts

Matt Cooper, PhD, Director, Business Development & Marketing, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre

The UK is tackling the global issue of costing and contracting head-on by introducing a new standardised national approach to costing and contracting for all NHS service provider sites in England conducting commercial clinical research. The next phase will effect change allowing life science companies to negotiate the resource allocation required to deliver the trial at any site with one single national coordinator. Once the resource allocation is agreed all sites thereafter partaking in the trial would abide by that agreement and use the mandated costing tool to price the study.

9:00 The Impact of ICH GCP E6 R2 Guideline Revisions on Contracts, Sites and Vendor Selection

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

The ICH revised E6 guidelines were issued to reflect on the current research landscape: increases in globalization, study complexity, and technological capabilities. The updated ICH GCP E6 R2 is more descriptive than the previous version and has 26 items of change. These changes consist of new items in definitions; new sections on investigator responsibilities, including oversight; a substantial new sponsor section on quality management, including risk assessment; monitoring plans defined and implemented; introducing Risk-Based Quality Management; serious breaches and a new section on computer validation and electronic records, to name a few.

9:25 Sample Contracts and Recommendations for Remuneration for Clinical Trials in Germany

Thorsten Ruppert, MD, Senior Manager, Research, Development and Innovation, Association of Research-Based Pharmaceutical Companies (vfa)

The time factor plays an important role for clinical trials internationally and so is relevant for the competitiveness of a trial location. To start a clinical trial as early as possible, the contracts between the parties involved should be completed quickly, simply, and comprehensively. Sample contracts are a new development in Germany and were developed by the German university clinics, coordination centres for clinical trials, and the pharmaceutical industry. The associated recommendations for remuneration are helpful if the potential partners in the contract have (in their respective negotiations) recommendations available that identify examples of recurrent cost items for the accurate determination of a fair remuneration in clinical trials.

9:50 Coffee Break in the Exhibit Hall

MASTERING AN OUTSOURCING STRATEGY IN A CHANGING GLOBAL LANDSCAPE

10:35 Outsourcing, Vendor Management and Vendor Oversight in the Time of Increasing Regulatory Demands

Klaus Peter Kammerer, MD, Global Head, Vendor Management & Vendor Oversight, Quality Management, Learning & Knowledge Management, Global Clinical Operation, Medicine, Human Pharma Business Unit, Boehringer Ingelheim Pharma GmbH & Co. KG

Outsourcing in Clinical Trials is common practice? What is the right outsourcing strategy? Which tasks can be outsourced and which should not? What is the right strategy for selecting a vendor? The presentation is going to discuss these topics and give tangible advice based on the experience of the speaker and his team. Further the changed regulatory environment after ICH E6 (R2) was released and the expectations from regulators on sponsor's oversight of conducted tasks within clinical trials will be discussed.

11:00 Moving from a Hybrid Model to Functional Service Provider Model: Benefits for Budgets and Resources

Marco Salami, Head, Clinical Outsourcing, Chiesi

There are a number of outsourcing models to follow in clinical trials, and every pharma and biotech company must weigh the pros and cons of each. This talk will discuss how Chiesi is revamping its outsourcing strategy from a hybrid model to a functional service provider model. We will discuss the benefits for budgeting and resourcing purposes, the strategies to implement this change, and the overall effect on clinical operations.

11:25 INTERACTIVE PANEL DISCUSSION: Best Practices and Lessons Learned: Outsourcing, Budgeting, and Resource Management

Moderator: Richard Scaife, Chair, Pharmaceutical Contract Management Group (PCMG)

Panelists: Marco Salami, Head, Clinical Outsourcing, Chiesi

Denis McMillan, Vice President, Solution Consultancy, Parexel

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

No clinical trial can kick off without the funds or the resources necessary to operate it. So what happens when an outsourcing strategy changes, and how does it dictate the financial and resource budgets? Or, if internal resources or financial budget changes, how does the outsourcing plan adapt? This panel will discuss best practices and lessons learned, and will attempt to answer all questions around what they wish they knew before they started their outsourcing projects.

