13th Annual

SCOPE

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FEBRUARY 7-10, 2022 • ORLANDO, FL • ROSEN SHINGLE CREEK + VIRTUAL

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Organized by Cambridge Healthtech Institute

FINAL AGENDA

SCOPEsummit.com

Table of Contents

CHI's Mandatory COVID-19 Vaccination Policy

Your Safety is Our Top Priority

To ensure maximum safety, CHI has instituted a mandatory **COVID-19 vaccination policy** for all in-person participants of our events. Attendees will be asked to furnish proof of vaccination. Additional details on the vaccine policy will be provided upon registration.

Attendees that cannot participate because of this policy, or due to travel restrictions, are encouraged to participate using our virtual event platform. CHI virtual events provide you with an in-person experience at your convenience, anywhere, anytime. **See our website for details.**

Our Code of Conduct

All in-person attendees must agree to CHI's Code of Conduct

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2022 Plenary Keynote Presentations






MONDAY, FEBRUARY 7, 2022

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 pm Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

5:05 SCOPE's Inaugural Masters of Clinical Research Golf Tournament Awards

5:10 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Matt Miller, President & CEO, StudyKIK

5:15 Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.

Panel Moderator: Speaker to be Announced, Circuit Clinical

Panelists:

Victoria DiBiaso, Global Head, Patient Informed Development & Health Value Translation, Sanofi

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

Kafayat Babajide, MBA, Associate Director, Patient Portals, Janssen

5:45 SCOPE's 2020 Participant Engagement Awards Introduction
David Sall, President & CEO, Patient Enrollment Advisors; Co-Creator of the SCOPE Participant Engagement Award

5:50 SCOPE's 2020 Participant Engagement Awards

6:35 SCOPE's Kick-Off Networking Happy Hour

TUESDAY, FEBRUARY 8, 2022

Morning Plenary Keynotes
NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

7:15 am Morning Coffee *(Sponsorship Opportunity Available)*
8:05 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Conferences, Cambridge Healthtech Institute (CHI)

8:10 Chairperson's Introduction
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World
Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.

Darren Weston, Vice President, Integrated Data Analytics & Reporting (IDAR), Janssen

Cynthia Pan, Senior Director, Program Operations Leader, Global Clinical Operations, Regeneron

The COVID-19 pandemic continues to reshape our world and our approaches to clinical trials. During the last 20 months, the risk-benefit ratios of many innovative methodologies and technologies has inversed. Risk averse organizations have grasped the realities that these new innovative methods are now the only means to efficiently execute clinical trials. This new reality and the ongoing need for real time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required and realized within our organizations and with our external partners and technology providers. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale
Justin Wright, Vice President, Global Head Connected Health, Novartis

Adama Ibrahim, EMBA, Director, Digital Solutions, Novartis

Connected Health has many connotations and may mean something different in healthcare vs research, or to a hospital vs pharma. This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients and to pharma research to improve the health care experience and improve access to trials. How do you give patients their own digital data so they can be more engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange and clinical research? How do you do this at scale, beyond a pilot?








2022 Plenary Keynote Presentations

9:55 Grand Opening Coffee Break in the Exhibit Hall

DATATRAK from Concept to Cure.

WEDNESDAY, FEBRUARY 9, 2022

Afternoon Plenary Keynotes
DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 pm Welcome Remarks from CHI and The SCOPE Team

Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:40 Chairperson's Introduction: Accelerating the Move to Digital Clinical Trials

Jim Reilly, Vice President, R&D Strategy, Veeva



2:00 Panel: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership

Panel Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative

Panelists: Karriem Watson, PhD, Chief Engagement Officer, NIH

Monique Phillips, Clinical Trial Recruitment Specialist, Bristol Myers Squibb

Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from the cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.

2:45 Booth Crawl & Refreshment Break in the Exhibit Hall (Sponsorhip Opportunity Available).




Media & Organization Partners

Official Event Publication

Clinical Research News — Clinical Trials to the Clinic

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Event at-a-Glance

Monday, February 7 AM & PM		Tuesday, February 8 AM & PM	Wednesday, February 9 AM	Wednesday, February 9 PM	Thursday, February 10 AM & PM
8:00 am – 12:00 pm SCOPE's Inaugural Masters of Clinical Research Golf Tournament *Interested in taking part in the Inaugural Golf Tournament? For complete event information, including registration* details visit the website.* **Separate registration and fee required for Golf.*	**FEASIBILITY & STUDY START-UP**	Conference 1A **Protocol Development, Feasibility, and Global Site Selection**		Conference 1B **Improving Study Start-up and Performance in Multi-Center and Decentralized Trials**	
	RECRUITMENT & ENGAGEMENT	Conference 2A **Enrollment Planning and Patient Recruitment**		Conference 2B **Patient Engagement, Enrollment and Retention through Communities and Technology**	
	BUDGETING & RESOURCES	Conference 3A **Clinical Trial Forecasting, Budgeting and Contracting**		Conference 3B **Resource Management and Capacity Planning for Clinical Trials**	
2:00 – 5:00 pm Monday Afternoon Pre-Con User Group Meetings & Hosted Workshops	**OUTSOURCING**	Conference 4A **Mastering an Outsourcing Strategy**		Conference 4B **Managing Outsourced Clinical Trials**	
	CLINICAL SUPPLY	Conference 5A **Data Technology for End-to-End Clinical Supply Management**		Conference 5B **Clinical Supply Management to Align Process, Products and Patients**	
5:00 – 6:30 pm Kick-Off Plenary Keynote and 6th Annual Participant Engagement Awards	**DATA**	Conference 6A **Clinical Data Strategy and Analytics**		Conference 6B **Artificial Intelligence in Clinical Research**	
	TECHNOLOGY	Conference 7A **Sensors, Wearables and Digital Biomarkers in Clinical Trials**		Conference 7B **Decentralized Trials and Clinical Innovation**	
6:30 – 7:45 pm SCOPE's Kick-Off Networking Happy Hour	**REAL WORLD EVIDENCE**	Conference 8A **Accessing and Generating RWD**		Conference 8B **Leveraging Real World Data for Clinical and Observational Research**	
	BIOMARKERS & BIOSPECIMENS	Conference 9A **Clinical Biomarkers Operations and Innovation**		Conference 9B **Clinical Biospecimens Technology and Outsourcing**	
	QUALITY & MONITORING	Conference 10A **Risk-Based Quality Management**		Conference 10B **Central and Remote Monitoring**	
	MED DEVICE TRIALS	Conference 11A **Medical Device Trial Regulations, Quality and Data Management**		Conference 11B **Medical Device Clinical Trial Design, and Operations**	

2022 Event Highlights

Masters of Clinical Research

SCOPE's Inaugural Golf Tournament

February 7 at 8:00am

Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament, starting at 8:00am on Monday, February 7. Opportunities are available for those who would like to golf or attend. If you would like to sponsor the event, please refer to the packages below and contact our sales managers.

Interested in taking part in the Inaugural Golf Tournament? For complete event information, including registration* details visit the website.

**Separate registration and fee required for Golf.*

SCOPEsummit.com/sponsor-exhibitor/masters-of-clinical-research

Attention Pharma!

25 for 25

If you are an employee of the following TOP 25 Pharmaceutical Companies as cited by Pharmaceutical Executive* you may attend this meeting at a 25% discount off the current rate.

Enter Keycode PH25 upon checkout when registering.

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For More Information and Group Discounts, Please Contact:
Melissa Dolen, Account Manager
T: +1 781.972.5418 | E: mdolen@healthtech.com

Host a User Group, Workshop, or Company Meeting

nurocor bringing order to clinical data

Co-locate your User Group, a Workshop, or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market to prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point!

For Partnering and Sponsorship Information:

Companies A-K
Ilana Quigley
Senior Manager, Business Development
T: 781-972-5457
E: iquigley@healthtech.com

Companies L-Z
Patty Rose
Senior Manager, Business Development
T: 781-972-1349
E: prose@healthtech.com

2022 Event Highlights

Sixth Annual

PARTICIPANT ENGAGEMENT AWARD

IN MEMORY OF JERRY MATCZAK
#BELIKEJERRY #SCOPE2022

February 7 at 5:50pm

WHAT IS IT?

Now in its 6th year, SCOPE's Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. PEA embodies the values and personal accomplishments of Jerry Matczak, who sadly passed away soon after receiving the inaugural 2017 award. We dedicate this award to Jerry in the hopes that it will serve as a reminder of his ideals and accomplishments.

HOW DOES IT WORK?

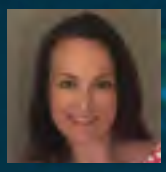
We welcome submissions from all facets of the industry, including, but not limited to Sites, CRO's, e-Patient Advisors, Agencies, Start-Ups, and Sponsors and invite you to submit your best work in the Patient Recruitment and Retention communications field. All submissions will be reviewed and finalists will be selected to present their concepts in person at SCOPE taking place February 7-10, 2022 in Orlando, Florida. This exciting competition will bring awareness to you and your company for excellent and engaging work.

HOW TO WIN?

Your submission must truly be designed to engage potential, current, or alumni study participants and/or their influencers and show marked improvements in the status quo.

EVENT HOSTS & JUDGES

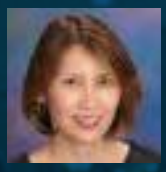
CHAIRPERSON: David Sall, President & CEO, Patient Enrollment Advisors; Co-Creator of the SCOPE Participant Engagement Award



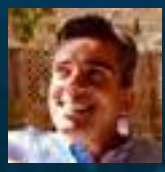
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata; Co-Creator of the SCOPE Participant Engagement Award

SUBMIT YOUR PROPOSAL NOW

Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative



Michelle Crouthamel DBA, Head, Digital Science, AbbVie



Irfan Khan, MD, CEO, Circuit Clinical

Gretchen Goller, Sr. Director, Head of Patient Recruitment, Clinical Development Operations, Seagen

Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Senior Director, Patient Engagement, Medidata

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

Learn More at: SCOPEsummit.com/participant-engagement-award

Partnering Organizations

Cure SMA leads the way to a world without spinal muscular atrophy (SMA), the number one genetic cause of death for infants. We fund and direct comprehensive research that drives breakthroughs in treatment and care, and we provide individuals with SMA and their families the support they need for today.

If your organization wants to learn more about standards-based donations, please contact:

Lori Warrens, MedSuplus Alliance
lori.warrens@medsurplusalliance.org

curesma.org

The MedSurplus Alliance's (MSA) Kits4Life Initiative is an award-winning program developed by the clinical research community to help close the healthcare gap worldwide. Lab kits, equipment, and supplies donated via Kits4Life reach recipient aid organizations through MSA accredited Medical Surplus Recovery Organizations (MSROs), which ensure the supplies are used for health care, diagnostic labs, medical training programs, and animal shelters in low resource settings. Kits4Life members include Bayer, Eli Lilly, Labcorp Drug Development, Janssen, Roche, Sanofi US, Sanofi Espoir Foundation, and the Society for Clinical Research Sites. Since 2020, over 184 clinical research sites in 30 U.S. states have participated.

If your organization wants more information on Kits4Life membership, please contact:

Josh Kravitz, The Task Force for Global Health
jkravitz-consultant@taskforce.org

Kits4life.com

The MedSurplus Alliance, a program of the Task Force for Global Health, engages and inspires cross-sector medical donation stakeholders to develop standards-based donation programs and practices that advance quality donations and protect the environment. Through its code of conduct, accreditation program, and operational expertise, the Medsurplus Alliance improves medical donation quality while encouraging stakeholder-led donation initiatives that expand healthcare delivery in low-resource settings.

If your organization wants to learn more about standards-based donations, please contact Lori Warrens.

medsurplusalliance.org

The Leukemia and Lymphoma Society is at the forefront of the fight to cure cancer. We are the largest nonprofit dedicated to creating a world without blood cancers. Since 1949, we've invested nearly $1.3 billion In groundbreaking research, pioneering many of today's most innovative approaches. **Learn more.**

To find out more about our free services and how we can help you and your patients, contact an Information Specialist at 1 800 955-4572.

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Program Advisory Board

February 8-9, 2022 | All Tmes EST

Oriol Serra Ortiz,
Head, Site Intelligence & Site Selection, Study Optimization Global Product Development, Pfizer

Michelle Shogren,
Senior Director Innovation, Pharma R&D Clinical Operations, Bayer HealthCare

Sandra Smyth,
Director, Global Feasibility and Site Intelligence, AstraZeneca

Chris Hoyle,
CEO and Founder, Elite Research Network

Melissa Easy,
Vice President, Head, Clinical Technologies, IQVIA

MONDAY, FEBRUARY 7

8:00 am SCOPE's Inaugural Masters of Clinical Research Golf Tournament

Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 Conference Registration Open (Gatlin Foyer)

2:00 pm User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)

Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

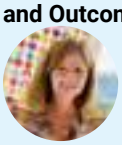
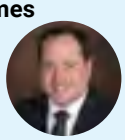
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

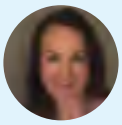



Moderator: Irfan Khan, MD, CEO, Circuit Clinical
Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

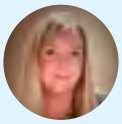
5:45 SCOPE's 2022 Participant Engagement Awards Introduction
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President,

Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co., Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 **SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)**

7:45 **Close of Day**

TUESDAY, FEBRUARY 8

7:15 am **Registration Open (Gatlin Foyer)**

7:15 **Morning Coffee** *(Sponsorship Opportunity Available)*

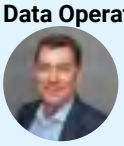
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 **Chairperson's Introduction**
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: **Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World**



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:55 **Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin A4

DIGITAL INNOVATIONS FOR PATIENT-CENTRIC DESIGN AND FEASIBILITY

10:55 **Chairperson's Remarks**
Todd Kole, Vice President, Clinical Project Services, Almac Clinical Technologies, Almac Group

11:00 **CO-PRESENTATION: Leveraging Digital Innovations for an Integrated Patient-Centric Strategy Across the Value Chain of R&D**
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Terttu Haring, MD, Global Head, Clinical Digital Innovation, Sanofi
At Sanofi R&D, Patient Centricity is defined as the "commitment to listen and translate patient insights into actions that develop new healthcare solutions with meaningful outcomes, address unmet needs and improve health-related quality of life." Current and future technologies provide opportunities to engage and collaborate with patients, trial sites, and health data, opening new ways of making trial participation possible for more individuals, including those traditionally underrepresented in clinical development.

11:30 **Re-Defining Feasibility to be Future Perfect**
Sandra Smyth, Senior Director, Global Feasibility and Site Intelligence, Development Operations, AstraZeneca
At AZ, we re-defined our feasibility approach placing emphasis on indication landscape assessments and early strategic engagement with sites. Maximizing indication landscaping, we build foundational datasets that subsequent projects can leverage. This means our downstream design assessment and protocol feasibility is more efficient, and our investigators are engaged earlier in the process. Learn more about our re-designed feasibility process, tools, and how we collaborate to re-use insights for reliable predictability.

12:00 pm **Panel Discussion: Diversity and Inclusion in Early Protocol Design and Clinical Trial Optimization**
Moderator: Michelle Shogren, Senior Director Innovation, Pharma R&D Clinical Operations, Bayer HealthCare
As the diversity topic continues to gain momentum it is clear we cannot truly address this only in our recruitment campaigns at the start of a study. What can we do earlier in the process to ensure we are not unintentionally excluding or making it harder for diverse populations to participate? Join this fireside chat to hear examples of where we can proactively approach this important topic.
Panelists:
Lorena Kuri, Head, Diversity Strategy, Bristol Myers Squibb Co.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.

12:30 **Virtual Training as an Essential Solution in a Post-Pandemic World**
Dave Hadden, President, Pro-ficiency
- Identify how using the right tools for remote training can improve the performance management of sites

- Exploring how best to implement virtual training to reduce protocol deviations
- Finding the right virtual training supplier who can simulate critical protocol challenges by using lifelike, online scenarios that allow learners to practice decision making in a consequence-free environment
- Remote Site Performance Management tech – what's available and what would work with your study

1:00 Transition to Lunch

1:05 CO-PRESENTATION: LUNCHEON PRESENTATION: Leveraging Artificial Intelligence and Machine Learning to Deliver Next Generation Feasibility & Site Selection

Travis Caudill, Vice President, Feasibility, Site Identification, and Clinical Informatics, ICON

Ashley Schwalje, Director, Strategic Partnerships, Informa Pharma Intelligence

Informa Pharma Intelligence and ICON plc partnered to deliver next-gen trial feasibility by enhancing Informa's predictive analytic, Citeline Study Feasibility, and powering it with combined datasets from both organizations. Our goals were to accelerate timelines, select more high performing sites, optimize operational performance, and reduce manual effort involved in scenario modelling. This session will focus on applications of Citeline Study Feasibility in ICON's strategic feasibility work.

1:35 Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)

ANALYTICS AND MODELING FOR STUDY PLANNING, SITE FEASIBILITY, AND ENROLLMENT PREDICTION

2:30 Chairperson's Remarks

Dave Hadden, President, Pro-ficiency

2:35 Advanced Predictive Modeling to Predict Enrollment and Project Milestone Dates (Time to Endpoint Maturation)

Li Wang, PhD, Senior Director & Head, Statistical Innovation, AbbVie, Inc.

This presentation will share the proposed advanced predictive modeling methodology and results to predict enrollment and key milestone dates (time to endpoint maturation). The methodology can be used to predict milestone dates for time-to-event trials like in Oncology and for fixed duration trials like in Rheumatology. The talk will also share the evolution of our thinking, the process of development and the challenges we have faced thus far.

2:50 Using AI and Analytics to Predict Best Performing Sites

Olga Bershevits, PhD, Advisor, Design Hub Data Insights, Eli Lilly & Co.

Using AI and analytics, we can speed clinical trial enrollment and accelerate overall clinical development timelines by predicting and including best performing sites into the study. An integrated set of data and advanced analytical tools allows users to identify best performing site based on historical performance and site health. Diversity and decentralized trials and their effect on site selection will be also discussed.

3:05 CO-PRESENTATION: Automate and Orchestrate Clinical Planning and Execution Process

Paul Bidez, Industry Vice President, Life Sciences, Manufacturing & Automotive, Sales, Appian

Tom Coleman, Strategic Account Executive, Sales, Appian

The life sciences industry has been exploring ways to accelerate the study start-up processes from design through execution to get products to the patients who need them faster. Hear from our experts on how a low-code platform can help improve the efficiency of the study start-up process and product life cycle. We'll discuss how to bring people, process, and data together across clinical operations and make automation work for your organization.

3:35 How Janssen's Feasibility CoE Leveraged Data and Analytics to Deliver Rapid Enrolment Across a Diverse and Representative Participant Group

Gina Rothenberger, Global Feasibility Therapeutic Area Head, Infectious Disease and Vaccines, Janssen Pharmaceuticals, Inc.

In this presentation, we will share key strategies used to optimize site selection for Ensemble 1, to ensure diverse recruitment targets were met across age, ethnicity, and co-morbidities while also satisfying aggressive timelines through the evolving pandemic. This required a multi-faceted approach layering quantitative and qualitative data in support of the efforts which resulted in record breaking enrollment, 3 months from FPI to LPI, 43,000 patients enrolled with impressive diversity.

4:05 Unlocking the Power of Integrated, Patient-Centric Data Science to Answer the Biggest Questions in Clinical Development

Gen Li, PhD, President & Founder, Phesi

With the industry under more pressure than ever to ensure high success rates for clinical programs, we look at the key questions across the development cycle that if answered correctly can ensure a successful trial. We explore how, by leveraging the power of patient-centric data science and the world's largest clinical development database, biopharmaceutical companies are unlocking the insight required to ensure shorter cycle times, fewer amendments and deliver faster cures.