11:50 Sponsored Presentation (Opportunity Available)

12:15 Lunch in the Exhibit Hall (Community Networking)

13:25 Transition to Breakouts & Keynotes

BREAKOUT DISCUSSION GROUPS

13:35 Find Your Table and Meet Your Moderator

13:40 Interactive Breakout Discussion Groups (Session #2)

See pages 15-17 for details.

14:10 Clinical Research News' European Innovations Awards & Closing Plenary Keynotes

See page 3 for details.

15:25 Close of Conference

Interactive Breakout Discussion Groups

See details at ScopeSummitEurope.com/breakout-discussions

Concurrent breakout discussion groups are interactive, guided discussions hosted by a facilitator or set of co-facilitators to discuss some of the key issues presented earlier in the day's sessions. Delegates will join a table of interest and become an active part of the discussion at hand. Bring your pharma, biotech, CRO, site, hospital or patient perspective to each of the discussions below. To get the most out of this interactive session and format please come prepared to share examples from your work, vet some ideas with your peers, be a part of group interrogation and problem solving, and, most importantly, participate in active idea sharing.

This year due to positive feedback we will be running two breakout discussion sessions, one on Tuesday afternoon and a second on Wednesday afternoon. Attendees will thus have a chance to join two topic discussions.

DAY 1 BREAKOUTS

Tuesday Afternoon | 17 September 2019

16:10 - 16:15 Find Your Table and Meet Your Moderators

16:15 - 17:00 Interactive Breakout Discussion Groups

TABLE: What Is Holding Back the Adoption of eConsent?

- Is eConsent for every trial? Discuss when eConsent is or isn't appropriate
- Understand IRB and regulatory feedback on the eConsent process
- Discuss how eConsent technology integrates with other systems
- Review a typical implementation timeline and how it impacts all stakeholders

Co-Moderators: Thorsten Ruppert, MD, Senior Manager, Research, Development and Innovation, Association of Research-Based Pharmaceutical Companies (vfa)

Begonya Nafra, Clinical Research Unit, Sant Joan de Deu Barcelona Children's Hospital, Research Foundation Barcelona Children's Hospital

Ana Herradon, Associate Director, Site Monitoring Manager and Regional Clinical Operations, Iberia, Bristol-Myers Squibb

TABLE: Leverage RWD to Optimize Protocol Design, Reduce Protocol Amendments, Accelerate Recruitment and Increase Patient Centricity – A European Perspective

- What are the updated metrics on the prevalence and causes of protocol amendments and trial/recruitment delays and what does this mean for us?
- How can we as an industry leverage RWD to improve the process of protocol design and recruitment?
- What are some community initiatives and individual company approaches to finding success?
- What's in it for the sponsor, the investigator and ultimately the patient (in protocol design, reduction of amendments, accelerating recruitment, increasing patient centricity)?

Co-Moderators: Marcy Kravet, Head, Operational Design Center (ODC), Global Clinical Operations, Merck KGaA

Gareth Powell, Business Operations, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre

Camilla Ramdeen PhD, Director, Strategic Feasibility, Integrated Solutions, PAREXEL International

Marija Todorovic, Bridges Associate, Hospital Engagement Lead/Data Sciences, Janssen R&D, Clinical Innovation

TABLE: Strategies for Accelerating Recruitment in Complex Clinical Trials in a Resource Constrained Environment

- Dealing with the Acute Patient where timing is critical
- Do traditional/past tactics still work in current environment? What tactics (new and old) work best today?
- Ensuring success for procedure driven protocols (non-conventional administration, device and/or diagnostic intense)
- Utilization of supportive field resources to accelerate recruitment (caregivers, Medical Science Liaisons, Clinical Trial Educators)

Co-Moderators: Keir Hodge, Global Studies Leader, Global Clinical Operations, Hoffman La Roche

Mark Summers, President, Patient Engagement, WCG

Jessica Cordes, Head, Clinical Operations, Medigene AG

TABLE: Optimizing Country and Site Selection: Strategies for Positioning Trials for Success Using a Global Footprint