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 Find Your Table and Meet Your Moderators

4:40 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)

6:40 Close of Day

WEDNESDAY, FEBRUARY 9

7:15 am Registration Open (Gatlin Foyer)

BREAKFAST PRESENTATIONS

Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 Practical Approaches for Operationalizing DCTs Room Location: Gatlin A1

Kyle Hogan, President, Datacubed Health

Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2

Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS

Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin A4

REIMAGINING PROTOCOL FEASIBILITY AND SITE SELECTION WITH RWE, MACHINE INTELLIGENCE… AND HUMAN INTUITION

8:20 Chairperson's Remarks

Nina Pruitt, MA, VP, Global Strategic Marketing, Commercial, Clinical Ink

8:25 Enabling "Superminds" to Select Right Site On-Time: Combining Human Intuition with Machine Intelligence

Oriol Serra Ortiz, Vice President, Link for Clinical, Veeva

Inspired by the interplay between humans and machines in chess, during this presentation we will showcase to the audience how combining human intuition and machine intelligence can help create Superminds that amplify the power of making evidence-driven decisions in trial design and site identification in today's clinical trials environment.

8:55 CO-PRESENTATION: Building an End-to-End Study Planning & Execution Predictive Platform - A Collaboration Between PPD & Medidata Acorn AI

Fareed Melhem, SVP, Acorn AI, Medidata, a Dassault Systèmes Company

John Van Hoy, Executive Director, Data Science & Advanced Analytics, PPD, part of Thermo Fisher Scientific

PPD and Medidata Acorn AI have a deep collaboration based on a shared vision that data can power better clinical trial planning and study management. As biopharma companies require better site feasibility and forecasting to manage studies, we have collaborated to build predictive models and technology combined with data to deliver real-time trial management. In this session, we'll share the impact of these models, how they're being deployed, and insights gained.

9:25 CO-PRESENTATION: Reimagining Protocol Feasibility and Country-Site Selection with RWE and Deeper Analytics

Sarah McClure, Global Data Engagement Lead, Feasibility Management, R&D, Sanofi

Siva Thiagarajan, MBA, Leader, R&D Practice, ZS Associates

Sanofi's vision is to use technology and data to disrupt the clinical research model and enable systematic data value (comparison, simulation, automation, innovations) to adapt protocols and clinical operations design for patients, sites, and effectiveness of the study (optimize recruitment and enhance accuracy of enrollment projections). This talk will show how we set up the evidence-based program to define an integrated landscape from study design up to study start-up.

9:55 CO-PRESENTATION: Assessing and Applying Participation Burden to Inform Patient Engaged Protocol Design

Bazgha Qutab, Principal, ZS

Ken Getz, TBC, Tufts University

10:25 Coffee Break in the Exhibit Hall

DEVELOPING A PROTOCOL SIMPLIFICATION AND OPTIMIZATION CAPABILITY DURING THE PANDEMIC

11:20 Chairperson's Remarks

Wayne Baker, Chief Commercial Officer, Greenphire

11:25 CO-PRESENTATION: Developing a Protocol Simplification/ Optimization Capability through Pandemic Response

Mike Jacobs, Senior Director, Study Optimization and Assessment Planning, Bristol Myers Squibb Co.

Gaelan Ritter, Senior Director, Innovation and Digital Health, Bristol Myers Squibb Co.

This new capability is a novel approach to protocol development. Building trials with a 'quality by design' approach will provide a better understanding regarding how trial designs can impact our patients, sites, resources, and downstream trial costs. Study teams are now provided with analytics that will drive more informed and proactive decision making upfront in the design process. The desired outcomes are centered around improvements in quality, speed, and cost.

11:55 Transition to Lunch

12:00 pm CO-PRESENTATION: BRIDGING LUNCHEON PANEL PRESENTATION: Decentralized Trials: Improving Participant & Site Experience through Technology

Zach Hales, Associate Director, Product Management, Greenphire

Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites

Steve Wimmer, Director of Partnerships, 1nHealth

While we are still facing collective uncertainties, one this is certain; the clinical research community is working together to ensure trials can continue and that we are supporting sites and participants. in this session, you will hear from a panel - representative of the participant, site, and solution provider voice - on experiences with decentralized trials and how associated technology and processes can drive the future of clinical research.

12:30 **Coffee and Dessert Break in the Exhibit Hall** *(Sponsorship Opportunity Available)*

1:30 **Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!***
Separate registration required for access to Part B conferences, upgrade to Best Value Package.

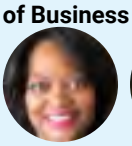
KEYNOTE LOCATION: Gatlin A1 & A2

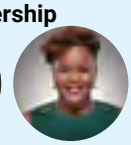
DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 **Welcome Remarks from CHI and the SCOPE Team**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: **Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative**
Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:00 **Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership**






Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.
Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**
Don't forget Part B Conferences begin at 3:45pm **Separate registration required, upgrade to Best Value Package.

Program Advisory Board

February 9-10, 2022 | All Tmes EST

WEDNESDAY, FEBRUARY 9

ROOM LOCATION: Gatlin A4

BRIDGING LUNCHEON PRESENTATION

12:00 pm **CO-PRESENTATION: BRIDGING LUNCHEON PANEL PRESENTATION: Decentralized Trials: Improving Participant & Site Experience through Technology**

Zach Hales, Associate Director, Product Management, Greenphire

Jimmy Bechtel, Vice President, Site Engagement, Society for Clinical Research Sites

Steve Wimmer, Director of Partnerships, 1nHealth

While we are still facing collective uncertainties, one this is certain; the clinical research community is working together to ensure trials can continue and that we are supporting sites and participants. in this session, you will hear from a panel - representative of the participant, site, and solution provider voice - on experiences with decentralized trials and how associated technology and processes can drive the future of clinical research.

12:30 **Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)** *(Sponsorship Opportunity Available)*

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 **Welcome Remarks from CHI and the SCOPE Team**

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

Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

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Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

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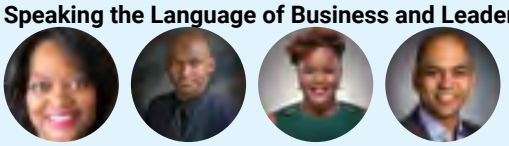

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Panelists:

Karriem Watson, PhD, Chief Engagement Officer, NIH

Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.

Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin A4

IMPROVING STUDY START-UP PROCESS, BUSINESS OPS AND GLOBAL SITE ACTIVATION AT SCALE

3:45 **Chairperson's Remarks**

Chris J. Hoyle, Executive Director, Elite Research Network

3:50 **Improving Study Start-Up Processes at Scale: Keys to Efficient, Global Site Activation**

David Rudnick, CRA Manager, Global Drug Development, Novartis

Study Start-up involves several key inputs to prepare for site activation, including feasibility and site selection, regulatory approval, vendor set-up, and site training. Management of these activities must carefully balance between centralized functional specialists and local experts. An effective start-up strategy should focus on speed and efficiency while positioning for successful patient recruitment and quality data collection.

4:20 **Balancing the Two Sides of the Study Start-Up Equation**

Melissa Easy, Vice President, R&D Technology Solutions, IQVIA

Improving Study Start-up and Performance in Multi-Center and Decentralized Trials

Study start-up is a costly process that can consume up to 60% of total trial duration. To deliver on their promise of subtracting time from study start-up, digital solutions must balance both sides of the site-sponsor equation. We'll discuss what's needed to give trials a head start that lasts:

Get sites to embrace rather than avoid your study start-up tech platform

Empower your clinical development organization to continually improve start-up times

4:50 CO-PRESENTATION: Making Strategic Study Start-Up & Enrollment a Reality through Practical Application & Results

Suzanne Caruso, Senior Vice President, Clinical Solutions – Insights and Analytics, WCG

Amanda Steenbergen, Senior Director, Global Clinical Training & Business Analyst, WCG Trifecta

The industry has been talking about study start-up for more than 20 years, yet it is still one of the most challenging and unpredictable parts of a clinical trial. This presentation will discuss how to remove variability from the study start-up process and move towards practical, predictable applications that will allow sponsors to build and deliver upon operational timelines, while also bringing in the investigators' point of view.

5:20 CO-PRESENTATION: Rethinking the Business of Clinical Trials and How We Plan and Deliver Strategically and Operationally

Michelle Everill, Senior Director, Head, Clinical Business Operations, Bristol Myers Squibb Co.

Dana Cole, Director, Clinical Trial Business Planning, Bristol Myers Squibb Co.

Megan Coleman, Associate Director, Clinical Trial Business Delivery, Bristol Myers Squibb Co.

Through recognition and acceptance of the growing complexity within the Clinical Trial landscape, the necessity of building a foundation for real-time observation becomes clear; only then will nimble implementation of strategy and tactics occur.

5:50 Close of Day

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast

ROOM LOCATION: Gatlin A4

DEPLOYING AND DE-RISKING TECH FOR STUDY START-UP

8:20 Chairperson's Remarks

Jill Johnston, President, Study Planning & Site Optimization, WCG

8:25 CO-PRESENTATION: Global Enterprise Implementation of Site Single Sign-On Technology at Janssen

Sandra Freeman, Director, Global Clinical Operations, Janssen Pharmaceuticals

Gary Summer, IT Director, Clinical Investigator Systems, Global Clinical Operations, Janssen

Janssen has consistently heard feedback from sites regarding the complexity of managing multiple credentials for the myriad of applications required by a sponsor to conduct a study at their site. Janssen launched a single sign-on platform in August 2021 which supports a single, non-expiring credential that will support a majority of clinical applications by 2Q2022. Ease of engagement with applications should increase likelihood of compliance and improve end user experience.

8:50 CO-PRESENTATION: De-Risking Tech with the Study Team First: Tech4Trials Program at Bayer

Michelle Shogren, Senior Director Innovation, Pharma R&D Clinical Operations, Bayer HealthCare

Julien Kroll, Clinical Trial Technology Strategist, Bayer HealthCare

Kimberly Todd, PhD, PMP, Innovation Manager, Americas, Bayer Pharmaceuticals

How many times have we heard "That is a great idea but not in my study" because teams are concerned about the perceived risk of working differently? Change is hard and scary but also necessary. Come hear how Bayer is supporting study teams, sites, and patients adopt technology in clinical trials.

EXPANDING INTO COMMUNITY-BASED SITES & RE-THINKING SITE RELATIONSHIPS FOR INTERNAL CHANGE MANAGEMENT

9:15 CO-PRESENTATION: Case Study: How Expanding into Community-Based Sites Broadens Access to Patients and Combats Increased Trial Competition

Kim Hawkins, Head, Clinical Project Operations & Dossier Delivery, Sanofi

Liz Beatty, Chief Strategy Officer, Inato

In planning for upcoming trials in highly competitive disease areas, Sanofi was seeking a solution to accelerate timelines and reach new patient pools. Learn how, by partnering with pre-verified, community-based sites through Inato's Marketplace, Sanofi was able to overcome early trial delays and access new sites and their patients. Attendees will learn: approaches to partner with a broader range of community sites; strategies to succeed in competitive disease areas and meet trial timelines; insights from community site leaders.

9:45 Panel Discussion: Rethinking Site Relationships, Utilizing Sites to Pave the Way to Internal Change

Moderator: Valerie Reynaert, Executive Director & Head, Global Clinical Operations, CSL Behring

Discover how we obtain real time insights from patients, key opinion leaders and sites to streamline our internal structure, build out new therapeutic areas and foster ongoing engagement.

Panelists:

Jennifer Weaver, Director, Study Delivery Shared Services and Analytics, CSL Behring

Ross Watson, Director, Global Site Partnerships, CSL Behring

10:10 CO-PRESENTATION: Q&A: What do Olympic Medalist Lindsey Vonn and Protocol Compliance Management Have in Common?

Esther Howard, CEO, Bezyl Inc.

Mark Surles, CEO, ScienceMedia, Inc.

Efficiency, quality, endurance, speed. Those are the qualities needed for winning an Olympic medal—and what you should and can expect from

active protocol compliance management. Through a dialog of industry trends and real-world experiences, learn ways to reduce key risks to study startup and site performance in the context of site-based and hybrid trials, and recognize how significant study-related education is to improving compliance.

10:40 Networking Coffee Break

LESSON LEARNED FROM COVID AND BEYOND IN REMOTE DECENTRALIZED CLINICAL TRIALS (RDCTs)

10:55 Chairperson's Remarks
Charlie Speno, Senior Director, Business Development, Clinical Trials, Matrix Clinical Trials

11:00 CO-PRESENTATION: IMI Trials@Home: 'Remote Decentralized Clinical Trials' (RDCTs) Technology and Process Lessons for Sponsors, Sites and Patients
Megan Heath, Vice President, Region Head, Clinical Studies Unit Europe, Sanofi
Kim Hawkins, Head, Global Clinical Project Operations & Dossiers Delivery, Sanofi
Trials@Home aims to reshape clinical trial design, conduct and operations by developing and piloting standards, recommendations and tools for the definition and operationalization of remote decentralized trials in Europe. We will discuss the experience to date, including lessons learned, barriers and hurdles as well as next steps in the project, including the pilot study to evaluate different RDCT operating models.

12:00 Transition to Shared Sessions or Brief Session Break

ROOM CHANGE: Gatlin A1

ENGAGING AND SUPPORTING PATIENTS AND SITES E2E WITH DIGITAL OUTREACH, VIRTUAL WAITING ROOMS, AND TECHNOLOGY

12:00 pm Chairperson's Remarks
Melissa Easy, Vice President, R&D Technology Solutions, IQVIA

12:05 CO-PRESENTATION: What We Learned About E2E Trial Engagement through Smart Use of Technology
Maura Snyder, Global Head Clinical Trial Engagement, Clinical Insights & Experience, Janssen Pharmaceuticals, Inc.
Lieven Van Vijnckt, Head, Investigator & Patient Engagement, Infectious Disease and Vaccines (ID&V), Janssen Pharmaceuticals, Inc.
Janssen collaborated to engage several novel patient platforms for Ensemble 1, a phase 3 trial of Janssen's COVID-19 vaccine. This talk will share what we learned about E2E trial engagement through smart use of technology and Home Health Services in Janssen's phase 3 COVID-19 vaccine trial, ENSEMBLE 1.

12:30 Sponsors Supporting Sites with Digital Outreach and Virtual Waiting Rooms for Patients
Melanie Goodwin, Director, Patient Recruitment Programs, Clinical Development & Operations, Global Product Development, Pfizer Inc.
Innovators from sponsor/vendors/CROs/sites have responded to the Covid pandemic with grit and creativity. One of the outcomes is the continued drive to create and deliver truly patient-centric trials. Our team at Pfizer has challenged ourselves to enable faster, safer and more flexible trials that match patient need and the new reality of reduced timelines. This presentation will share some new work in digital outreach and virtual waiting room for patients.

1:05 Transition to Lunch

SCOPE SEND OFF LUNCHEON PRESENTATIONS

Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring
Nekzad Shroff, Vice President, Product Management, Saama Technologies
Aditya Gadiko, Director of Clinical Informatics, Saama Technologies
Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials
Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 SCOPE Summit 2022 Adjourns

Program Advisory Board

February 8-9, 2022 | All Tmes EST

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

Kafayat Babajide, MBA,
Associate Director, Patient Portals, Janssen

Kimberly Richardson,
Research Advocate, Founder of the Black Cancer Collaborative

Laurie Myers,
Director, Global Health Literacy, Merck & Co Inc

Alicia Staley, MBA,
Trial Volunteer & Cancer Survivor; Senior Director, Patient Engagement, Medidata

Lori Abrams,
Executive Director, Patient Advocacy & Diversity, WCG

Adama Ibrahim,
EMBA, Director, Digital Solutions, Novartis

MONDAY, FEBRUARY 7

8:00 am **SCOPE's Inaugural Masters of Clinical Research Golf Tournament**
Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 **Conference Registration Open (Gatlin Foyer)**

2:00 pm **User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)**
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 **Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants**
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 **Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes**



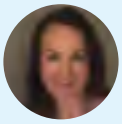

Moderator: Irfan Khan, MD, CEO, Circuit Clinical

Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

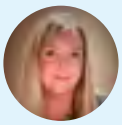
5:45 **SCOPE's 2022 Participant Engagement Awards Introduction**
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 **SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards**










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries,

Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co., Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 **SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)**

7:45 **Close of Day**

TUESDAY, FEBRUARY 8

7:15 am **Registration Open (Gatlin Foyer)**

7:15 **Morning Coffee** *(Sponsorship Opportunity Available)*

KEYNOTE LOCATION: Gatlin A1 & A2

NNEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 **Chairperson's Introduction**
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: **Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World**



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron

The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: **Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale**
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange, and clinical research? How do you do this at scale?

9:55 **Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin A1

BUILDING DIVERSITY, EQUITY AND INCLUSION (DE&I) INTO OUR TRIALS AND ENROLLMENT

10:55 **Chairperson's Remarks**
Neil Weisman, President, Continuum Clinical

11:00 **CO-PRESENTATION: Developing and Deploying a D, E & I Strategy in Clinical and Beyond**
Kim Hawkins, Head, Global Clinical Project Operations & Dossiers Delivery, Sanofi
Paul Cox, PhD, Country Head U.S. Clinical Study Unit, Clinical Science & Operations, Sanofi
Sanofi is committed to increasing diversity in clinical trials based on the belief that all individuals should have the opportunity to be included in clinical trials, particularly people from diverse populations who are often under-represented in clinical research. We will provide an overview of the current state and discuss how Sanofi has approached the barriers, challenges, and environment and developed a strategy and collaborations for increasing diversity in clinical trials.

11:30 **CO-PRESENTATION: How to Enroll Minority Patients: Disparities in Trials, Developing a Research Plan, Using Education and Technology**
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Ryan Nguyen, DO, Chief Hematology Oncology Fellow, University of Illinois Cancer Center
Cancer clinical trials have historically lacked equitable representation of racial and ethnic minority populations and have the potential to perpetuate outcome disparities. Barriers to equitable clinical trial enrollment are multi-level and include exclusionary clinical trial design, access to care,

and provider bias and cultural competency. Patient-focused educational modules offer a technology solution to empower patients to make informed decision about clinical trial enrollment.

12:00 pm CO-PRESENTATION: Bridging the Diversity Gap in Clinical Trials

Adrelia Allen, PharmD, PMP, Director, Clinical Trial Patient Diversity, Merck

Lynne Howell, Associate Director, Clinical Research-Infectious Disease, Merck

COVID-19 put a spotlight on health disparities and the need to focus on inclusion of diverse patients in trials. This HIV study team did not let the pandemic prevent them from achieving their goal of enrolling a diverse population in three U.S. trials for a once-daily treatment for HIV. This case study will highlight the strategies implemented to make these HIV trials more inclusive of the patients impacted by HIV.

12:30 Patient Compensation Taboo: Navigating Compensation's Impact on Patients' Ability & Motivation to Participate in Trials

Ivor Clarke, CEO, SubjectWell

With limited industry discussion or standardization, each trial faces the challenge of setting appropriate patient compensation. We'll share data on how varied compensation messaging and stipend amounts impact patients' willingness and ability to participate in a trial. Plus, we'll explore the complex relationship between diversity, clinical benefit, compensation, and enrollment.

1:00 Transition to Lunch

1:03 CO-PRESENTATION: LUNCHEON PRESENTATION: Pandemics, Pipelines and Patients: A Fireside Chat with Takeda's Patient Recruitment and Retention Team

Robert Loll, Senior Vice President, Business Development & Strategic Planning, Praxis Communications, LLC

Amanda Decoker, Director, Patient Recruitment & Retention Global Clinical Operations, Takeda Pharmaceutical Company Limited

The pandemic has made a permanent impact on how clinical research is conducted. Join this unplugged discussion focusing on key patient recruitment and retention takeaways from the pandemic and how to incorporate these learnings into strategic planning moving forward. We'll explore how the adjustments tie into being able to work together to advance research and deliver results while keeping patients top of mind.

1:35 Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)

MOTIVATING HCPs & UTILIZING PATIENT INSIGHTS FOR IMPROVED RECRUITMENT

2:30 Chairperson's Remarks

Kent Siri, Vice President of Marketing and Head of Diversity Initiatives, Reify Health

2:35 Encourage and Support Communities and Community Health Systems to Engage in the Clinical Trial Referral Process

Karen Correa, PhD, Vice President, Clinical Operations, Takeda Pharmaceutical Co., Ltd.

There are no standards or processes in place for how to effectively educate and motivate HCPs to be ongoing clinical trial referrers. This is an area of high potential and under-utilization. Engaging with communities and community health systems will help increase education, awareness and access to clinical trials in underrepresented populations. This presentation will focus on supporting these entities with a sustainable process.

3:05 CO-PRESENTATION: Increasing Site Enrollment Capacity: A Combination of Strategy and Augmentation that Works

Seth Halvorson, General Manager, WCG Threewire

Tyler Bye, Director, Program Strategy and Product Development, WCG ThreeWire

Each patient's journey begins with proper identification, but how are sponsors utilizing the right tactics to best support (and adapt) their enrollment strategy in the long run? In this session, our enrollment experts will describe how sponsors and sites have implemented tools and processes that fulfill evolving demands in study conduct. Learn how best-in-class knowledge across industry-sponsored trials has enabled sites to adapt and perform—even with never-before-seen resource constraints.

3:35 CO-PRESENTATION: How Insights Inspired Successful Recruitment and Retention Strategies

Maura Snyder, Global Head Clinical Trial Engagement, Clinical Insights & Experience, Janssen Pharmaceuticals, Inc.

Alyson Gregg, Director Patient Insights, Janssen Pharmaceuticals, Inc.

How insights inspired successful recruitment & retention strategies for Janssen's phase 3 COVID-19 vaccine trial, ENSEMBLE 1. Ensemble 1 is a phase 3 trial of Janssen's COVID-19 vaccine (Ad26.COV2.S.) involving approximately 45,000 adult participants. Hear how Janssen collaborated with CISCRP to develop insights that led to the development of successful operational strategies to support rapid enrolment of a diverse participant population and to engage and support them through the trial.

4:05 Improving the Research Experience for Patients through Omnichannel Engagement and the Decentralized Trial Method

Parag More, Executive Director, Healthcare Analytics Solutions, Quest Diagnostics

Traditional Clinical Trial recruitment has long struggled with the issues of inadequate enrollment, participant diversity, and retention resulting in underpowered and prematurely closed studies. Using multiple outreach channels (Omnichannels) Quest Diagnostics is establishing community based service locations to reach a more diverse population by meeting people "where they live", including rural, culturally, and racially diverse communities.

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 Find Your Table and Meet Your Moderators

4:40 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please

come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)

6:40 Close of Day

WEDNESDAY, FEBRUARY 9

7:15 am Registration Open (Gatlin Foyer)

BREAKFAST PRESENTATIONS

Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 Practical Approaches for Operationalizing DCTs Room Location: Gatlin A1

Kyle Hogan, President, Datacubed Health

Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2

Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS

Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin A1

IMPROVING DIGITAL OUTREACH AND COMMUNITY ENGAGEMENT WITH HI-TECH AND HI-TOUCH

8:20 Chairperson's Remarks

Rob Bohacs, Founder & Chief Solutions Officer, ClinOne

8:25 Leveraging Trustworthy Voices and Big Data to Improve Digital Outreach and Community Engagement

Mary Murray, Vice President, Collaborative Action Networks, National Minority Quality Forum

Social media and big data are critical drivers for forming communities around healthcare issues. For clinical trials, we can unite communities by sharing accurate data and information through trustworthy voices in a way that brings more community members into the conversation. We will share examples of successful strategies and campaigns, offering insights into effective practices, toolkits, and meaningful metrics to drive and track engagement down to the zip code level.

8:55 CO-PRESENTATION: Improving Oncology Clinical Trials with Technology to Connect, Inform, and Empower Patients

Rob Bohacs, Founder & Chief Solutions Officer, ClinOne

Amanda Siegert, Associate Director, Patient Recruitment, Medpace

It's no longer good enough to be "good enough." What are five simple things we can implement today to make it easier for patients to say "yes" to participating (and staying) in our clinical trials?

9:25 Predicting and Achieving Enrollment for Global Programs through Virtual Reality and Simulation

Sara Pierson, Director, Patient Recruitment Programs, Pfizer Inc.

Virtual Reality is more realistic than ever and can simulate a scenario-based encounter with a patient. The simulation allows learning and experimentation through active decision-making that can be applied in real-world practice. The application of VR and simulation between participants and their clinical team immerses both parties into the experience and can enable a study team to better predict flaws early on and increase the likelihood of successful enrollment.

9:55 CO-PRESENTATION: Diversity in Clinical Trials: Moving from Insight to Action, Earlier in the Funnel

Ralph Passarella, Chief Executive Officer, Reify Health

Natalie Cheung Rotelli, Advisor of Diversity in Clinical Trials, Eli Lilly and Company

Neha Londoño, Director, Clinical Trial Diversity and Inclusion, Seagen

Improving clinical trial participant diversity is a key priority for the life sciences industry. But how can sponsors take corrective action with limited demographic data captured during a trial?A new category of solutions has emerged to provide race and ethnicity data earlier in recruitment, unveiling how trial design affects candidates throughout enrollment. D&I leaders will discuss strategies they are deploying to improve diversity, access, and equity across their trials.

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

IMPLEMENTING AN EVIDENCE- AND VALUE-BASED CLINICAL ENROLLMENT PLAN

11:20 Chairperson's Remarks

Robert Loll, Senior Vice President, Business Development & Strategic Planning, Praxis

11:40 Protocol Design from a Site's and Sponsor's Perspective: What Sponsors Should Know to Increase Diverse Populations in Their Trials

Audrey Escobedo-Escotto, MD, MPH, Director, Research, Emerson Clinical Research Institute

Inclusion of diverse populations in clinical trials has been brought more to light in these last years. Many sponsors have realized the importance of having specialized teams to develop tools to increase diverse populations in their studies. Today, sponsors will learn what they are missing in their protocols based on a site's experience in diversity enrollment. Strategies for inclusion, retention, protocol development, and more.

11:25 CO-PRESENTATION: The Making of Merck's new Clinical Trial Finder website

Gwenn Oakes, Director, Global Trial Optimization, Merck

Neil Weisman, President, Continuum Clinical

Kara Monson, Sr. Scientist, Global Trial Optimization, Merck

In this case study, Merck and partner Continuum Clinical explore the challenges and opportunities uncovered in the making of Merck's new clinical trial finder website. From planning to startup through development and execution, learn how Merck organized its ~1,700 ongoing clinical trials as part of an engaging platform that prioritized health literacy, the importance of participant diversity, and the demand for transparency while fueling trial enrollment and improving retention.

11:55 Transition to Lunch

12:00 pm CO-PRESENTATION: LUNCHEON PRESENTATION: Think Further: Platform Communications Across a Portfolio of Studies

Klaira Simon, Managing Director, Clinical Trial Experience, Langland

Andrea Bartucca, Director, Trial Awareness, Forma Therapeutics

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

1:30 Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!*

**Separate registration required for access to Part B conferences, upgrade to Best Value Package.*

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 Welcome Remarks from CHI and the SCOPE Team

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

Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative

Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:00 Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership

Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative

What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.

Panelists:

Karriem Watson, PhD, Chief Engagement Officer, NIH

Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.

Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)

*Don't forget Part B Conferences begin at 3:45pm **Separate registration required, upgrade to Best Value Package.*

Program Advisory Board

February 9-10, 2022 | All Tmes EST

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

Kafayat Babajide, MBA,
Associate Director, Patient Portals, Janssen

Kimberly Richardson,
Research Advocate, Founder of the Black Cancer Collaborative

Laurie Myers,
Director, Global Health Literacy, Merck & Co Inc

Alicia Staley, MBA,
Trial Volunteer & Cancer Survivor; Senior Director, Patient Engagement, Medidata

Lori Abrams,
Executive Director, Patient Advocacy & Diversity, WCG

Adama Ibrahim,
EMBA, Director, Digital Solutions, Novartis

WEDNESDAY, FEBRUARY 9

ROOM LOCATION: Gatlin A1

BRIDGING LUNCHEON PRESENTATION

12:00 pm **CO-PRESENTATION: LUNCHEON PRESENTATION: Think Further: Platform Communications Across a Portfolio of Studies** LANGLAND

Klaira Simon, Managing Director, Clinical Trial Experience, Langland
Andrea Bartucca, Director, Trial Awareness, Forma Therapeutics

12:30 **Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)** *(Sponsorship Opportunity Available)*

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 **Welcome Remarks from CHI and the SCOPE Team**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
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Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin A1

INTEGRATED PATIENT CENTRICITY IN R&D FROM DISCOVERY TO DELIVERY

3:45 **Chairperson's Remarks**
Ivor Clarke, CEO, SubjectWell

3:50 **CO-PRESENTATION: Evolving Model for Integrated Patient Centricity in R&D from Discovery to Delivery**
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Anthony Yanni, MD, Senior Vice President and Global Head, Patient Centricity, Astellas
Join former colleagues Vicky DiBiaso, Global Head, Patient Informed Development & Health Value Translation at Sanofi, and Anthony Yanni, Senior Vice President and Global Head of Patient Centricity at Astellas Pharma Inc., in their conversation on the evolution of patient centricity and what it means to holistically deliver value to patients from drug discovery to delivery.

4:20 **Leveraging Critical Insights from Patients and Care Partners in Trial Protocols to Create More Inclusive, Patient-Friendly Studies**
Michelle Shogren, Senior Director Innovation, Pharma R&D Clinical Operations, Bayer HealthCare

Deploying patient-facing digital technology and incorporating patient and care partner voice in decentralized clinical trials enable the generation of critical insights. In this talk, TransCelerate will share best practices for deploying digital technologies in DCTs with a focus on understanding patient and care partner voice; they will analyze lessons learned from engaging patients, care partners, sites, sponsors, and regulators in conversations about deploying technology and improving patient experience with DCTs.

4:50 The Rise of Decentralized Trials is Disrupting Patient Engagement SubjectWell

Ivor Clarke, CEO, SubjectWell

Decentralized clinical trials (DCTS) with all of their well-loved patient accommodations ironically pairs with a reduction in the role of sites, previously dedicated to patient care. This session explores the holes created by DCTs with sites' reduced involvement. We'll look at patients' preferred accommodations based on extensive data from patient surveys. Plus, we'll share case studies from recent DCTs, detailing the emerging education, technology and engagement solutions.

ACCESSIBILITY FOR DIVERSE AND UNDERSERVED PATIENT POPULATIONS

5:20 Panel Discussion: Lack of Diversity in Clinical Trials is a Public Health Issue: An Issue We Can NO Longer Ignore

Moderator: Lori B. Abrams, Vice President, Patient Advocacy & Clinical Research Diversity, WCG

The lack of diversity in clinical trials mimics the health disparities and racial health injustices that have been pervasive in our country for centuries. When looking for sustainable solutions that address underrepresentation in clinical research trials, we must examine the imbalance between multiple stakeholder actions and other factors outside of healthcare.

Panelists:

Allison Kemner, Vice President, Clinical Sciences and Operations, Tyra Biosciences

Jeanne Regnante, Chief Health Equity and Diversity Officer, LUNGevity Foundation

LaTasha Lee, PhD, Adjunct Professor, Clinical Research & Leadership, George Washington University

5:50 Close of Day

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast (Gatlin Foyer)

ROOM LOCATION: Gatlin A1

LISTENING, CONNECTING, INFORMING AND EMPOWERING PATIENTS FOR IMPROVED TRIALS

8:25 Mining Real-Time Experience with My Trial Community

Kafayat Babajide, MBA, Associate Director, Patient Portals, Janssen Research & Development, LLC

My Trial Community is a patient platform educating Janssen trial participants on what to expect, empowering them with a selection of their own personal data and study results, and engaging them as valued stakeholders. The Janssen team has learned a lot from patients since initially launching the site in August 2021 and is happy to share key insights.

8:50 Incorporating Site and Patient Input into Clinical Development Planning

Michele Teufel, Patient & Site Engagement Lead, Development Operations, AstraZeneca Pharmaceuticals, Inc.

At AstraZeneca, we are committed to improving the whole patient experience by embedding patient-centric thinking in the medicines, products, and services we develop. For clinical trials, this means we engage and listen to our patients and sites throughout clinical development planning. During this presentation, you will hear how we are implementing this approach by setting up processes and by engaging early with key stakeholders.

9:15 Talk Title to be Announced Lightship

David MacMurchy, Chief Executive Officer, Lightship Inc.

9:45 Our Journey in Developing a More Patient Centric Informed Consent Template

Jennifer Ribeiro, Director, Clinical Trial Model Documents & Informed Consent, Bristol Myers Squibb Co.

BMS has been working through a full revamp of our informed consent main template during 2020 and 2021. This was a process that required multiple cross functional stakeholders' engagement & change management in order to develop a more robust template.

10:10 CO-PRESENTATION: Q&A: What do Olympic Medalist Lindsey Vonn and Protocol Compliance Management Have in Common? ScienceMedia

Esther Howard, CEO, Bezyl Inc.

Mark Surles, CEO, ScienceMedia, Inc.

Efficiency, quality, endurance, speed. Those are the qualities needed for winning an Olympic medal—and what you should and can expect from active protocol compliance management. Through a dialog of industry trends and real-world experiences, learn ways to reduce key risks to study startup and site performance in the context of site-based and hybrid trials, and recognize how significant study-related education is to improving compliance.

10:40 Networking Coffee Break (Gatlin Foyer)

THE "BEHAVIORAL ECONOMICS" OF PATIENT ENGAGEMENT

10:55 Chairperson's Remarks

Melissa Easy, Vice President, R&D Technology Solutions, IQVIA

11:00 The "Behavioral Economics" of Patient Engagement in Clinical Trials: Understanding Patient Need and Behavior to Make Informed Decisions in Enrollment Planning

Karen Horgan, CEO & Co-Founder, VAL Health LLC

We're adding new tools based on how we want patients to act, not around how people actually behave. Telehealth, digital health tools, and patient portals are expanding initiatives, but we know that technology alone doesn't drive behavior change as we see patients, providers, consumers, and other stakeholders struggle to begin to engage with the offerings, let alone to continue engaging with them in the long term.

11:30 CO-PRESENTATION: How the Use of a Real-World Data Driven Strategy Informs and Delivers a IQVIA

More Meaningful Patient Centric Trial Experience

Katie Shaw, Senior Director, Patient Recruitment & Enablement, Global Patient and Site Services, IQVIA

Elizabeth Powers, Vice President & Category Lead of Regulatory and Safety Offerings, Real World Solutions, IQVIA

The drug development industry has access to vast stores of real-world data (RWD) that reflect the healthcare journeys of millions of patients across the globe. And the scale of these assets grows exponentially every day. Armed with more information than ever about a patient's health journey, means sponsors can accelerate recruitment, engage with diverse populations, and deliver a patient centric trial experience.

12:00 **Transition to Shared Sessions or Brief Session Break**

ENGAGING AND SUPPORTING PATIENTS AND SITES E2E WITH DIGITAL OUTREACH, VIRTUAL WAITING ROOMS, AND TECHNOLOGY

12:00 pm **Chairperson's Remarks**

Melissa Easy, Vice President, R&D Technology Solutions, IQVIA

12:05 **CO-PRESENTATION: What We Learned About E2E Trial Engagement through Smart Use of Technology**

Maura Snyder, Global Head Clinical Trial Engagement, Clinical Insights & Experience, Janssen Pharmaceuticals, Inc.

Lieven Van Vijnckt, Head, Investigator & Patient Engagement, Infectious Disease and Vaccines (ID&V), Janssen Pharmaceuticals, Inc.

Janssen collaborated to engage several novel patient platforms for Ensemble 1, a phase 3 trial of Janssen's COVID-19 vaccine. This talk will share what we learned about E2E trial engagement through smart use of technology and Home Health Services in Janssen's phase 3 COVID-19 vaccine trial, ENSEMBLE 1.

12:30 **Sponsors Supporting Sites with Digital Outreach and Virtual Waiting Rooms for Patients**

Melanie Goodwin, Director, Patient Recruitment Programs, Clinical Development & Operations, Global Product Development, Pfizer Inc.

Innovators from sponsor/vendors/CROs/sites have responded to the Covid pandemic with grit and creativity. One of the outcomes is the continued drive to create and deliver truly patient-centric trials. Our team at Pfizer has challenged ourselves to enable faster, safer and more flexible trials that match patient need and the new reality of reduced timelines. This presentation will share some new work in digital outreach and virtual waiting room for patients.

1:05 **Transition to Lunch**

SCOPE SEND OFF LUNCHEON PRESENTATIONS

Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 **CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring**

Nekzad Shroff, Vice President, Product Management, Saama Technologies

Aditya Gadiko, Director of Clinical Informatics, Saama Technologies

Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 **Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials**

Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 **SCOPE Summit 2022 Adjourns**

"It was so great to hear firsthand what so many organizations are doing to make sure the patient voice is heard throughout their clinical journey, not just in the planning but the execution as well. Thank you!"

MONDAY, FEBRUARY 7

8:00 am SCOPE's Inaugural Masters of Clinical Research Golf Tournament

Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 Conference Registration Open (Gatlin Foyer)

2:00 pm User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)

Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

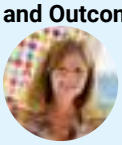
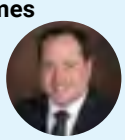
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

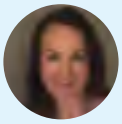
Moderator: Irfan Khan, MD, CEO, Circuit Clinical
Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

February 8-9, 2022 | All Tmes EST

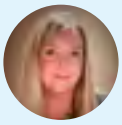
5:45 SCOPE's 2022 Participant Engagement Awards Introduction
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co., Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine

Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)

7:45 Close of Day

TUESDAY, FEBRUARY 8

7:15 am Registration Open (Gatlin Foyer)

7:15 Morning Coffee *(Sponsorship Opportunity Available)*

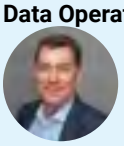
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 Chairperson's Introduction
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange, and clinical research? How do you do this at scale?

9:55 Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

ROOM LOCATION: Gatlin A3

CLINICAL TRIAL MANAGEMENT: EXPLORING STRATEGIES IN FORECASTING, BUDGETING, AND CROSS-DEPARTMENT COLLABORATION

10:55 Chairperson's Remarks
Christopher Chan, Vice President, FP&A, IGM Biosciences, Inc.

11:00 A Large Pharma's Approach to Clinical Trial Cost Forecasting and Management
Piet Theisohn, Vice President, Resource Management, Clinical Operations, R&D Clinical Operations, Bayer AG – Pharma
Bayer implemented an integrated system to manage the finances of all interventional clinical trials. This covers the early planning five years down the road and the operational management of ongoing trials, including forecasting on annual, quarterly, and monthly level, whole study and per country. We'll give an intro to our approach and integration with different systems and discuss strength and development areas and give an outlook.

12:00 pm Leveraging Operational Data in Clinical Trial Forecasting
Keith Jones, Senior Director, Financial Planning & Analysis, Ovid Therapeutics, Inc.
Biopharmaceutical sponsors with little institutional clinical history are often at the mercy of large clinical datasets. Benchmark comparisons are often not relevant when studies are in rare or ultra-rare diseases. Leveraging internal clinical metrics, even when the data is sparse, can help immensely to hone clinical trial forecasts. This session will look at CTA contracting timelines, feasibility, patient recruitment, and other clinical data as forecasting sources.

12:30 Fueling the Future of Clinical Research Planning and Execution
Kyle Cunningham, Chief Product Officer, Greenphire
The ability to accurately forecast and predict is critical to clinical trial outcomes, yet this remains a top challenge in study planning and execution. We turn to data for guidance but how do we ensure the data we are referencing is reliable? This session will touch on key use cases for better, industry-indicative data points and how technology can help to ensure data integrity for better decision making and smarter trials.

1:00 Transition to Lunch

1:05 LUNCHEON PRESENTATION: Site Budgeting &

Payments: Keep the Fundamentals While Introducing Innovation to Financial Management
Meghan Harrington, Vice President, Clinical Financial Management, Medidata, a Dassault Systèmes Company
Budgeting and payments are always hot topics. But why do we always seem to talk about the same strategies? While the fundamentals of these processes still ring true, technology is now enabling novel approaches to operationalize clinical finance strategies. Join this session with Medidata's VP of Product to learn how to optimize what we know already works well, and hear industry examples of fresh approaches to managing budget and payment processes.

1:35 **Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)**

STRATEGIES FOR ROI AND COST SAVINGS

2:30 **Chairperson's Remarks**
Anca Copaescu, CEO, Strategikon Pharma

2:35 **Case Study: Building the Financial Rationale (Return on Investment) for a Rollover Protocol**
Kenneth Wilson, Outsourcing Lead, Global Product Development Center of Excellence, Pfizer Inc.
This talk will discuss how to build the financial justification for rolling parent protocols into a single asset rollover protocol, including: examining financial projections for each parent protocol; projecting parent protocol spend if maintaining in current structure; building the rollover study specifications; projecting costs of the rollover protocol and examining costs savings of rollover protocol versus parent protocols.