- Optimizing the site feasibility process: Improving global site feasibility assessment to identify sites that will recruit on time and within budget
- Objective country feasibility and selection: Where are the patients?
- Data-driven site selection: Understand the number of sites, their probability of success, and the impact of site non-performance

Co-Moderators: Matt Cooper, PhD, Director, Business Development & Marketing, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre

Sophie Evett, PhD, Director, Feasibility Lead, Clinical Development & Operations, Global Product Development, Pfizer

Daoying Hu, MBA, PhD, Associate Director, Strategic Feasibility, UCB BioSciences

Claire Sears, Director, Product Communications, IQVIA Technologies

Jill Johnston, President, Site Activation Solutions, WCG

TABLE: Improving Both Time and Quality in Site Activation and Study Start-Up (Sponsor, CRO and Site Perspectives)

- Identifying and consolidating site start up activities that are redundant, inefficient and needlessly complex
- What are key learnings and opportunities for different approaches, including a centralized approach of study activation and site performance?
- How can sponsors, CROs and site streamline site activation and study start-up?

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

Chibby Ebhogiaye, Head, Feasibility Services, Solution Adoption Center, IQVIA

TABLE: Centralized Monitoring

- Common misconceptions about centralized monitoring
- What are the tech needs to implementing centralized monitoring?
- Best practices and lessons learned from those using centralized monitoring

Moderator: Elspeth Carnan, Vice President Supplier Performance

Management, Global Clinical Operations, EMD Serono

TABLE: Implications of Sourcing Model on Financial and Resource Budgeting

- Choosing a sourcing model to complement your portfolio strategy, and its implication on internal and external sourcing
- Approaches for accurately forecasting financial and resource demands
- Quantitative and qualitative considerations for adapting resources and budgets for a particular sourcing model

Co-Moderators: Bella Sessoms, MPH, Director, Portfolio Sourcing

Management, Portfolio Sourcing and Relationship Management, Astellas Pharma Global Development

Richard Butterworth, Senior Director, Alliance Management, Global Clinical Operations, Merck KGaA

Anja Pietsch-Ottinger, Resource Manager, Clinical Operations - Resource Management, Bayer AG

TABLE: Advanced Analytics and Artificial Intelligence in Clinical Trials

- Will data science and machine learning disrupt the provision of clinical evidence or compliment it?
- With Machine Learning becoming needing Big data sets, how could the industry share more data in a precompetitive framework?
- As more Deep learning techniques are deployed - how can we gain confidence in "Black Box" approaches?
- In what ways, if any, will we have to change how we work with regulators?

Co-Moderators: Jonathan Crowther, PhD, Site Intelligence Lead, Study Optimization, Global Product Development, Pfizer Inc.
Marc Philipp, MBA, Partner, Managing Director, Pharma & Life Sciences, Accenture GmbH

TABLE: Wearable Devices in Clinical Trials

- What is the value, beyond scientific interest?
- Where do we want to be in 5 years (and why we are not there already!)?
- Key challenges for industry uptake?
- Opportunities for industry-wide collaborations

Co-Moderators: Raj Pallapothu, mHealth Global Business Lead, Bayer Pharmaceuticals; mHealth Global Advocate
Maya Zlatanova, FindMeCure Foundation

17:00 Networking Reception in the Exhibit Hall

DAY 2 BREAKOUTS

Wednesday Afternoon | 18 September 2019

13:35 - 13:40 Find Your Table and Meet Your Moderators

13:40 - 14:10 Interactive Breakout Discussion Groups

TABLE: Impact of the Delays Regarding the Application of the New EU-CTR (EU-Regulation 536/2014)

- What is the current implementation status of the EU-CTR (EU-Regulation 536/2014)?
- What are the consequences of these delays for Europe as a clinical trial location?
- How should organizations prepare for various outcomes/timelines?