3:05 **Forecasting Investigator Site Costs in Your Overall Clinical Trial Budget: Common Challenges and How to Mitigate Them as Painlessly as Possible**
Christopher Chan, Vice President, FP&A, IGM Biosciences, Inc.
Unfortunately, budgeting for investigator site costs is not as simple as composing a site budget and multiplying by projected number of sites and patients. Trials may have multiple complex variables, including out-of-scope procedures, unscheduled visits, mid-study protocol changes, SOC reimbursements, inconsistent screen failure time-points, patient expense, and more. This presentation will discuss relatively painless ways to budget for site costs and how to deal with confounding variables reasonably and effectively.

3:35 **Short Staffed? Forecasting and Budgeting the Cost of Your Clinical Trial Portfolio: Many Trials. One Financial Analyst**
Jennifer Sydney Goldman, Director, Clinical Business Operations, Deciphera Pharmaceuticals, Inc.
Small companies with limited cash need to accurately budget and forecast the cost of their clinical trial portfolio, but also cannot afford a team of clinical financial analysts to do so. Join me in this presentation to hear about techniques that expand the capacity of one person to efficiently budget and forecast a portfolio of trials, without losing their mind!

4:05 **Considerations for Service Provider Performance Management: Budget Oversight**
Anca Copaescu, CEO, Strategikon Pharma
In this session learn: What are the key oversight elements in the financial management of clinical service providers; Evaluation of cost drivers for different clinical study models: classic, remote, decentralized; Considerations for milestone tracking and payment schedules; Importance of analyzing different clinical study scenarios to determine the impact on execution strategy; How to leverage technology to expedite decision making and improve transparency in vendor financial oversight.

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 **Find Your Table and Meet Your Moderators**

4:40 **Interactive Discussions**
Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 **Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)**

6:40 **Close of Day**

WEDNESDAY, FEBRUARY 9

7:15 am **Registration Open (Gatlin Foyer)**

BREAKFAST PRESENTATIONS
Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 **Practical Approaches for Operationalizing DCTs**
Room Location: Gatlin A1
Kyle Hogan, President, Datacubed Health
Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 **Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2**
Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS
Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin A3

STREAMLINING THE CONTRACTING PHASE

8:20 Chairperson's Remarks
Mike Martin, Principal, ZS

8:25 Contracting & Budgeting Module in a New Study Start-up Tool: Initial Learnings
Donna Libretti Cooke, JD, Director, Contracting & Budgeting & Sustainability Champion, Bayer
Hear about Bayer's preparation for rolling out a new study start-up tool, specifically related to the Contracting & Budgeting module. Development of an ideal "wish list" for the module, sprint workshops, critically assessing processes, and garnering a new working group to champion the new way of working have all been part of the overall strategy. There will be more to share, perhaps even overcoming identified pain points. Stay tuned!

8:55 Model Contract Clauses on a National Level: Overview on Current Status
Thorsten Ruppert, PhD, Senior Manager, R&D & Innovation, Verband Forschender Arzneimittelhersteller eV
Industry-sponsored clinical trials benefit from favorable research infrastructures and streamlined study start-up processes. Currently, clinical trials worldwide face challenges regarding study start-up due to the time needed to finalize the contracting for a specific trial between the sites involved and the sponsor. This process currently in many countries is difficult and time-consuming. The talk should provide an overview of examples from different trial locations to address this problem.

9:25 Negotiating Site Contracts by Visit vs. Procedure: An Examination of Advantages and Challenges
Dave Posselt, Director, Site Contract Management, Abbvie, Inc.
In today's climate of increasingly compressed start-up timelines, there is an increased focus on negotiation timelines for clinical trial agreements. In this session, we will explore ways to reduce bottlenecks, measure team performance and speed up negotiations. We will explore in depth the benefits of negotiating site budgets by visit versus procedure.

9:55 Rate Cards, Start-Up Agreements, and Additional Discounts from Your Ancillary Providers
Bryan Clayton, M.S., Senior Vice President, Strategic Solutions, YPrime
Ancillary technologies and services can be a headache for the most seasoned clinical operations veterans. Often times the contract process drags on; and as a result, those same services end up on the critical path to the first-patient-in milestone.

This practical presentation will present ideas on how to leverage a predefined rate card to generate an easy to execute startup agreement, all while finding the potential for additional discounts.

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

ROOM CHANGE: Gatlin E5

CONTRACT LANGUAGE AND CYBERSECURITY

11:20 Talk Title to be Announced
Glenda Guest, Vice President, NCRA; President, Assured of Quality Consulting & Training

11:25 Cybersecurity in CTAs and Vendor Agreements: Proactive Management vs. Cleaning Up the Mess
Katherine Leibowitz, JD, Lawyer, Leibowitz LLC
While cyber risk is not new, cybersecurity language in CTAs and remote monitoring agreements is. Security incidents can impact multiple parties, creating mutuality of risk. This session will discuss sample cybersecurity language from research institutions and pitfalls for sponsors. Hear about lessons learned from sponsor audits of their vendor agreements for compliance with CTA cybersecurity obligations. Common gaps make sponsor CTA obligations heavier. Learn about contract provisions that mitigate risk.

11:30 Outsourcing Decision-Making Strategies and Partnership Models
Michelle Everill, Senior Director, Head, Clinical Business Operations, Bristol Myers Squibb Co.

12:00 pm Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

1:30 Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!*
Separate registration required for access to Part B conferences, upgrade to Best Value Package.

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 Welcome Remarks from CHI and the SCOPE Team
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative
Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:00 Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership




Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative

What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.

Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)

*Don't forget Part B Conferences begin at 3:45pm**Separate registration required, upgrade to Best Value package.*

WEDNESDAY, FEBRUARY 9

12:00 pm Enjoy Lunch on Your Own

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

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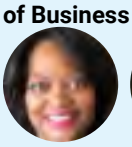

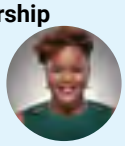


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2:45 Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)

ROOM LOCATION: Gatlin A3

TOOLS AND ALGORITHMS FOR RESOURCE MANAGEMENT AND CAPACITY PLANNING

3:45 Chairperson's Remarks

Jeff Kingsley, Founder & CEO, IACT Health

3:50 Developing Resource Planning and Management Capabilities

Jennifer Heckman, Executive Director, Clinical Portfolio & Capacity Management, Incyte

This presentation will highlight the journey a rapidly growing biopharma company has been on to accurately forecast resource needs to operationalize a robust portfolio of clinical trials. It will include challenges faced with introducing the concept of capacity planning, developing role-based algorithms, understanding needs based on trial complexity and sourcing models, introducing new tools and dashboards, and using the data to drive decision making.

4:20 Leveraging Data Visualization Tools to Develop Algorithms for Resource Forecasting

Geoff Kremer, Director, Portfolio Resourcing, Merck

Understanding how many resources are needed to fully execute clinical trials is critical to delivering the portfolio within required timelines. Credible and accurate algorithms are necessary to ensure functional areas are appropriately staffed and resources are on-board prior to study start. This talk will share best practices on how to leverage data visualization tools to effectively collaborate with stakeholders while building algorithms (and build trust in the final calculations).

4:50 CO-PRESENTATION: Solving Resource Challenges at Community Research Sites with JIT Models: Community Health Network & Tempus TIME Trial

TEMPUS

Matthew M. Cooney, Vice President of Therapeutic Development, Oncology, Tempus

Bert H. O'Neil, M.D., Director of Oncology Research, Community North Cancer Center

Providing patients in the community with access to clinical research is critical for health equality. Just-in-time approaches to clinical trial site activation, such as the Tempus TIME Trial program for oncology, have helped remove some of the resource barriers preventing community participation in research. Join our discussion with Community Health Network about their approach to bring more research opportunities to patients using the Tempus TIME Trial program.

5:20 Time and Cost Benefits of Master Protocols

Anthony Davidson, Associate Consultant, Design Hub Medical Writing, Eli Lilly & Company

With the consistent need for speed and "doing more with less," the establishment of Master Protocols offers a way to ease those with capacity limitations. This talk will highlight the advantages of Master Protocols and

the ways in which they reduce overall cost and time, freeing up resources for other tasks.

5:50 **Close of Day**

THURSDAY, FEBRUARY 10

7:15 am **Registration Open and Breakfast (Gatlin Foyer)**

ROOM LOCATION: Gatlin A3

COLLABORATION AMONG STAKEHOLDERS TO ADDRESS RESOURCES

8:20 **Chairperson's Remarks**
Speaker to be Announced

8:25 **CO-PRESENTATION: Using Machine Learning to Optimize Contract Resourcing and Speed Study Start-Up**
Natasha Gupta, PhD, Senior Data Scientist & Manager, Advanced Insights, Janssen Research
Allison Milack, Manager, Contracts and Centralized Services, Janssen
Xinyang Li, Senior Data Analyst, Advanced Insights, Janssen
Strategically prioritizing site startup is critical to accelerating study startup. Contracting cycle time is a rating-limiting step to study startup, and thus, a crucial part of startup time. We adopt machine-learning methods to predict contract cycle time to help prioritize which sites should go first for quick wins and earlier enrollment. The predictors used in model development include historical metrics, geographic location, and protocol information.

8:55 **: Site-Pharmacy Collaboration to Add Capacity, Improve Enrollment, and Enhance Patient Satisfaction**
Moderator: Jeff Kingsley, Founder & CEO, IACT Health
Patient enrollment and engagement remain the most challenging aspect of the clinical research process. You will learn: 1) How to engage with large geographically diverse healthcare institutions; 2) What processes will need to be in place to ensure a successful engagement; 3) What roles and responsibilities are altered, shared, or maintained by all individuals involved. And you will receive take-away material to assist in your ability to do the same.
Panelists:
Michael Cohen, Clinical Trial Innovation, CVS Health
Jessica Perry, Director, Patient Centricity, Clinical Innovation, Moderna

9:40 **Optimizing Strategic Enrollment Planning and Management with Country Operations**
Anisa Khan, Senior Scientist, Global Trial Optimization, Oncology Early Development, Merck & Co., Inc.
Key stakeholder alignment is critical in optimizing strategic enrollment. Collaborative resource planning can improve enrollment forecasting and management plans. This presentation will provide an overview on leveraging country operations expertise to drive strategic enrollment planning and management. Examples scenarios will showcase opportunities for applying country operations expertise and translating expert feedback into study enrollment plans.

10:10 **CO-PRESENTATION: Re-Crafting Resource Management Capabilities and Decision Support in the Wake of One of the Industry's Largest Mergers**
Ankita Praharaj, Business Operations Manager, ZS
Rohit Bhagwat, Principal, R&D and Data Science, ZS
Gregory Bayer, Senior Director, Portfolio Operations & Governance, BMS
Christopher O'Donovan, Director, Resource Management, BMS
One of the largest ever bio-pharma acquisitions/mergers prompted a significant evolution of BMS's portfolio, organizational structures, and operating and sourcing models across R&D functions. This presentation will focus on efforts to evolve BMS's resource forecast models for the new combined organization, including implementing data science techniques and strengthening underlying capabilities to enable informed portfolio and operational decision making.

10:40 **Networking Coffee Break (Gatlin Foyer)**

ROOM CHANGE: St. John's 22 & 23

Budgeting for and Contracting with New Technology Companies: Strategies and Challenges

10:55 **Roundtable Discussions: Budgeting for and Contracting with New Technology Companies: Strategies and Challenges**

CO-PRESENTATION: In-Person Only: Roundtable Discussions: Budgeting for and Contracting with New Technology Companies: Strategies and Challenges
Michael Agard, Team Leader Clinical Consulting, NNIT
Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences

11:30 **Sponsored Presentation** *(Opportunity Available)*

12:00 pm **Transition to Shared Sessions or Brief Session Break**

CLINICAL SUPPLY CHAIN: LESSONS LEARNED IN OUTSOURCING AND RESOURCE MANAGEMENT

12:05 FEATURED PRESENTATION: **Communication and Strong Partnerships are Critical to Ensuring a Reliable Supply Chain**
Luiz A. Barberini, CQE, CSCP, CPIM, Head, External Manufacturing Operations, Bayer SA
Communication and strong partnerships are critical to ensuring a reliable supply chain. The pandemic has tested and stretched all partnerships across the supply chain and Bayer will shed light on how teams became more agile to ensure a reliable supply. Adequate communication pacing, the sharing of the customer´s focus and the building of trust are keys to anticipate potential problems and to keep a reliable and steady supply.

12:35 **Maintaining Continuous Clinical Trial Material (CTM) Supply to Patients during the COVID-19 Pandemic**
Bryan O'Neill, Senior Director & Head, Clinical Supply Operations, Daiichi Sankyo, Inc.
The COVID-19 pandemic has created a variety of challenges across the clinical trial conduct space, and CTM supply is one of the areas impacted. To mitigate risk of infection associated with patients receiving CTM at clinical sites and hospitals, Daiichi Sankyo developed several approaches to maintain CTM supply in close collaboration with both internal and external stakeholders.

1:05 Transition to Lunch

SCOPE SEND OFF LUNCHEON PRESENTATIONS

Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring

Nekzad Shroff, Vice President, Product Management, Saama Technologies

Aditya Gadiko, Director of Clinical Informatics, Saama Technologies

Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials

Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 SCOPE Summit 2022 Adjourns

MONDAY, FEBRUARY 7

8:00 am SCOPE's Inaugural Masters of Clinical Research Golf Tournament

Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 Conference Registration Open (Gatlin Foyer)

2:00 pm User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)

Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

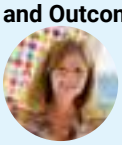
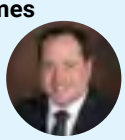
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

Moderator: Irfan Khan, MD, CEO, Circuit Clinical
Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical

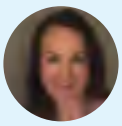
February 8-9, 2022 | All Tmes EST

Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

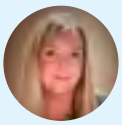
5:45 SCOPE's 2022 Participant Engagement Awards Introduction
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co., Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)

7:45 Close of Day

TUESDAY, FEBRUARY 8

7:15 am Registration Open (Gatlin Foyer)

7:15 Morning Coffee *(Sponsorship Opportunity Available)*

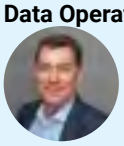
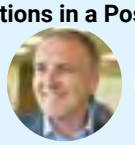
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 Chairperson's Introduction
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World


Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data

9:55 Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

ROOM LOCATION: St. John's 22 & 23

EXPLORING OUTSOURCING MODELS

10:55 Chairperson's Remarks
Rehbar Tayyabkhan, Head, R&D Sourcing & Procurement, Merck Research Labs

11:00 Objectives and Benefits for Development of a Business Strategy for Sourcing (BSS)
Leslie Williams, Associate Director, Vendor Strategy & Relationships, Clinical Development Operations, Abbvie
A well-defined business strategy for sourcing includes a business' short- and long-term goals identifies existing gaps, and leads to a focused strategy achieving business objectives. If the need for a sourcing event is identified, the BSS serves as the RFx, capability assessment, and future governance framework. This session will provide an overview of BSS development, elements of consideration, and a case study showing the positive impact of a proactive, strategic plan.

11:30 Outsourcing Decision-Making Strategies and Partnership Models
Michelle Everill, Senior Director, Head, Clinical Business Operations, Bristol Myers Squibb Co.

12:00 pm Think about Your FSP Model: Some Practical Considerations
Rehbar Tayyabkhan, Head, R&D Sourcing & Procurement, Merck Research Labs
Today's Pharma sponsors use a variety of sourcing approaches to support the execution of their development programs. Many sponsors partner with CROs under a functional service provider (FSP) model to serve as an execution arm or augment their internal teams. When considering models and the use of FSPs, there are some practical considerations and tips that can benefit both sponsors and service providers which we will aim to share and discuss.

12:30 Realizing the Benefits of the Largest Site Network in the Industry
Tim Schuckman, Chief Commercial Officer, WCG IRB
IRBs can be a conduit for sponsors looking to partner with institutions to streamline study start-up, significantly reduce site burden, and create a faster time for study enrollment. Speakers will share an example of how a top pharma company saved 276 day, eliminated redundant IRB reviews, improved quality, and reduced cost, all because they had the right institutional partners, the right data, and turned those insights into action.

1:00 Transition to Lunch

1:05 LUNCHEON PRESENTATION: The Role eRegulatory Technology Can Play to Support Clinical Trials
Rick Arlow, Founder & CEO, Complion

1:35 Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)

CASE STUDIES IN OUTSOURCING

Disease
Erin O'Boyle, Vice President, Clinical Operations, Rezolute, Inc.
Outsourcing strategy and vendor selection is one of the most important decisions for a Sponsor to make while setting up a clinical program. Depending on how many vendors need to be outsourced, that important decision may need to be made over a dozen times. Rare disease studies present the same challenges, but often the key vendors and stakeholders are underutilized and not appropriately resourced to support the study.

3:05 The Beginning of the Journey: Integrating Clinical Innovation into Clinical Outsourcing
Dennis Salotti, Senior Director & Head, Strategic Outsourcing & Clinical Innovation, Jazz Pharmaceuticals
Introducing clinical innovation into an organization as a capability and discipline can be approached in a variety of ways. This presentation will describe one approach – where clinical innovation is co-located within the clinical outsourcing function and will focus on the design, strategy and initial stages of implementation with a focus on key pieces of insight gained along the process.

3:35 Beyond the Brochure: Enhancing the Pediatric Patient Experience through Scientific Leader Engagement and Vendor Partnerships
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co., Inc.
Patients are the core of our research mission and our work expands beyond patient identification. Patient engagement is important to ensure continued support so participants can adhere to protocol requirements throughout treatment. Forging relationships to enhance the pediatric patient experience brought novel ideas to build on patient engagement and retention, allowing us to deliver on our common goal of making sure the patient remains at the center of our efforts.

4:05 Revolutionizing Outsourcing by Starting With the Patient
Pat Harrington, PhD, Vice President, Elligo Solutions, Elligo Health Research
What is the best way to access the 97% of patients who have never been involved in a clinical trial? A patient-first approach that maintains the trusted physician/patient relationship. Elligo Health Research® has access to known patients as well as their healthcare data and trusted physicians, and our eSolutions team, enabled by award-winning, innovative software, engages and retains patients throughout the clinical trial journey.

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 Find Your Table and Meet Your Moderators

4:40 Interactive Discussions
Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)

6:40 Close of Day

WEDNESDAY, FEBRUARY 9

7:15 am Registration Open (Gatlin Foyer)

BREAKFAST PRESENTATIONS
Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 Practical Approaches for Operationalizing DCTs Room Location: Gatlin A1
Kyle Hogan, President, Datacubed Health
Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2
Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS
Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin A3

STREAMLINING THE CONTRACTING PHASE

8:20 Chairperson's Remarks
Mike Martin, Principal, ZS

8:25 Contracting & Budgeting Module in a New Study Start-up Tool: Initial Learnings
Donna Libretti Cooke, JD, Director, Contracting & Budgeting & Sustainability Champion, Bayer
Hear about Bayer's preparation for rolling out a new study start-up tool, specifically related to the Contracting & Budgeting module. Development of an ideal "wish list" for the module, sprint workshops, critically assessing processes, and garnering a new working group to champion the new way of working have all been part of the overall strategy. There will be more to share, perhaps even overcoming identified pain points. Stay tuned!

8:55 Model Contract Clauses on a National Level: Overview on Current Status
Thorsten Ruppert, PhD, Senior Manager, R&D & Innovation, Verband Forschender Arzneimittelhersteller eV
Industry-sponsored clinical trials benefit from favorable research infrastructures and streamlined study start-up processes. Currently, clinical trials worldwide face challenges regarding study start-up due to the time needed to finalize the contracting for a specific trial between the sites involved and the sponsor. This process currently in many countries is difficult and time-consuming. The talk should provide an overview of examples from different trial locations to address this problem.