Moderator: Thorsten Ruppert, MD, Senior Manager, Research, Development and Innovation, Association of Research-Based Pharmaceutical Companies (vfa)

TABLE: Leverage RWD to Optimize Protocol Design, Reduce Protocol Amendments, Accelerate Recruitment and Increase Patient Centricity – A European Perspective

- What are the updated metrics on the prevalence and causes of protocol amendments and trial/recruitment delays and what does this mean for us?
- How can we as an industry leverage RWD to improve the process of protocol design and recruitment?
- What are some community initiatives and individual company approaches to finding success?
- What's in it for the sponsor, the investigator and ultimately the patient (In protocol design, reduction of amendments, accelerating recruitment, increasing patient centricity)?

Co-Moderators: Sophie Evett, PhD, Director, Feasibility Lead, Clinical Development & Operations, Global Product Development, Pfizer
Marc Philipp, MBA, Partner, Managing Director, Pharma & Life Sciences, Accenture GmbH
Maya Zlatanova, FindMeCure Foundation
Daoying Hu, MBA, PhD, Associate Director, Strategic Feasibility, UCB BioSciences

TABLE: Strategies for Patient-Centric Trial Design and Digital Patient Engagement

- What are current digital patient projects gaining traction, engagement pilots, new technologies, the role of patient communities?
- What is a complete digital patient experience? What is required to make this a reality for all trials?
- What are we getting right and what are we getting wrong as we realign our processes and our research organizations around the patient-centric model?

Co-Moderators: Matt Cooper, PhD, Director, Business Development & Marketing, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre
Keir Hodge, Global Studies Leader, Global Clinical Operations, Hoffman La Roche
Raj Pallapothu, mHealth Global Business Lead, Bayer Pharmaceuticals; mHealth Global Advocate
Jessica Cordes, Head, Clinical Operations, Medigene AG

TABLE: Optimizing Country and Site Selection: Strategies for Positioning Trials for Success Using a Global Footprint

- Optimizing the site feasibility process: Improving global site feasibility assessment to identify sites that will recruit on time and within budget
- Objective country feasibility and selection: Where are the patients?
- Data-driven site selection: Understand the number of sites, their probability of success, and the impact of site non-performance

Co-Moderators: Bettina Ryll, MD, PhD, Founder, Melanoma Patient Network Europe
Jonathan Crowther, PhD, Site Intelligence Lead, Study Optimization, Global Product Development, Pfizer Inc.

Gareth Powell, Business Operations, Research Delivery, National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre
Chibby Ebhogiaye, Head, Feasibility Services, Solution Adoption Center, IQVIA
Camilla Ramdeen PhD, Director, Strategic Feasibility, Integrated Solutions, PAREXEL International

TABLE: Improving Both Time and Quality in Site Activation and Study Start-Up (Sponsor, CRO and Site Perspectives)

- Identifying and consolidating site start up activities that are redundant, inefficient and needlessly complex
- What are key learnings and opportunities for different approaches, including a centralized approach of study activation and site performance?
- How can sponsors, CROs and site streamline site activation and study start-up?

Co-Moderators: Bella Sessoms, MPH, Director, Portfolio Sourcing Management, Portfolio Sourcing and Relationship Management, Astellas Pharma Global Development
Marcy Kravet, Head, Operational Design Center (ODC), Global Clinical Operations, Merck KGaA
Claire Sears, Director, Product Communications, IQVIA Technologies

TABLE: RBM in a Finance and Resource Limited Environment

- How can we adopt TransCelerate's RACT model for a resource limited company/organization?
- In terms of technology, what are nice to haves vs. need to haves for implementing RBM?
- Who is involved in putting RBM in action at smaller companies?

Moderator: Andy Lawton, Director & Consultant, Risk Based Approach Ltd.