9:25 Negotiating Site Contracts by Visit vs. Procedure: An Examination of Advantages and Challenges
Dave Posselt, Director, Site Contract Management, Abbvie, Inc.
In today's climate of increasingly compressed start-up timelines, there is an increased focus on negotiation timelines for clinical trial agreements. In this session, we will explore ways to reduce bottlenecks, measure team performance and speed up negotiations. We will explore in depth the benefits of negotiating site budgets by visit versus procedure.

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

ROOM CHANGE: Gatlin E5

CONTRACT LANGUAGE AND CYBERSECURITY

11:20 Talk Title to be Announced
Glenda Guest, Vice President, NCRA; President, Assured of Quality Consulting & Training

11:25 Cybersecurity in CTAs and Vendor Agreements: Proactive Management vs. Cleaning Up the Mess
Katherine Leibowitz, JD, Lawyer, Leibowitz LLC
While cyber risk is not new, cybersecurity language in CTAs and remote monitoring agreements is. Security incidents can impact multiple parties, creating mutuality of risk. This session will discuss sample cybersecurity language from research institutions and pitfalls for sponsors. Hear about lessons learned from sponsor audits of their vendor agreements for compliance with CTA cybersecurity obligations. Common gaps make sponsor CTA obligations heavier. Learn about contract provisions that mitigate risk.

11:55 Transition to Lunch

12:00 pm Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

1:30 Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!*
****Separate registration required for access to Part B conferences, upgrade to Best Value Package.***

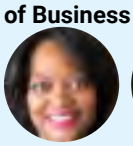
KEYNOTE LOCATION: Gatlin A1 & A2

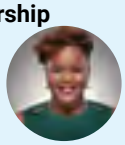
DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 Welcome Remarks from CHI and the SCOPE Team
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative
Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:00 Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership






Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.
Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)
*Don't forget Part B Conferences begin at 3:45pm**Separate registration required, upgrade to Best Value package.*

WEDNESDAY, FEBRUARY 9

12:00 pm Enjoy Lunch on Your Own

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

KEYNOTE LOCATION: Gatlin A1 & A2

1:30 Welcome Remarks from CHI and the SCOPE Team

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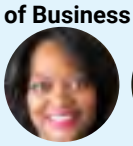

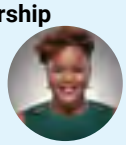


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Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)

ROOM LOCATION: St. John's 22 & 23

RELATIONSHIP MANAGEMENT AS AN ESSENTIAL PART OF SUCCESSFUL OUTSOURCED CLINICAL TRIALS

3:45 Chairperson's Remarks

May Litt, MBA, CCRA, Director, Global Clinical Operations, KPS Life, LLC

3:50 Developing the Perfect Sponsor-CRO Relationship: Insights from a Small Biotech

Michael McLaughlin, MS, MSEd, Director, Program Leadership and Alliance Management, Dermavant Sciences, Inc.

4:20 The Avoidable Pitfalls of Decentralized Trials

Ed Seguine, MBA, Chief Executive Officer, Executive Leadership, Clinical Ink

The emergence of Decentralized Trials has focused on patient options for decentralized participation. However, DCTs also 'CENTRALIZE' so many functional study activities requiring sites/CROs/sponsors greater access to study metrics, clinical data, and platform capabilities to enable decentralization and data insights. This talk explores some of the most common pitfalls in DCT approaches and how the CENTRALIZATION of DCTs requires common sense adjustments to realize the potential/vision of these approaches.

4:50 Importance of Establishing eClinical Vendor Communication Pathways in the Era of Emerging Data Ownership Guidance

Matthew Lowrie, Quality Assurance Manager, Almac Group

What's the difference between a vendor and a trusted partner? How do the latest regulatory landscape trends affect these relationships? Let's discuss how people, companies, and technologies talk to each other in the eClinical industry.

5:20 Panel Discussion: Building Strategic Relationships between Pharma/Biotech and Vendors – Challenges, Timing, Advantages

Moderator: Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences

This panel will discuss:

- How/when/why should a small, emerging company begin to build an overall outsourcing strategy
- What is the upside for vendors to engage with emerging companies
- What efficiencies are gained (financial, operational, consistency) through strategic relationships both for small and larger companies

Panelists:

Erin O'Boyle, Vice President, Clinical Operations, Rezolute, Inc.

Tami Klerr, President, Global Operations Biotech & Small-Mid Size Pharma, Global Operations, Bio-Pharma and SMID Division, ICON

5:50 Close of Day

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast (Gatlin Foyer)

ROOM LOCATION: St. John's 22 & 23

GOVERNANCE AND OVERSIGHT: FROM OUTSOURCING STRATEGY TO SUPPLIERS AND VENDORS

8:20 Chairperson's Remarks

Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences

8:25 CO-PRESENTATION: Enabling Internal Governance Framework: Driving Collaboration, Oversight and Fit-for-Purpose Sourcing Strategies

Sagarika Bollini, Senior Director, Global Development Sourcing, Regeneron Pharmaceuticals, Inc.

Brad Bower, Executive Director, Vendor & Relationship Management, Regeneron Pharmaceuticals, Inc.

Christine Enciso, Vice President, Development Services and Operational Excellence, Regeneron Pharmaceuticals, Inc.

Discuss the business objectives, structure, communication, and authority of the internal governance framework. This framework is a collaborative and organized approach to enable fit-for-purpose sourcing strategies, drives sourcing model implementation, provides oversight and direction to a dynamic Global Development organization.

8:55 RBQM Implementation in an Outsourced Model – Risk Assessment and Centralized and Site Monitoring Oversight

Linda Sullivan, MBA, Executive Director, WCG-Metrics Champion Consortium

Your organization outsources centralized, remote and onsite monitoring to your CRO… how do you oversee the new monitoring process? Who selects the KRIs? Are they the right KRIs? Are identified risks becoming actual issues? Are monitors focusing on the most important risks and issues? Are site issues being addressed? A multi-stakeholder group has been exploring these questions. Come hear about new monitoring metrics developed by the consortium.

9:25 Centering the Patient in Oversight, Risk, and Resource Management

Ian Greenfield, CEO, Tryl

We've all heard about the importance of patient-centricity in study design and implementation, but what does that mean in practice? Starting with the patient in mind magnifies the need for partnerships. Join YPrime to discuss working together to mitigate the risks of patient drop-off and data delays, as well as Best practices - overseeing the patient experience in an outsourced world.

9:40 Panel Discussion: Supplier Governance: Experiences Gained from Small Biotech to Medium and Large Pharma

Moderator: Rene Stephens, MSHS, Independent Consultant

During this session, the panelists will discuss the following:

- Best practices in management/oversight of supplier governance
- Compare and contract how working for a biotech vs a medium/large pharma looks at supplier governance
- Understand the value of sustaining a solid relationship between the sponsor and supplier

Panelists:

Ratan Ratnesh, Senior Director, Outsourcing & Vendor Management, Taiho Oncology, Inc.

Scott Sawicki, MA, Senior Director, Strategic Sourcing & Vendor Management, ADC Therapeutics

Kevin O'Brien, JD, MBA, Vice President Development Business Operations, Gilead Sciences

10:10 Achieving a Single Source of Truth in a Multi-Collaborative Study Environment

Franciska Darmer, Global Head of Clinical, NNIT

Outsourcing clinical trial conduct limits our ability to track study progress and inspection readiness. Data generating technology has accelerated the clinical trial conduct with new opportunities transforming resource heavy, manual processes. Focusing on consolidating dispersed data and content sources across a multi-collaborative environment, this presentation provides an overview of technologies such as AI and BI enabling a single source of truth – improving study team performance with complete study performance overview.

10:40 Networking Coffee Break (Gatlin Foyer)

THE WAR ON TALENT: IMPACT OF THE CHANGING WORKFORCE ON OUTSOURCING AND INTERNAL RESOURCES

Panel Discussion10:55 Roundtable Discussion: Budgeting for and Contracting with New Technology Companies: Strategies and Challenges

CO-PRESENTATION: In-Person Only: Roundtable Discussions: Budgeting for and Contracting with New Technology Companies: Strategies and Challenges

Michael Agard, Team Leader Clinical Consulting, NNIT

Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences

11:30 CO-PRESENTATION: Go Hybrid: The Future of Clinical Trials and Talent Management

Alexander W. Pastuszak, M.D., PhD, President of Clinical Care, Vault Health

Jason Feldman, Co-Founder & CEO, Vault Health

Learn about hybrid clinical trials and how they reduce friction for patients, providers and sponsors. Vault's Hybrid Clinical Trials platform connects in person visits and virtual care to help bring new therapies to market faster, while optimizing resource allocation across the supply chain.

12:00 pm Transition to Shared Sessions or Brief Session Break

12:05 FEATURED PRESENTATION: Communication and Strong Partnerships are Critical to Ensuring a Reliable Supply Chain

Luiz A. Barberini, CQE, CSCP, CPIM, Head, External Manufacturing Operations, Bayer SA

Communication and strong partnerships are critical to ensuring a reliable supply chain. The pandemic has tested and stretched all partnerships across the supply chain and Bayer will shed light on how teams became more agile to ensure a reliable supply. Adequate communication pacing, the sharing of the customer´s focus and the building of trust are keys to anticipate potential problems and to keep a reliable and steady supply.

12:35 Maintaining Continuous Clinical Trial Material (CTM) Supply to Patients during the COVID-19 Pandemic

Bryan O'Neill, Senior Director & Head, Clinical Supply Operations, Daiichi Sankyo, Inc.

The COVID-19 pandemic has created a variety of challenges across the clinical trial conduct space, and CTM supply is one of the areas impacted. To mitigate risk of infection associated with patients receiving CTM at clinical sites and hospitals, Daiichi Sankyo developed several approaches to maintain CTM supply in close collaboration with both internal and external stakeholders.

1:05 Transition to Lunch

SCOPE SEND OFF LUNCHEON PRESENTATIONS

Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring

Nekzad Shroff, Vice President, Product Management, Saama Technologies

Aditya Gadiko, Director of Clinical Informatics, Saama Technologies

Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials

Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

8:25 CO-PRESENTATION: Enabling Internal Governance Framework: Driving Collaboration, Oversight and Fit-for-Purpose Sourcing Strategies

Sagarika Bollini, Senior Director, Global Development Sourcing, Regeneron Pharmaceuticals, Inc.

Brad Bower, Executive Director, Vendor & Relationship Management, Regeneron Pharmaceuticals, Inc.

Christine Enciso, Vice President, Development Services and Operational Excellence, Regeneron Pharmaceuticals, Inc.

Discuss the business objectives, structure, communication, and authority of the internal governance framework. This framework is a collaborative and organized approach to enable fit-for-purpose sourcing strategies, drives sourcing model implementation, provides oversight and direction to a dynamic Global Development organization.

1:45 SCOPE Summit 2022 Adjourns

MONDAY, FEBRUARY 7

8:00 am SCOPE's Inaugural Masters of Clinical Research Golf Tournament

Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 Conference Registration Open (Gatlin Foyer)

2:00 pm User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)

Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

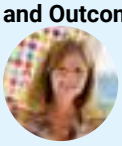
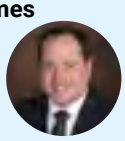
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

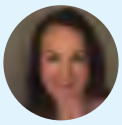



Moderator: Irfan Khan, MD, CEO, Circuit Clinical
Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

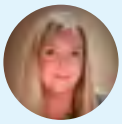
5:45 SCOPE's 2022 Participant Engagement Awards Introduction
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co., Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine

Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)

7:45 Close of Day

TUESDAY, FEBRUARY 8

7:15 am Registration Open (Gatlin Foyer)

7:15 Morning Coffee *(Sponsorship Opportunity Available)*

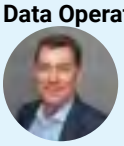
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 Chairperson's Introduction
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange, and clinical research? How do you do this at scale?

9:55 Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

ROOM LOCATION: St. John's 26 & 27

BIOGEN CASE STUDY: BRINGING REAL-TIME 360° TRANSPARENCY TO CLINICAL SUPPLY

10:55 Chairperson's Remarks
Ben Taylor, CEO, LedgerDomain

11:00 How Barcodes and Blockchain Unlock Supply Chain Collaboration
Imran M. Shakur, Associate Director, Clinical Supply Capabilities, Biogen
Digital transformation in clinical supply has the potential to reduce site burden and eliminate errors, but has often been stalled by workflow complexity and lack of interoperable standards. This session will highlight how barcodes and blockchain together provide a real-time picture of clinical supply inventory for all stakeholders – unlocking greater operational efficiencies and supporting the common effort to bring groundbreaking new drugs to market.

11:30 CO-PRESENTATION: Real-World, Real-Time: Bridging Study Sites & Study Leadership
Michael Keech, Senior Principal Commercial Compliance & Quality, IQVIA
Greg Plante, Principal, Digital Transformation, IQVIA
Blockchain is well-suited to supply chains where numerous organizations handle sensitive information and require a real-time "single-version of the truth." But for busy clinicians, study coordinators, and executive leadership, blockchain-backed mobile apps and dashboards are only half the picture – intuitive workflows and comprehensive data science are critical to successful adoption. Learn how IQVIA has navigated a fragmented data landscape and aligned stakeholder requirements towards greater collaboration in clinical supply.

12:00 pm Panel Discussion: Clinical Collaboration in a Personalized World
Moderator: Ben Taylor, CEO, LedgerDomain
Personalized medicine places new demands on patient data management. The most advanced cell and gene studies are stalled by the lack of real-time collaboration, even as the clock is ticking on short-lived samples that expire in a matter of days. In this panel discussion, we will discuss how new decentralized technologies like blockchain bridge gaps between stakeholders and accelerate personalized treatments to patients.
Panelists:
Michael Keech, Senior Principal Commercial Compliance & Quality, IQVIA
Greg Plante, Principal, Digital Transformation, IQVIA
Imran M. Shakur, Associate Director, Clinical Supply Capabilities, Biogen

12:30 Enhance Your Technology Playbook. Using Strategic Options to Boost your Supply Chain

Cheryl Kole, Head of Solutions Strategy and Commercialization, Almac Clinical Technologies, Almac Group

In the increasingly complex world of clinical trials, utilizing modern technology redefines the supply chain. Learn how to optimize your supply chain strategy and overcome the challenges associated with complex study designs using advanced technology solutions.

1:00 Transition to Lunch

1:05 LUNCHEON PRESENTATION: SmartSignals Supplies Forecasting & Planning; Introducing the New DRP Functionality from Signant Health

Andy Hinks, Senior Business Analyst, Signant Health

Signant Health will give a brief overview and demonstration of the new DRP functionality enhancement to their SmartSignals Supplies Forecasting and Planning applications; the industry's only fully integrated solution that puts you in full control of your clinical supply chain.

1:35 Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)

SUPPLY CHAIN 4.0 – DIGITALIZATION AND ANALYTICS

2:30 Chairperson's Remarks

Maria N. Humagain, Senior Manager, IRT Systems, BeiGene

2:35 How Digital Technologies Can Accelerate the Translation of Clinical Supply to Large-Scale Commercial Supply

Prashant Yadav, PhD, Senior Fellow, Center for Global Development; Lecturer, Global Health & Social Medicine, Harvard Medical School

Biopharmaceutical companies face increasing pressure to accelerate the timelines for development and the need for rapid post-approval capacity ramp-up. This requires a much faster and streamlined transition from the clinical supply chain to the commercial supply chain. The fast scale-up of COVID-19 vaccine and therapeutics have accelerated the expectations. This talk will focus on opportunities to enable a more rapid transition to commercial supply, especially using digital technologies.

3:05 Block Chain: Patient Safety & Supply Chain Security

Aaron Graham, Executive Director, Brand Safety & Security, Boehringer Ingelheim Pharmaceuticals Inc

3:35 How Interactive Response Technology (IRT) can Simplify your Overall Study Management and Costs

Maria N. Humagain, Senior Manager, IRT Systems, BeiGene

This presentation discusses how Supply Chain and Clinical Trial Teams can utilize Interactive Response Technology for Clinical Trials in the face of high speed timelines and reduced budgets, includes a look at what IRT can do for your study and Supply Chain Management, how to choose the right vendor, how to contract with preferred providers, how to set up basic standards, and how to ensure quality systems every time.

4:05 Panel Discussion: Leveraging Data to Cut Waste, Minimize Risk, Improve Resilience & Speed Decision Making in the Clinical Supply Chain

Moderator: Neeraj Shah, Director, Global Clinical Supply Chain Excellence, Bristol Myers Squibb Co

Digitalization is leveraging new relationship models throughout the entire clinical trial supply chain network. The transformative capability of incorporating valuable insights from multiple sources of data while increasing the amount/quality of data collected/analyzed saves time, money and increases productivity. Learn from this panel of experts as they share their insights on how data is transforming supply chain management.

Panelists:

Aaron Graham, Executive Director, Brand Safety & Security, Boehringer Ingelheim Pharmaceuticals Inc

Maria N. Humagain, Senior Manager, IRT Systems, BeiGene

Prashant Yadav, PhD, Senior Fellow, Center for Global Development; Lecturer, Global Health & Social Medicine, Harvard Medical School

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 Find Your Table and Meet Your Moderators

4:40 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)

6:40 Close of Day

WEDNESDAY, FEBRUARY 9

7:15 am Registration Open (Gatlin Foyer)

BREAKFAST PRESENTATIONS

Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 Practical Approaches for Operationalizing DCTs Room Location: Gatlin A1

Kyle Hogan, President, Datacubed Health

Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2

Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS

Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: St. John's 26 & 27

APPLYING BLOCKCHAIN FOR END-TO-END CLINICAL SUPPLY MANAGEMENT

8:20 Chairperson's Remarks
Hernando C. Giraldo, Digital Laboratory, Scouting and Innovation, Boehringer Ingelheim Pharmaceuticals, Inc.

8:25 Optimizing and Accelerating Clinical Trials and Health Data Marketplace with Blockchain
Disa Lee Choun, Head, ICOA, Janssen UK
Distributed Ledger Technology has been widely adopted in the Financial sector, unlike the Pharmaceutical and Healthcare industries. With the rise of digital health, e-patients, and patient empowerment, could blockchain be the game changer? Could we optimize and accelerate the drug development process and access to better care? Learn more about PharmaLedger project and the Clinical Trial and Health Data Use Cases using IoT and machine learning.

9:00 PharmaLedger's Journey through the eConsent Use Case
Baldwin C. Mak, Leader Strategic Feasibility & Manager, Clinical Trial Portfolio, Boehringer Ingelheim Canada
The global pandemic has accelerated the use of digital technologies and remote interactions changing the way clinical trials are conducted. Yet trust, transparency and security of data remains a concern that impacts patient engagement and confidence in the data. The e-consent use case aims to leverage the informed consent on blockchain technology to transform the conduct of clinical trials by improving trust, transparency, and security and increasing patient empowerment.

9:25 Powering Trust in Internet of Things (IoT) Trial Ecosystems
Maria Eugenia (Xenia) Beltran, PharmaLedger Project Coordinator, Universidad Politécnica de Madrid
Architectures for the IoT medical devices typically rely on transmitting data to centralized cloud servers which often generate isolated data silos in different medical devices platforms and concerns of trust and lack transparency in data processing, manipulation and concealment of IoT data. To overcome these downsides, the PharmaLedger IoT and Personalized Medicine use case provides data sharing schemas supporting data integrity and provenance, under consenting and domain-specific privacy principles.

9:55 Fractional Prediction Driving Supply Chain Efficiency
Craig Mooney, Vice President, Scientific E-tech Enabled Services, Calyx
This presentaton will be a case study where usual site stock management is not efficient enough, aiming to understand how fractional prediction works and how it can be applied, and provide insight into how it addresses protocol-specific challenges, resulting in a more efficient clinical supply chain.

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

11:25 Panel Discussion: Blockchain Consortium – The IMI PharmaLedger Project
Moderator: Disa Lee Choun, Head, ICOA, Janssen UK
Panelists:
Maria Eugenia (Xenia) Beltran, PharmaLedger Project Coordinator, Universidad Politécnica de Madrid
Baldwin C. Mak, Leader Strategic Feasibility & Manager, Clinical Trial Portfolio, Boehringer Ingelheim Canada
Hernando C. Giraldo, Digital Laboratory, Scouting and Innovation, Boehringer Ingelheim Pharmaceuticals, Inc.
Lynn H Wang, Director, Product Management, Supply Chain Visibility, Johnson & Johnson

11:55 Transition to Lunch

12:00 pm LUNCHEON PRESENTATION: Maximize Your Product Efficiency Using RTSM
Ian Davison, Subject Matter Expert, Medrio
Clinical trials often require the careful management of products that may be very precious due to scarcity or expense. Learn how RTSM can be used to optimize the supply chain, as well as optimize the use of products at site to ensure as much of your IP as possible ends up in subjects and not in the returns or destruction process.

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

1:30 Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!*
**Separate registration required for access to Part B conferences, upgrade to Best Value Package.*

KEYNOTE LOCATION: Gatlin A1 & A2

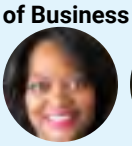
DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

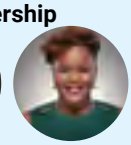
1:30 **Welcome Remarks from CHI and the SCOPE Team**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: **Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative**
Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**
Don't forget Part B Conferences begin at 3:45pm**Separate registration required, upgrade to Best Value package.

2:00 **Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership**






Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.
Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

WEDNESDAY, FEBRUARY 9

ROOM LOCATION: St. John's 26 & 27

BRIDGING LUNCHEON PRESENTATION

12:00 pm **Bridging Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 **Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)**

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

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Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

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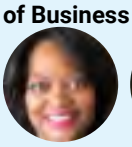

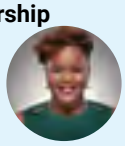


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Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: St. John's 26 & 27

REDEFINING THE ROLE OF PHARMACISTS IN DECENTRALIZED CLINICAL TRIALS

3:45 **Chairperson's Remarks**
Gerald E. Finken, Founder & CEO, RxE2

3:50 **Building Clinical Supplies into the Specialty Pharmacy Channel**
Jeremy Faulks, PharmD, Vice President, Pharmacy Operations, Thrifty White Pharmacy
We're creating a new model for virtual/site-less trials and direct-to-patient medication delivery using techniques we've perfected over the last 10+ years in our commercial specialty pharmacy operation. This session will review the hurdles, learnings, and success stories from our journey. Everything the FDA requires, alongside what the State Boards of Pharmacy require, delivering a better patient experience at a lower cost.

4:20 **Digital Direct-to-Patient Solutions for End-to-End Clinical Supply**
Smit Patel, Director, Digital Medicine, Digital Medicine Society (DiMe)
The field of digital medicine continues to experience explosive growth. DiMe's Library of Digital Endpoints observed 665% spike in the number of unique digital endpoints being used in clinical trials of new medical products over the past two years. Pandemic catalyzed the use of digital clinical measures and other decentralized approaches to clinical research. But what does it mean to develop and select digital clinical measures that matter to patients?

4:50 **Multistate Review of Pharmacy Law Governing Clinical Trials**
Kimberly B. Moore, Clinical Pharmacist, GLO & Associates
As clinical trials become more complex, patient-specific, and expensive, pharmacist involvement greatly improves their efficiency and effectiveness. For clinical drugs, federal regulations cover manufacturing while individual state pharmacy laws govern dispensing. Reviewing state pharmacy laws and regulations reveal great state variability. Continued individual state regulation monitoring is necessary to support successful clinical trials, especially decentralized trials. This presentation highlights the importance of state variance awareness.

5:20 **When Applying a DCT/ DtP Model, Everyone is a Winner!** MEDIDATA
Marc Kaufman, Director, RTSM Customer Adoption and Value Realization, Medidata, a Dassault Systèmes company
Clinical trials must be nimble and adaptive. The landscape is evolving towards fully decentralized models. We will explore how a direct to patient shipping model and process can impact and provides great benefits to study personas such as supply managers, sites, sponsors and patients.

5:50 **Close of Day**

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast (Gatlin Foyer)

ROOM LOCATION: St. John's 26 & 27

SUPPLY CHAIN LOGISTICS FOR UNIQUE PRODUCTS

8:20 Chairperson's Remarks

Donna Libretti Cooke, JD, Director, Contracting & Budgeting & Sustainability Champion, Bayer

8:25 Cold Chain Challenges - A Clinical Trial Logistics Conversation

Thomas J. McDonald, MS, Associate Director, Strategic Biospecimen & Vendor Logistics Management, Bristol-Myers Squibb Co.

Biospecimen derived data drives clinical trial decisions. A significant portion of biospecimens are transported via cold chain. In this session, we will evaluate best practices for cold chain shipping. Dialog will focus on identifying historic and COVID-19-related risks and exploring solutions as they relate to biospecimen sample collection and pack out, consolidation, courier capabilities, service levels and regional strategies that can be considered for your logistics supply chain.

8:55 CO-PRESENTATION: Receiving High Quality Biospecimens – A Testing Lab Perspective

Robert Sever, PhD, Director, Technology, Linde Inc.

David Trollinger, MBA, Director, Business Development, Advanced Diagnostic Laboratories, National Jewish Health

Collection, storage, and transport of temperature-sensitive biospecimens are critical factors for most clinical trials. Several challenges can arise in preserving the quality of these biospecimens between the patient and the testing lab. This presentation shares a testing lab's experiences encountering and solving such challenges. Case studies will be presented for thermally labile blood Complement proteins.

9:25 Decentralized Clinical Trial Solutions: A Flexible Supply Chain Strategy

Robin Douglas, MA, Senior Director Global Patient Centric Services, Marken

Join me in exploring industry trends and the evolving patient journey in decentralized clinical trials. Together, we will examine the components of a patient-focused flexible supply chain strategy, solutions for sponsors and investigator sites as well as lessons learned.

9:40 CO-PRESENTATION: Case Study: Reimagining Reverse Supply Chain Logistics to Make a Meaningful Impact on Global Health

Donna Libretti Cooke, JD, Director, Contracting & Budgeting & Sustainability Champion, Bayer

Greg Folz, CCRP, Founder, Kits4Life

Josh Kravitz, Kits4Life Program Coordinator, MedSurplus Alliance

It's costly and meaningless to dispose of usable excess supplies from clinical trials. A new initiative safely and securely turns surplus into donations that impacted over 13,000 lives since 2020. This platform epitomizes successful reverse logistics operations, valued use of unused clinical trial supplies. We examine results of a 157 site pilot by Bayer, recognized by the US Chamber of Commerce Foundation for best Health and Wellness program of 2021.

10:10 CO-PRESENTATION: Clinical Supply Chain Waste Reduction Using AI/ML

Ankush Chandna, Data Science Manager, R&D Excellence, ZS

Simon Ladd, Senior Director, Trial Supplies Management, BMS

Clinical Supplies, especially comparators and co-medications, represent a significant portion of the total cost of clinical trials. Across our industry, average waste is estimated at 55% of total production volume. In this session we will discuss an AI/ML based approach which aims to minimize clinical wastage, whilst accounting for demand uncertainty, supply side constraints and the need to maintain very high patient service levels.

10:40 Networking Coffee Break (Gatlin Foyer)

ROOM CHANGE: St. John's 22 & 23

10:55 Roundtable Discussions: Budgeting for and Contracting with New Technology Companies: Strategies and Challenges

CO-PRESENTATION: In-Person Only: Roundtable Discussions: Budgeting for and Contracting with New Technology Companies: Strategies and Challenges

Michael Agard, Team Leader Clinical Consulting, NNIT

Chuck Bradley, Senior Vice President, Global Development Operations, Annexon Biosciences

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Transition to Shared Sessions or Brief Session Break

LESSONS LEARNED OVER THE PAST YEAR IN PROJECT MANAGEMENT & SUPPLY CHAIN: THE IMPORTANCE OF COMMUNICATION, COLLABORATION & OUTSOURCING

12:05 FEATURED PRESENTATION: Communication and Strong Partnerships are Critical to Ensuring a Reliable Supply Chain

Luiz A. Barberini, CQE, CSCP, CPIM, Head, External Manufacturing Operations, Bayer SA

Communication and strong partnerships are critical to ensuring a reliable supply chain. The pandemic has tested and stretched all partnerships across the supply chain and Bayer will shed light on how teams became more agile to ensure a reliable supply. Adequate communication pacing, the sharing of the customer´s focus and the building of trust are keys to anticipate potential problems and to keep a reliable and steady supply.

12:35 Maintaining Continuous Clinical Trial Material (CTM) Supply to Patients during the COVID-19 Pandemic

Bryan O'Neill, Senior Director & Head, Clinical Supply Operations, Daiichi Sankyo, Inc.

The COVID-19 pandemic has created a variety of challenges across the clinical trial conduct space, and CTM supply is one of the areas impacted. To mitigate risk of infection associated with patients receiving CTM at clinical sites and hospitals, Daiichi Sankyo developed several approaches to maintain CTM supply in close collaboration with both internal and external stakeholders.

1:05 Transition to Lunch

SCOPE SEND OFF LUNCHEON PRESENTATIONS

Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring

Nekzad Shroff, Vice President, Product Management, Saama Technologies

Aditya Gadiko, Director of Clinical Informatics, Saama Technologies

Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials

Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 SCOPE Summit 2022 Adjourns

Program Advisory Board

February 8-9, 2022 | All Tmes EST

Sina Djali,
Head of Clinical & Operations Analytics, Janssen R&D LLC

Demetris Zambas,
Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.

MONDAY, FEBRUARY 7

8:00 am SCOPE's Inaugural Masters of Clinical Research Golf Tournament
Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 Conference Registration Open (Gatlin Foyer)

2:00 pm User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

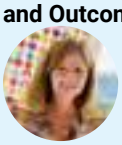
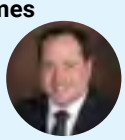
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

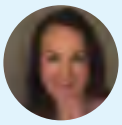



Moderator: Irfan Khan, MD, CEO, Circuit Clinical
Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

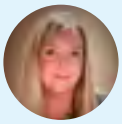
5:45 SCOPE's 2022 Participant Engagement Awards Introduction
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co.,

Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 **SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)**

7:45 **Close of Day**

TUESDAY, FEBRUARY 8

7:15 am **Registration Open (Gatlin Foyer)**

7:15 **Morning Coffee** *(Sponsorship Opportunity Available)*

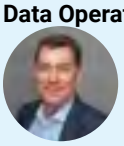
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 **Chairperson's Introduction**
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: **Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World**



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: **Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale**
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange, and clinical research? How do you do this at scale?

9:55 **Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E1

ADDRESSING DATA NEEDS FOR NEW NORMAL

10:55 **Chairperson's Remarks**
Aman Thukral, Director & Head, Clinical Systems & Digital Operations, AbbVie, Inc.

11:00 **Frictionless Data Flow**
Xiaoying Wu, Vice President, Data Platforms & Privacy, Janssen Pharmaceuticals, Inc.
This presentation will address issues and solutions related to data flow and data management in novel trials including decentralized trials.

11:25 **Data and Analytics Needed to Keep "Light Speed" Studies on Track from Planning through Submission**
Ralph Russo, Senior Director & Global Head, Clinical Database Management, Pfizer Inc.
Keeping every aspect of a 'light speed' clinical trial/program requires data analytics and dashboards in real time across various data sources and types. This session will provide an overview of what helped Pfizer deliver the COVID-19 Vaccine data set for Emergency Use Authorization.

11:50 **CO-PRESENTATION: Direct Data Capture (DDC) for Clinical Development – an Abbvie Case Study**
Aman Thukral, Director & Head, Clinical Systems & Digital Operations, AbbVie, Inc.
Anna Fuquay, eCOA and Digital Operations Associate II, AbbVie
Different Modalities of Direct Data Capture from EHR, EMR and Syndicated Data Sources Key Considerations and Lessons Learned from Abbvie's Pilots

12:15 pm **Design StuDIO to Optimize Study Design and Delivery**
Jade Dennis, Advisor, Design Hub, Eli Lilly and Company
Using data and analytics, study teams can optimize their protocol design with a direct impact on clinical development timelines, patient burden and study cost. An integrated set of advanced analytical tools and processes was developed that allows users to identify trends and make data informed decisions on study design leading to more feasible designs with reduced patient burden, cost and risk of protocol amendments.

12:30 **What Should You Add to Your Current Data Strategies and Analytics Platforms for Disruptions**

Driven by COVID-19??
Greg Jones, eClinical Enterprise Strategy, Health Sciences, Oracle
The past 2 years have translated directly into "go faster" and embrace "virtual". Your data strategies and analytics platforms can be foundational to the need to make this shift. This presentation will discuss critical elements to add to your data strategy and your analytics platform to facilitate your successful evolution to this new normal.

1:00 **Transition to Lunch**

1:05 **LUNCHEON PRESENTATION: Faster, Smarter, Safer: Three Clinical Data Management Practices for the New Data Normal**
Wayne Walker, SVP, Rave Platform Technology, Medidata, a Dassault Systèmes Company
Not all data is created equal. The variety of data sources and the volume and velocity of data, accelerated by the growth in decentralized trials bring new challenges for data management and monitoring teams. We'll explore the changing data landscape and its challenges, and describe three pillars for modernizing clinical data management technology and processes to deliver higher quality data and critical insights, faster.

1:35 **Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)**

CLINICAL DATA FOR ENTERPRISE-LEVEL SOLUTIONS

2:30 **Chairperson's Remarks**
Chairperson to be Announced

2:35 **CO-PRESENTATION: Building a Data Governance Structure Across R&D at Scale**
Kiran Kodali, MBA, Global Data Strategy & Governance Lead, R&D, Sanofi
Karen Fanouillere, Head of Clinical Information Governance, Sanofi
We see the trend of a rapid growth at which data is being generated and consumed across organizations and industries. Most organizations have the ambition to manage 'data as a strategic asset.' To achieve this, organizations need to build a strong governance framework that would enable fast and seamless access to high quality data which will be used in generating insights that are critical for decision making across the value.

3:05 **Simplifying AI adoption for clinical data analysis**
Gary Shorter, Head, AI and Data Science, Artificial Intelligence, IQVIA Technologies
The shift from point solutions and manual tasks to a streamlined, connected, AI/ML driven data strategy can be a hard sell for risk averse stakeholders. But when life sciences companies take a well-defined crawl/walk/run/fly approach it can ease the transition and win over skeptics. Learn how taking a staged approach to automation can ease the transition and help move your data teams from data management to data science.

3:35 **CO-PRESENTATION: Clinical Data for Translational Research – From Simple Questions to Complex Data Science Projects**
Andrea De Souza, Senior Director, Research Data Sciences & Engineering, Eli Lilly & Company
Yue Wang Webster, PhD, Director, Information and Digital Solutions, Eli Lilly & Co.
Translational research is the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals. This is a bidirectional process. In the last two years, we have built a platform that enables scientists to gain biological insights from clinical observations by putting analysis-ready data in the hands of the scientists with speed and security.

4:05 **How to Measure Success in a Decentralized Trial**
Jennifer Price, Executive Director, Data & Analytics, THREAD
It's estimated that one quarter of all clinical studies have included a decentralize component or components. Our tools for measuring performance and success within these types of studies need to change to stay relevant to this new paradigm. There are currently no standards for metrics in decentralized trials. This presentation will provide thought leadership on a new analytics methodology to measure the compliance, timeliness and quality in a decentralized trials environment.

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 **Find Your Table and Meet Your Moderators**

4:40 **Interactive Discussions**
Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 **Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)**

6:40 **Close of Day**

WEDNESDAY, FEBRUARY 9

7:15 am **Registration Open (Gatlin Foyer)**

BREAKFAST PRESENTATIONS
Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 **Practical Approaches for Operationalizing DCTs Room Location: Gatlin A1**
Kyle Hogan, President, Datacubed Health
Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 **Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2**
Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS
Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions

offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin E1

NOVEL APPROACHES TO ENSURE DATA QUALITY FOR ADVANCE ANALYTICS APPLICATIONS

8:20 Chairperson's Remarks
Paul Bidez, Industry Vice President, Life Sciences, Manufacturing & Automotive, Industry Sales, Appian

8:25 Risk-Based Clinical Data Review: The Case for Expanding Risk-Based Approaches in Data Management
Catherine Celingant, Executive Director, Data Monitoring & Management & Lead, Oncology TA, Pfizer Inc.
Regulators have been encouraging trial sponsors to incorporate risk-based approaches into their clinical trial management practices for a few years now. Moreover, regulatory thinking seems to be evolving toward a pragmatic definition of data quality as "the absence of errors that matter". This presentation will include current thinking and actual implementation of risk-based approaches to clinical data and metadata review.

8:55 10X Efficiency in Clinical Data Quality Processes
Srinivasan Anandakumar, Vice President, Product Management, Saama Technologies
Current clinical data quality processes are manual, time-consuming, and prone to error. With a standards-based approach, accompanied by advanced systems that provide automation, analytics, and AI, sponsors can drive the efficiencies required to keep up with the explosive growth of data. In this session, you'll learn best practices for cleaning, analyzing, and standardizing data from disparate sources so it's ready for analysis and submission in record time.

9:25 Staying Ahead of the Curve: The Future Direction of Modernization of Statistical Analytics (MSA)
Lin Taft, Statistical Leader, Clinical Research, GSK
Following the successful launch of the Modernization of Statistical Analytics (MSA) Framework in 2021, and a conference and webinar tour across the industry, the TransCelerate Modernization of Statistical Analytics (MoA) team will provide an update on where they see the industry is, with respect to modernized analytical platforms, and what impact the MSA Framework has made.

9:55 CO-PRESENTATION: Using Smart Standards-Driven Digital Protocols to Simplify the Design and Implementation of Clinical Trials
Eugene Schneider, M.D., EVP, Chief Clinical Development Officer, Clinical Development, Ionis Pharmaceuticals, Inc.
Scott Chetham, Ph.D., Co-Founder & CEO, Faro Health Inc.
In clinical trials, documents, data, and applications are separate with no single source of truth. Imagine a world where we can design/implement clinical trials in days. This vision is becoming reality with the use of smart templates to build trials and standards based ontologies linking downstream systems while using data to build real-time patient journeys and budget insights. Key learnings from co-developing and piloting a standards based platform will be shared.

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

NOVEL APPROACHES TO ENSURE DATA QUALITY FOR ADVANCE ANALYTICS APPLICATIONS

11:20 Chairperson's Remarks
Aman Thukral, Director & Head, Clinical Systems & Digital Operations, AbbVie, Inc.

11:25 CO-PRESENTATION: Procedures Library Utilization: The Devil is in the Data Details
Mitzi Allred, PhD, Director, Clinical Operations & Head, Clinical Content Standards, Merck
Michael Morozewicz, Senior Manager, Biomedical Data Stewardship, Amgen
Development of standardized protocol structure has resulted in increased consistency across industry, but continued standardization efforts are needed to modernize clinical research. By partnering with Standard Setting Organizations (SSOs) to develop common procedure descriptions accessible through user friendly technologies, numerous benefits could be realized. The project team examined several existing terminologies and data exchanges, summarized findings, and proposed a call to action for SSOs and collaborators to advance next steps.

11:55 Transition to Lunch

12:00 Bridging Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:00 pm CO-PRESENTATION: LUNCHEON PRESENTATION: What Is a Digitalized Clinical Trial and Why Should I Care About It?
Barrie Nelson, Vice President, Digital Clinical Innovations & Chief Standards Officer, Nurocor
Ralph Russo, Senior Director, Cliinical Database Management and Standards, Pfizer
Steve Stowers, Director of R&D IT Business Partnering for Clinical Late Development Therapeutic Areas, R&D IT, Bristol Myers Squibb
In terms of industry adoption of digitalized processes, the Pharma industry is outpaced by every other industry sector apart from Oil & Gas.

Digitalization opportunities exist for many aspects of clinical research. A digital backbone for clinical trials replaces analog documents, offers opportunity to reuse content across the lifecycle, allows more processes to run in parallel, connects systems and significantly shortens cycle times. Digitalization is the future for the Pharma industry.

1:30 Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!*

****Separate registration required for access to Part B conferences, upgrade to Best Value Package.***

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 Welcome Remarks from CHI and the SCOPE Team

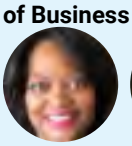
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

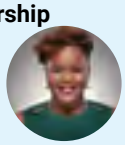
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative

Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:00 Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership






Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative

What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.

Panelists:

Karriem Watson, PhD, Chief Engagement Officer, NIH

Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.

Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)

Don't forget Part B Conferences begin at 3:45pm**Separate registration required, upgrade to Best Value package.