TABLE: The Impact of Final ICH GCP E6 Guideline and R2 Addendum in Globalization Environment: Changes Affecting Sponsors, CROs, Clinical Investigators, Sites

- Describe the E6 R2 terms that are new/updated
- Identify the changes impacting investigators, sites, Sponsors, and CROs for budgeting and contract development and execution
- Explain the impact of the revisions on clinical trials conduct and organizational practices
- Evaluate solutions for applicability/modification of organizational processes, procedures for forecasting, budgeting and costs estimation
- Apply lessons learned for effective implementation of the new ICH GCP E6 R2 guideline

*Moderator: Marina Malikova, PhD, Executive Director, Surgical Translational Research: Operations and Compliance, Boston University School of Medicine
Ana Herradon, Associate Director, Site Monitoring Manager and Regional Clinical Operations, Iberia, Bristol-Myers Squibb*

TABLE: Implications of Sourcing Model on Financial and Resource Budgeting

- Choosing a sourcing model to complement your portfolio strategy, and its implication on internal and external sourcing
- Approaches for accurately forecasting financial and resource demands
- Quantitative and qualitative considerations for adapting resources and budgets for a particular sourcing model

*Co-Moderators: Rikke Winther, Senior Director, Outsourcing & Contracts Management R&D, Lundbeck
Elspeth Carnan, Vice President Supplier Performance Management, Global Clinical Operations, EMD Serono*

TABLE: Data Science and AI to Advance Clinical Trials

- Will data science and machine learning disrupt the provision of clinical evidence or compliment it?
- With Machine Learning becoming needing Big data sets, how could the industry share more data in a precompetitive framework?
- As more Deep learning techniques are deployed - how can we gain confidence in "Black Box" approaches?
- In what ways, if any, will we have to change how we work with regulators?

Moderator: Mishal Patel, PhD, Head, Health Informatics, AstraZeneca

TABLE: Advanced Analytics and Artificial Intelligence in Clinical Trials

- How do you see digitization making clinical trials more efficient?
 - Enrollment
 - Decision making
 - Adherence
- What do you see as major obstacles in implementing advanced analytics, ML and AI in Clinical Trials?
- Do you have case studies from your own industry/company (Successes/Failures)?
- How do you see the future developing (low-hanging fruit/ beyond the horizon)?

*Co-Moderators: Ronald Dorenbos, PhD, Head Innovation Management & Scouting, Innovation & Technology Science, Takeda
Mishal Patel, PhD, Head, Health Informatics, AstraZeneca*

14:10 Shared Plenary Keynote

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For sponsorship and exhibitor information, please contact:

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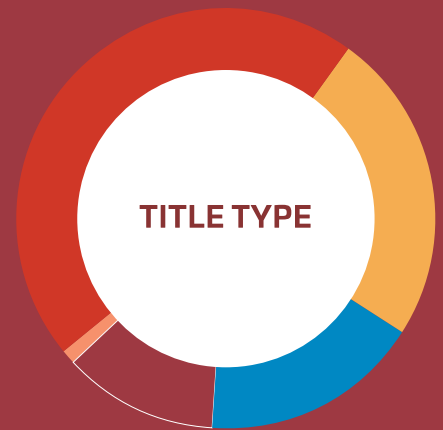
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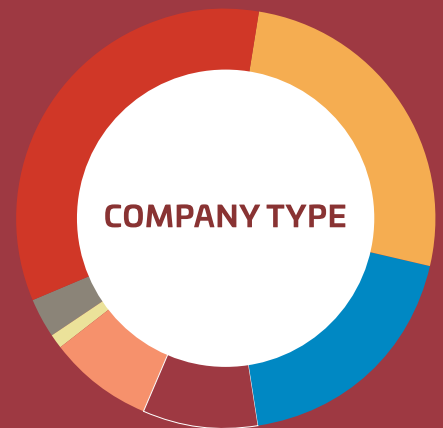
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- 46% Executive/Director
- 24% Manager
- 17% Sales & Marketing
- 12% Scientist
- 1% Other



- 34% CRO
- 26% Pharmaceutical
- 19% Biotech
- 9% Services
- 8% Hospital/Healthcare Provider
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PROGRAM SELECTIONS

Tuesday 17 - Wednesday 18

C1: Analytics-Driven Feasibility, Site Selection and Study Activation

C2: Patient-Centric Enrollment Planning and Engagement

C3: Risk-Based Monitoring Europe

C4: Digitalization of Clinical Trials

C5: Budgeting, Resource Management, and Outsourcing for Clinical Trials

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