Program Advisory Board

February 9-10, 2022 | All Tmes EST

Faisal Khan, PhD,
Executive Director, Advanced Analytics & AI, AstraZeneca Pharmaceuticals, Inc.

Brian Martin,
Head of AI, R&D Information Research, Research Fellow, AbbVie

Prasanna Rao,
Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.

WEDNESDAY, FEBRUARY 9

ROOM LOCATION: Gatlin E1

BRIDGING LUNCHEON PRESENTATION

12:00 pm **Bridging Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 **Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)**

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

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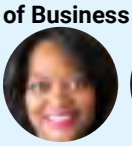

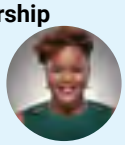


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Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E1

AI TO ENABLE CLINICAL INNOVATION

3:45 **Chairperson's Remarks**
Timothy Riely, Vice President, Clinical Data Analytics, IQVIA

3:50 **AI for Pfizer Vaccine Study**
Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.
In this session, we will describe Pfizer's AI journey through the lens of clinical data, use cases, implementation and key to success. Clinical Data Management for the Vaccine Study presented an opportunity for ML/NLP to assist in saving valuable time reconciling data. The foundation for a Smart Data Quality strategy was expanded to other TAs thanks to the solution's Pattern Recognition, Clinical Inference capabilities that will be explained in detail.

4:20 **Driving Value from AI Insights**
Timothy Riely, Vice President, Clinical Data Analytics, IQVIA
Once life sciences companies have proven the value and reliability of AI models, they need to deploy that insight to the right person at the right time to drive the right decision. This presentation will discuss how to implement AI in the workflow and discuss three examples where organizations have successfully done this.

4:50 **Accelerating Data Access and Quality with AI**
Julie Smiley, Sr. Director Life Sciences Product Strategy, Oracle Health Sciences Global Business Unit, Oracle
Gaining insights from data has traditionally been a laborious and time-consuming effort. It includes ingestion of data from many sources, aggregation via programming, cleaning through listings review and validation checks, and provisioning of data to downstream stakeholders in various formats. This session explores the challenges with these processes and provides methods for automation with the use of artificial intelligence to accelerate access to downstream data consumers for quicker critical decision-making.

5:20 : AI in Drug Development: Opportunities and Pitfalls
Moderator: Prasanna Rao, Head, AI & Data Science, Data Monitoring and Management, Clinical Sciences and Operations, Global Product Development, Pfizer Inc.
AI/ML is over-hyped, this panel will discuss machine learning techniques that are in production in various organizations that are adding value and accelerating Clinical Development. We will also discuss best practices, lessons learnt, how to pick a ML use case from idea to implementation and more.
Panelists:
Brian Martin, Head of AI, R&D Information Research, Research Fellow, AbbVie, Inc.
Faisal Khan, PhD,

5:50 Close of Day

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast (Gatlin Foyer)

ROOM LOCATION: Gatlin E1

8:55 Natural Language Understanding and Knowledge Graphs
Malaikannan Sankarasubbu, Vice President, Artificial Intelligence Research, Saama Technologies, Inc.
Natural language understanding and knowledge graphs in pharma. Biomedical text mining is hard. Recent techniques, like transformers, trained on publically available data, like Pubmed, can give better language models for use in pharma. How do new techniques like transformers help with better language models? Knowledge graphs and graph convolutional network applications in pharma.

9:25 Mining the Depths of Unstructured Healthcare Data to Accelerate Clinical Trial Operations
Jason Attanucci, Vice President and General Manager, Life Sciences, Deep 6 AI
Over 80% of healthcare information is buried in unstructured data like provider notes, pathology results and genomics reports. Leveraging AI and NLP technologies to mine, contextualize and temporalize medical concepts can have a dramatic effect on clinical trial operations. We discuss how effective use of this information can accelerate multiple operational objectives across the clinical trial continuum such as study design, site selection, patient recruitment, SAE adjudication, RWE and beyond.

9:40 AI for Clinical Data Utilization Across Full Product Cycle
Brian Martin, Head of AI, R&D Information Research, Research Fellow, AbbVie, Inc.
This presentation will discuss approaches and case studies for extracting knowledge from clinical trial data and connecting it with preclinical and post-approval data.

10:10 Using Real-World Data and AI/ML for Clinical Trial-Site Matching to Simultaneously Improve Enrollment Rate and Diversity
Lucas Glass, Vice President, Analytics Center of Excellence, R&D Solutions, IQVIA
In feasibility, trial-sites are chosen based on medical expertise and patient access. Using principles of fairness in machine learning, a model that maps clinical trial descriptions to a ranked list of sites was developed and tested on real-world data. It resulted in a list of potential trial-sites that accounted for performance and diversity. This presentation looks at data sources and ML algorithms that could solve diversity problems in site selection.

10:40 Networking Coffee Break (Gatlin Foyer)

11:30 CO-PRESENTATION: Applying AI to Improve Efficiencies in Clinical Trials
Łukasz Kidziński, PhD, Director, AI, Clario
Kevin Thomas, PhD, Director, AI, Clario
Janine Jones, Senior Product Manager, Clario
David Billiter, Founder and CEO, Deep Lens
Artificial Intelligence has the potential to dramatically improve the speed and accuracy of clinical trials. Medical and operational experts can incorporate AI algorithms into use cases including automation of image analysis, predictive analytics about trends in the meta data, and tailored patient engagement for improved compliance. This panel will discuss opportunities for AI to help sponsor and site stakeholders focus more on patient outcomes and perform their jobs more effectively.

12:00 pm Transition to Shared Sessions or Brief Session Break

AI FOR REAL WORLD AND TRIAL DESIGN APPLICATIONS

12:05 Multimodal Clinical Prediction Models in Research and Beyond
Patrick Schwab, PhD, Director, Artificial Intelligence and Machine Learning, GSK
Machine learning holds promise for integrating comprehensive, deep phenotypic patient profiles across time for (i) predicting outcomes, (ii) identifying patient subtypes and (iii) associated biomarkers. In this talk, we will outline opportunities and challenges for clinical prediction models built from deep phenotypic patient profiles in clinical research and beyond.

12:35 Case Studies for AI-Based Intelligent Automation in Pharmacovigilance
Neal Grabowski, Director, Safety Data Science, AbbVie, Inc.
Learn which AI-based technologies are in production for which ICSR process steps. Understand various considerations for planning, implementation, and validation. Understand key learnings from early adopters of AI-based technologies within the ICSR process.

1:05 Transition to Lunch

SCOPE SEND-OFF LUNCHEON PRESENTATIONS
Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring
Nekzad Shroff, Vice President, Product Management, Saama Technologies
Aditya Gadiko, Director of Clinical Informatics, Saama Technologies

Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials

Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 SCOPE Summit 2022 Adjourns

Program Advisory Board

February 8-9, 2022 | All Tmes EST

Michelle Crouthamel, PhD,
Head, Digital Science, AbbVie, Inc.

Christian Gossens, PhD,
Global Area Head; pRED Informatics and Digital Biomarkers, Roche

MONDAY, FEBRUARY 7

8:00 am SCOPE's Inaugural Masters of Clinical Research Golf Tournament
Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 Conference Registration Open (Gatlin Foyer)

2:00 pm User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

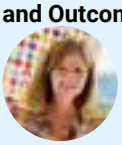
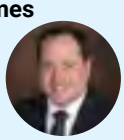
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

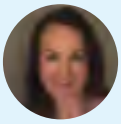
Moderator: Irfan Khan, MD, CEO, Circuit Clinical

Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

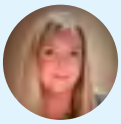
5:45 SCOPE's 2022 Participant Engagement Awards Introduction
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries,

Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co., Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 **SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)**

7:45 **Close of Day**

TUESDAY, FEBRUARY 8

7:15 am **Registration Open (Gatlin Foyer)**

7:15 **Morning Coffee** *(Sponsorship Opportunity Available)*

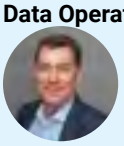
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 **Chairperson's Introduction**
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: **Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World**



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: **Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale**
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange, and clinical research? How do you do this at scale?

9:55 **Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin A2

DIGITAL BIOMARKERS AND ENDPOINTS: INNOVATION IS HERE

10:55 **Chairperson's Remarks**
David Anderson, PhD, Senior Scientist, Clinical Ink

11:00 **Digital Health in Clinical Trials**
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Novel digital endpoint, if used as the prespecified ranked endpoint in the registrational studies, may enhance labels and enable market access. Many pharmaceuticals are developing novel digital measures of health and disease to accelerate drug development and support product differentiation.

11:25 **CO-PRESENTATION: Regeneron's Framework in Developing Novel Digital Endpoints Through a Case Study**
Rinol Alaj, Director, Head of COA and Patient Innovation, Regeneron
Bharat Koyani, Senior Manager, Patient Innovation, Regeneron Pharmaceuticals Inc.
Regeneron will share how the company is leveraging the advancement and adoptability of consumer health monitors to further their goals of finding, developing and validating digital endpoints. The session will provide an overview of the different stages of digital endpoint validation the company used through a case study.

11:50 **Methodological Validation of Novel Digital Endpoints**
Carrie A Northcott, PhD, Director & Project Lead, Digital Medicine & Translational Imaging, Pfizer Inc
Digital health technologies (DHT) are transforming how we develop new therapies and assess their impact on patients. The shift was accelerated by the COVID-19 pandemic as clinical teams have rushed to enable decentralized trials and improve patient monitoring. While the industry still faces significant obstacles in validation of novel digital endpoints (NDE) we

are working toward a new methodological framework to validate wearable sensors and advanced analytics.

12:10 pm Leveraging Digital Biomarkers for Internal Decision Making and Modernizing Endpoints

Timothy Kilchenmann, Digital Biomarker Scientist, pRED Informatics, Roche Pharma

This presentation will share case studies of leveraging digital biomarkers for internal decisions as well as for modernizing endpoints.

12:30 Talk Title to be Announced

Adam Halbridge, Principal of Medical Infomatics & Digital Health, Medical Infomatics, ICON

1:00 Transition to Lunch

1:05 LUNCHEON PRESENTATION: eSource Data Collection: a Modern Approach to Sensor Data

Mark Mentzer, Senior Director, Connected Devices, IQVIA

Diagnostic devices and wearables have become commonplace and their presence is increasing within clinical trials. In addition to providing novel collection of data these solutions must meet quality and regulatory standards. eSource technology provides sites and patients with the opportunity to collect quality data. This presentation will provide an overview of why eSource technology is the key to scalable and compliant devices and sensors being employed now and in the future.

1:35 Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)

IMPLEMENTATION FRAMEWORK FOR DIGITAL MEASUREMENTS IN CLINICAL TRIALS

2:30 Chairperson's Remarks

Gillian Livock, SVP & GM, Connected Devices, Digital Solutions, Medable

2:35 Wearable-Enabled Digital Endpoints: Navigating the Path from Digital Data to Clinical Impact

Christine Guo, PhD, Chief Scientific Officer, ActiGraph

Digital measures enabled by wearables offer a patient-centric approach to assess real-world behaviors of clinical trial participants. Objective insights into how people function in their natural environment help us better understand meaningful aspects of treatment effect. Several recent cases have demonstrated the ability of digital endpoints to assist clinical decisions/development. This presentation discusses the framework for deploying and validating digital endpoints and the path from digital data to clinical insights.

3:05 A Case Study: Keeping a Pulse on Patients During a Pandemic

Tom Healy, Senior Director Data Architecture, PPD Digital, PPD, part of Thermo Fisher Scientific

In this case study, PPD will illustrate how the amalgamation of a DCT platform, remote patient monitoring, wearables, sensor devices, and rapid response home healthcare services contributed to the success of a clinical trial conducted during the COVID-19 pandemic. We will highlight the thoughtful design and data and systems architecture allowed the trial to be more patient-centric while simultaneously providing high quality, real-time data to ensure stronger health outcomes.

3:35 Regulatory Pathways for Digital Endpoint Development

Lada Leyens, PhD, PD Regulatory - Personalized Healthcare - Digital Health Regulatory Shaping Lead, Clinical Trial Innovation, F. Hoffmann-La Roche Ltd

There are different regulatory pathways available for digital endpoint development teams to get health authority advice on the validation of novel digital measures and their acceptability as label enabling endpoint in pivotal clinical trials. This presentation will cover examples of digital endpoint developments that used different regulatory pathways, their challenges and opportunities and considerations for regulatory strategies.

3:50 Panel Discussion: Implementation Framework for Digital Measurements in Clinical Trials

Moderator: Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.

Merging the best of two worlds - clinical trials and real-world – is now increasingly possible. Mobile sensors are rapidly becoming a part of everybody's lives. They allow for objective, precise and continuous measurements. This panel will share best practices and solutions for implementing digital measurements in clinical trials.

Panelists:

Robert J. Mather, Executive Director & Head, Advanced Science & Collaboration Group, Pfizer Inc.

Jennifer Goldsack, Executive Director, Digital Medicine Society (DiMe)

Lindsay Kehoe, Project Manager, Clinical Trials Transformation Initiative

Rinol Alaj, Director, Head of COA and Patient Innovation, Regeneron

Lada Leyens, PhD, PD Regulatory - Personalized Healthcare - Digital Health Regulatory Shaping Lead, Clinical Trial Innovation, F. Hoffmann-La Roche Ltd

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 Find Your Table and Meet Your Moderators

4:40 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)

6:40 Close of Day

WEDNESDAY, FEBRUARY 9

7:15 am Registration Open (Gatlin Foyer)

BREAKFAST PRESENTATIONS

Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 Practical Approaches for Operationalizing DCTs

Room Location: Gatlin A1

Kyle Hogan, President, Datacubed Health

Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2

Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS

Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin A2

STRATEGIES AND CASE STUDIES

8:20 Chairperson's Remarks

Jennifer Goldsack, Executive Director, Digital Medicine Society (DiMe)

8:25 Implementing a Digital Visit Testing Site for Clinical Trials

Ariel Dowling, PhD, Director of Digital Strategy, Data Sciences Institute, Research and Development, Takeda Pharmaceuticals

Within a pharma company, developing a digital visit testing site using internal volunteers to test electronic devices and digital platforms will enable more successful usage of these technologies in clinical trials. The goal of the digital visit is to address basic usability issues, "test-drive" the proposed visit protocol, and identify necessary training mechanisms. This presentation will discuss Takeda's efforts to create a lightweight and agile digital visit testing site.

8:55 How Real-Time, Real-World Data Creates Value Across the Therapeutic Lifecycle

Christopher McCann, CEO & Co-Founder, Current Health

The push to decentralize healthcare is touching every part of the patient journey, from how patients engage in research to how they receive clinical care. Today, sensors and wearable technology can provide a window into the home, improving patient engagement as well as the ability to measure outcomes and prove efficacy. However, data insights are only as powerful as the data collected. Knowing what data to capture, which devices to use, and how to effectively engage patients is critical to your ability to unlock the benefits of real-time, real-world data. Pulling from our experience working with leading health systems and global pharmaceutical companies, we'll explore the ways we've helped them leverage the power of patient data in the home to generate rich insights, improve patient experience and create value.

9:25 Expanding Neuro Digital Measurement Solutions in Clinical Trials

Thibaud Guymard, General Manager, Digital Measurement Solutions, Biogen Digital Health

Neuro clinical trials become the breaking ground for implementation and adoption of digital measurements. This presentation will share recent advantages and case studies of digital biomarkers in several CNS trials.

9:55 CO-PRESENTATION: Harnessing Connected Sensors and Wearables to Ease and Enhance the Continuum of Care

Gillian Livock, SVP & GM, Connected Devices, Digital Solutions, Medable

Russell Griffith, Director of DCT, Syneos

With worldwide spending on wearables estimated to exceed $90 billion by the end of 2022, connected sensors and wearables will continue to become more ubiquitous within clinical research.

With this increase in use comes more opportunity to leverage new health insights while adding minimal burden to our healthcare landscape.

Gain insights into the benefits of utilizing a single data platform for data collection along with use cases from previous trials.

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

DATA INTEGRATION FROM DIGITAL DATA SOURCES

11:20 Chairperson's Remarks

Ariel Dowling, PhD, Director of Digital Strategy, Data Sciences Institute, Research and Development, Takeda Pharmaceuticals

11:25 CO-PRESENTATION: Fireside Chat: Data Integration from Digital Data Sources

Ariel Dowling, PhD, Director of Digital Strategy, Data Sciences Institute, Research and Development, Takeda Pharmaceuticals

Jennifer Goldsack, Executive Director, Digital Medicine Society (DiMe)

Katherine Vandebelt, Gobal Vice President, Clinical Innovation, Oracle Health Sciences

More and more clinical trials are using wearables and sensors as part of their protocols. Data collected from digital data sources has to be integrated into the overall clinical data paradigm. This panel discussion will feature challenges and solutions for frictionless clinical data flow and integration.

11:55 Transition to Lunch

12:00 pm CO-PRESENTATION: LUNCHEON PRESENTATION: DCTs & Devices: Lessons Learned from a Women's Health Med Device Trial

Matty Culbreth-Notaro, BSN, RN, COO, ObvioHealth

Robin Sutherland, Vice President of Human Resources and Clinical Operations, Renovia

"Kegel" exercises are considered the most effective, non-invasive treatment for stress urinary incontinence in women. However, more than 75 percent of women perform these exercises incorrectly. Renovia, an innovative digital therapeutics company dedicated to improving women's Pelvic Floor Health partnered with ObvioHealth a Decentralized Clinical Trial expert, to evaluate the efficacy of an at-home pelvic digital health system (PDHS) benchmarked against the current standard of care. The 8 week randomized trial amongst 350 women in the US was the first fully virtual study in the urogynocological category. Women used a downloadable app to report on symptoms while also capturing actual device use. This enabled the virtual team to closely track progress, measure adherence and engage with

participants accordingly. Sponsor and CRO will discuss the findings and the implications for study design going forward.

12:30 **Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)**

1:30 **Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!***
**Separate registration required for access to Part B conferences, upgrade to Best Value Package.*

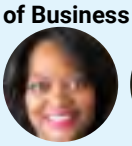
KEYNOTE LOCATION: Gatlin A1 & A2

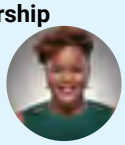
DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 **Welcome Remarks from CHI and the SCOPE Team**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: **Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative**
Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:00 **Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership**






Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.
Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**
*Don't forget Part B Conferences begin at 3:45pm**Separate registration required, upgrade to Best Value package.*

Program Advisory Board

February 9-10, 2022 | All Tmes EST

Joe Dustin,
Head of Clinical Innovation, Bristol-Myers Squibb Co.

Terry Murphy,
Vice President, Global Head Enabling Business Information Solutions, GCDO, COVID-19 Clinical Development Relaunch Leader, The Janssen Pharmaceutical Companies

Isaac Rodriguez-Chavez, PhD,
Senior Vice President, Scientific & Clinical Affairs, Head, Global Center of Excellence DCT Strategy, PRA Health Sciences

WEDNESDAY, FEBRUARY 9

ROOM LOCATION: Gatlin A2

BRIDGING LUNCHEON PRESENTATION

12:00 pm **CO-PRESENTATION: LUNCHEON PRESENTATION: DCTs & Devices: Lessons Learned from a Women's Health Med Device Trial**
Matty Culbreth-Notaro, BSN, RN, COO, ObvioHealth
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12:30 **Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)**

KEYNOTE LOCATION: Gatlin A1 & A2

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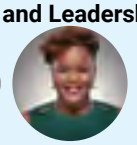
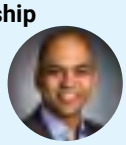

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Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin A2

CHALLENGES, SOLUTIONS AND LESSONS LEARNED FROM GLOBAL DCT ADOPTION

3:45 **Chairperson's Remarks**
Lillian Stone, Associate Director, Study Start-Up, Firma Clinical Research

3:50 **Panel Discussion: Incentivizing Decentralized Research**
Moderator: Joe Dustin, Vice President of Product Strategy, Medable Inc
What are the different stakeholders that need to change across the ecosystem and how do we set up new incentive structures to manage successful change and accelerate adoption?
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Antonios Clapsis, Vice President, Clinical Trial Services, CVS Health
Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative

4:20 **Putting "Community" Into Clinical Research**
Antonios Clapsis, Vice President, Clinical Trial Services, CVS Health
Putting "Community" Into Clinical Research: How do we effectively engage and involve local communities and underserved populations in their health

and clinical research? In this session, we will talk about how to go beyond "outreach" from awareness and access to community partnerships and decentralized options with the objective of improving health equity and trial effectiveness.

4:50 CO-PRESENTATION: 'The New Normal' is Only Beginning: Leveraging a Connected Ecosystem to Keep Research Moving Forward

James Riddle, MCSE, CIP, CPIA, CRQM, Vice President, Research Services & Strategic Consulting, Advarra

Jonathan Shough, President, Technology Solutions, Advarra

In the past 24 months, our industry has experienced a revolution, led by unprecedented innovation. But challenges still lie ahead to make research effective, efficient, and inclusive. In this session, we'll outline how we can leverage progress during the pandemic to optimize our DCT strategies around people, process, and technology. We'll discuss how a connected research ecosystem will accelerate future development, enabling stakeholders for success in any type of trial model.

5:20 Abiding and Transient COVID Innovation

Balazs Flink, Senior Director, Clinical Development Operations, Daiichi Sankyo, Inc.

Two years into the pandemic there are numerous solutions and innovative ideas that received a huge boost from the outbreak and will likely shape the future of clinical trials. Others are likely to become a one-hit-wonder. The presentation will highlight key trends seen in Oncology trials and the black swans amongst them.

5:50 Close of Day

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast (Gatlin Foyer)

ROOM LOCATION: Gatlin A2

8:20 Chairperson's Remarks

Isaac R. Rodriguez-Chavez, PhD, Senior Vice President, Scientific & Clinical Affairs, Decentralized Clinical Trials & Digital Medicine, ICON

8:25 What Are Decentralized Trials Of The Future? Ask Patients

Jen Horonjeff, PhD, Founder & CEO, Savvy Cooperative

Long before the pandemic, patients have wanted clinical trials to be more accessible and less disruptive of their lives. Enter COVID-19, and the industry deployed tools and strategies to allow patients to participate in trials remotely. While this alleviated some stressors, did it inadvertently create new ones? We will unpack the patient perspective on decentralized trials of today, and provide a pathway to designing trials of the future.

8:45 Innovation in DCTs

Joe Dustin, Vice President of Product Strategy, Medable Inc

What is next in DCTs? This presentation will feature some novel solutions that help making DCTs more sustainable.

9:05 Where Are We with DCTs – a Sponsor's Review of the Current Regulatory Landscape and Potential Barriers to Scale

Scott Askin, Global Program Regulatory Director for Innovation, Regulatory Affairs, Novartis Pharma AG

Whilst DCT's continue to be a Hot Topic across the industry and the impact of the COVID-19 pandemic was anticipated to "flip the switch" in terms of acceptability of DCTs by global regulators, the industry is still facing challenges in implementation and moving to scale continues to have it's barriers. This session will explore the implementation of DCTs within the current regulatory landscape and offer potential solutions to mitigate challenges.

9:25 Navigating the Top 3 Tech Challenges in Decentralized Trials

Nagaraja Srivatsan, SVP & Chief Digital Officer, Clinical Technologies, IQVIA

The rapid, widespread – and unanticipated – adoption of decentralized trials in 2020 unearthed new challenges inherent to deploying innovative DCT technologies at scale. In this session, we'll discuss the top three technology challenges in DCTs – and ways to address them head-on – drawing upon IQVIA's experience as an industry leader designing and delivering hybrid trial solutions. Attendees will walk away with strategies for effective, efficient and compliant patient-centric studies.

9:40 CO-PRESENTATION: Stronger Together: How Can a Partnership Unlock the Key to DCT?

Kelly McKee, Vice President, Patient Registries and Recruitment, Medidata, a Dassault Systèmes Company

Irfan Khan, CEO, Circuit Clinical

Join leaders in the industry to explore the past, present, and future of Decentralized Trials. Learn what it takes to optimize the patient experience by utilizing connected capabilities from patient to sponsor. Through the partnership between Medidata and Circuit Clinical, explore the future of clinical research with a turn key DCT solution accompanied with unmatched expertise.

10:10 Regulatory Considerations when Implementing Decentralized Clinical Trials Enabled by Digital Health Technologies – Lessons Learned

Isaac Rodriguez-Chavez, Senior Vice President, Scientific and Clinical Affairs, Decentralized Clinical Trials & Digital Medicine, ICON

The clinical research enterprise is risk-averse and has influenced the slow growth of DCTs in the early 2000s, followed by a 7% compound annual growth rate from 2014 to 2019, and an explosive DCT implementation that has gone over 77% due to tCOVID-19 pandemic in 2019 and 2020. Regulatory agencies have enabled fast DCT adoption in the field by issuing guidance documents.

10:40 Networking Coffee Break (Gatlin Foyer)

DATA CAPTURE IN DECENTRALIZED TRIALS

10:55 The Role of Electronic Data Capture in Decentralized Trials: Opportunities for Patient Access and Study Optimization

Ebony N Dashiell-Aje, PhD, Senior Director, Patient Engagement and Outcomes Research, BioMarin Pharmaceutical Inc.

11:15 A Practical Guide to Direct Data Capture (DDC)

Susan M. Bornstein, Senior Director, Data Monitoring & Management, Clinical Sciences & Operations & Global Product Development, Pfizer Inc.

DDC is one of the eSource modalities as defined by Transcelerate BioPharma. EHR/EMR, Devices, Apps&Devices, Non-CRFs (labs, images), and DDC. With the increase in DCTs the use of DDC to collect eCRF data is increasing. This presentation will focus on a practical guide to DDC. How DDC differs from traditional EDC. Considerations for delivery of DDC data will be discussed.

12:00 pm Transition to Shared Sessions or Brief Session Break

TOKENIZATION OF CLINICAL TRIAL PARTICIPANTS

12:05 Panel Discussion: Introducing Unique, Anonymized Identifiers (Tokens) in Clinical Research to Link Participants to Real-World Data

Moderator: Kyle Holen, Head, Development Design Center, AbbVie, Inc.

This panel discussion will feature use cases and address the key questions regarding clinical trial participant's tokenization such as Why tokens? What are potential pitfalls? When will this be global?

Panelists:

Craig Lipset, Founder & Advisor, Clinical Innovation Partners; Co-Chair, Decentralized Trials & Research Alliance (DTRA)

Vera Mucaj, CSO, Datavant

Kathleen Mandziuk, MPH, RN, Vice President, Patient Strategy, ICON plc

Timothy Riely, Vice President, Clinical Data Analytics, IQVIA

Sandy Leonard, SVP, Partnerships and RWD, HealthVerity

1:05 Transition to Lunch

SCOPE SEND-OFF LUNCHEON PRESENTATIONS

Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring

Nekzad Shroff, Vice President, Product Management, Saama Technologies

Aditya Gadiko, Director of Clinical Informatics, Saama Technologies

Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials

Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 SCOPE Summit 2022 Adjourns

Program Advisory Board

February 8-9, 2022 | All Tmes EST

Dorothee Bartels, PhD,
Global Head of RWE and Digital Sciences, UCB

Aaron Kamauu, MD,
Managing Director, Ikaika Health LLC

Xia Wang, PhD,
Director, Healthcare and Imaging Analytics, Data Science & AI, R&D, AstraZeneca Pharmaceuticals LP

MONDAY, FEBRUARY 7

8:00 am SCOPE's Inaugural Masters of Clinical Research Golf Tournament

Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 Conference Registration Open (Gatlin Foyer)

2:00 pm User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)

Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

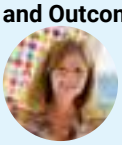
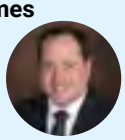
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

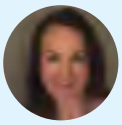



Moderator: Irfan Khan, MD, CEO, Circuit Clinical
Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

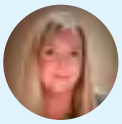
5:45 SCOPE's 2022 Participant Engagement Awards Introduction
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co.,

Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 **SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)**

7:45 **Close of Day**

TUESDAY, FEBRUARY 8

7:15 am **Registration Open (Gatlin Foyer)**

7:15 **Morning Coffee** *(Sponsorship Opportunity Available)*

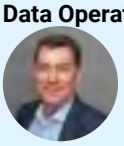
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 **Chairperson's Introduction**
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: **Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World**



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: **Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale**
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange, and clinical research? How do you do this at scale?

9:55 **Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E2

RWD IN PERI-PANDEMIC WORLD

10:55 **Chairperson's Remarks**
Boshu Ru, PhD, Associate Director, Real-World Data Analytics and Innovation, Center for Observational and Real-World Evidence (CORE), Merck & Co. Inc.

11:00 **RWD Strategies in Peri-Pandemic World**
Charles Makin, Global Head, Medical Health Outcomes Research, Biogen
Thanks to the prevailing digital revolution, and advances in predictive analytics and computing platforms, a new frontier has emerged to enhance the drug development process. We elucidate pertinent aspects of the use of real-world evidence in regulatory settings, with emphasis on study design, analytical strategies, data quality, and regulatory requirements

11:30 **Connecting Clinical Research and Healthcare through Data Interoperability: The Case for HL7 FHIR**
Amy Cramer, Director, Global Product Development Strategic Partnerships, Pfizer Pharmaceuticals
This presentation will explore how to bridge gaps between clinical research and clinical care to leverage the power of healthcare data to bring medicines to patients faster and reduce the burden place on researchers through the use of HL7 FHIR.

12:00 pm **Novel Methods for Prospective Research Data Collection at the Point of Care**
Lauren Sutton, Director, Product Management, Clinical Research, Flatiron Health
The electronic health record can be used and modified at the point of care to capture intentionally collected data for prospective research use cases. "Intentionally collected data" is data that is collected for the purpose of research and not per standard of care. We'll discuss a real example of how this was done in support of oncology clinical trials being run in the community setting.

12:30 **Using RWD and AI for Patient Identification and Trial Optimization**
Joseph Zabinski, PhD, Senior Director, AI & Precision Medicine, OM1

- Clinical trial success can be enhanced by finding the right patients - those more likely to qualify, more likely to respond, and less likely to experience adverse events
- Trained on deep longitudinal data, AI algorithms can isolate these characteristics and identify patients most likely to have them
- Successful 'last-mile' deployment of these algorithms is finally possible - and is critical to achieving actual real-world benefit

1:00 Enjoy Lunch on Your Own

1:35 Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)

DIGITAL EPIDEMIOLOGY

2:30 Chairperson's Remarks
Aaron Berger, Executive Director, US Late Stage Operations and RWE, UBC

2:35 Epidemiology and Data Science: Creating a Powerful Mix of Skills and Goals
Dorothee B. Bartels, PhD, Global Head of RWE and Digital Sciences, UCB
The real-world data hype caused high expectations, including RCTs, might only play a minor role in future drug development. But they are rather complementary to RCT data and cannot replace them. Artificial intelligence may change drug development and time to market significantly, but will not replace past knowledge and experience. Real-World Evidence generation can be enhanced by AI and is key for public health.

3:05 Patient-Centricity as a Catalyst for RWD Drives Clinical Trial Success SEQSTER
Ardy Arianpour, CEO & Co-Founder, Seqster
To keep up with the rapidly changing environment and to emerge as a winner, life science enterprises need to embrace patient-centricity that provides longitudinal, comprehensive, and real-time Real World Data. Faster enrollment through automated, patient-mediated data collection leads to Real World Evidence as well as a decrease in time, cost and resources for clinical trials. Come see how Seqster is redefining Real World data collection through the patient.

3:35 Machine Learning Methods For Causal Inference in Epidemiology Studies Using RWD
William H. Crown, PhD, Distinguished Research Scientist, Brandeis University
Considerable progress has been made in the ability to draw causal inferences from analyses of RWD. ML methods provide powerful analysis tools that have traditionally been used for prediction and classification problems. However, they also show promise for outperforming traditional statistical causal inference methods if used in the context of a causal framework. This presentation will provide an overview of the use of ML methods for causal inference in epidemiology.

4:05 Optimizing Real-World Evidence Generation with Decentralized Research THREAD
Joss Warren, Executive Director and Head of Strategy & Partnerships, THREAD
Decentralization has become a central strategy for conducting clinical research over the past few years, and while the focus has often centered on clinical trials, the benefits of decentralization are magnified in the generation of real-world evidence (RWE). This session will focus on how decentralized research technologies can both optimize prospective RWE generation while creating opportunities to combine with existing RWD to provide a more comprehensive view of the research participant.

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 Find Your Table and Meet Your Moderators

4:40 Interactive Discussions
Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)

6:40 Close of Day

WEDNESDAY, FEBRUARY 9

7:15 am Registration Open (Gatlin Foyer)

BREAKFAST PRESENTATIONS
Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 Practical Approaches for Operationalizing DCTs Datacubed Health
Room Location: Gatlin A1
Kyle Hogan, President, Datacubed Health
Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2
Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS
Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin E2

DATA INTEROPERABILITY

8:20 Chairperson's Remarks
Aaron W. Kamauu, MD, Managing Director, Ikaika Health LLC

8:25 Use-Case Specific Relevance and Quality Assessment For Real-World Data (RWD) – Implementation and Outlook
Boshu Ru, PhD, Associate Director, Real-World Data Analytics and Innovation, Center for Observational and Real-World Evidence (CORE), Merck & Co. Inc.
The variety and fragmentation of healthcare data across institutions and software programs continue to pose a challenge for researchers to select "fit-for-purpose" real-world data (RWD). We designed a Use-case specific Relevance and Quality Assessment (UReQA) framework1 to evaluate the fitness of commercial RWD offerings in the US and implemented Oncology use cases of real-world time-to-treatment discontinuation. We are expanding the framework to support more use cases and additional therapeutical areas.

8:55 CO-PRESENTATION: Modernizing Observational Research with Patient Mediated Electronic Medical Record Release
Aaron Berger, Executive Director U.S. Late Stage Operations and RWE, UBC
Dana Hosseini, Chief Business Officer and Co-Founder, Seqster
Data acquisition in observational studies has been disrupted now that interoperability solutions enable the use of real world data for research. One solution that is fundamentally changing observational research is patient mediated electronic medical record release, which allows the patient to obtain their consolidated medical record and contribute to research directly. Join us for a discussion on the application of this RWD technology to enable modernized observational and direct-to-patient study designs.

9:25 To Replicate or Continue to Learn in the Real-World?
John Cai, MD, PhD, Executive Director, Real-World Data Analytics and Innovation, Merck
A number of studies have been conducted to examine if RWE generated from RWD can replicate findings from randomized clinical trials (RCTs). Researchers may also ask what can be learned from the differences between RCT evidence and RWE, and decision-makers may even ask whether such differences can be predicted. This presentation will cover several use cases across the Pharma, Payer/HTA, and regulatory settings that require different questions to be addressed.

9:55 Biosimilar Uand Utilization Patterns: An Analysis of Real-World Medical and Pharmacy Data
Ria Westergaard, Product Strategy Lead, Evernorth Intelligence Solutions, Evernorth
Despite an abbreviated approval pathway, a relatively small number of biosimilars have been approved and an even smaller number have entered the marketplace. Slow uptake has stakeholders looking for strategies to optimize adoption in the future. This session will discuss real-world data research using medical and pharmacy claims to reveal the proportion of prescriptions for originator product versus biosimilar as well as switching patterns.

10:10 CO-PRESENTATION: Navigating the RWD Landscape in Japan
Shuta Mitomo, Director, Digital and Innovation Planning, CRO Business, CMIC Group
Yohei Hayashi, Specialist, Health Economic and Outcomes Research/Real World Evidence Department, CRO Business, CMIC Group
When utilizing RWD, the selection of the medical information database used for analysis is an important consideration. It is necessary to understand the insurance system in Japan and recognize the characteristics of each database. This presentation will take a deep dive into the current system and database utilized in Japan and provide tips for database selection and how it should be selected according to target disease area and desired result.

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

REGULATORY GRADE RWD

11:25 Developing a Quality Management Checklist to Support Audits of Real-World Data (RWD) Used in Regulatory Submissions
Jerome Calmejane, Senior Director, GCP Quality Assurance, Janssen Pharmaceuticals, Johnson & Johnson
This session will focus on TransCelerate's work on a forthcoming proposal for a quality management checklist to support audits of RWD used for regulatory decision-making.

11:55 Transition to Lunch

12:00 pm CO-PRESENTATION: LUNCHEON PRESENTATION: How Quality Real-World Data and Industry Expertise are Accelerating Clinical Trials
Jennifer Duff, Watson Health Life Sciences, eClinical and Client Solutions Leader, Product Management, IBM Watson Health
Alice Landis-McGrath, MD, Watson Health Associate Chief Health Officer, HOPE, IBM Watson Health
Complexity and challenges in clinical trials are well-known, but are magnified when organizations underinvest in the quality of data and the industry expertise of their partners. Join IBM Watson Health for lunch and hear real examples of how organizations are seeing a meaningful impact in their studies with quality real-world data and partnership with industry experts.

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

1:30 Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!*
****separate registration required for access to Part B conferences, upgrade to Best Value package.***

KEYNOTE LOCATION: Gatlin A1 & A2

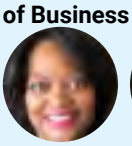
DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

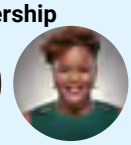
1:30 **Welcome Remarks from CHI and the SCOPE Team**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: **Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative**
Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**
Don't forget Part B Conferences begin at 3:45pm**Separate registration required, upgrade to Best Value package.

2:00 **Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership**






Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.
Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

SCOPE's 2020 Participant Engagement Awards

Program Advisory Board

February 9-10, 2022 | All Tmes EST

WEDNESDAY, FEBRUARY 9

ROOM LOCATION: Gatlin E2

BRIDGING LUNCHEON PRESENTATION

12:00 pm **Bridging Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 **Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)**

KEYNOTE LOCATION: Gatlin A1 & A2

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Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E2

RWE FOR TRIAL OPTIMIZATION

3:45 **Chairperson's Remarks**
Aaron W. Kamauu, MD, Managing Director, Ikaika Health LLC

3:50 **Bridging the RCT and RWE Universes with Calibration Trials**
Sebastian Schneeweiss, MD, Professor, Medicine & Epidemiology, Harvard Medical School; Chief of the Division of Pharmacoepidemiology, Department of Medicine, Brigham and Women's Hospital
Regulators are evaluating the use of noninterventional real-world evidence (RWE) studies to assess the effectiveness of medical products. The RCT DUPLICATE initiative (Randomized, Controlled Trials Duplicated Using Prospective Longitudinal Insurance Claims: Applying Techniques of Epidemiology) uses a structured process to design RWE studies emulating randomized, controlled trials (RCTs) and compare results.

4:20 **External Control Arms: Framework and Path Forward**
Aaron W. Kamauu, MD, Managing Director, Ikaika Health LLC
ECAs have a "long history" in regulatory decision-making and are used when randomization is unethical or unfeasible. They can also serve as a benchmark in health technology assessments. Advances in data access, quality, methodologies, and societal influence have broaden the use cases for ECAs. If data confidence is relatively high, an ECA could become an option when a randomized controlled trial (RCT) is impractical to do.

4:50 **Talk Title to be Announced**
Kathleen Mandziuk, MPH,RN, Vice President Real World Solutions & Tokenization, ICON, Commercialization & Outcome Services (ICO), ICON

5:20 **ROPRO – Real-World Data Prognostic Score – A Novel Tool to Assess Patients' Performance Status**
Anna Bauer-Mehren, PhD, Head, Data Science, Roche Diagnostics GmbH
The assessment of patients' performance status is important for toxicity monitoring, treatment selection, and clinical trial eligibility. By mining data of >120,000 cancer patients from Flatiron Health, we derived the ROPRO score for overall survival in cancer patients. We are using baseline ROPRO for patient selection as a quantitative, unbiased decision support to

determine 12-week life expectancy. Longitudinal delta ROPRO analyses may help clinicians detect treatment benefits or progression early.

5:50 Close of Day

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast (Gatlin Foyer)

ROOM LOCATION: Gatlin E2

8:20 Chairperson's Remarks

Sandy Leonard, SVP, Partnerships and RWD, HealthVerity

8:30 Methodological and Related Issues in the Use of Real-World Evidence to Enhance Drug Development

Demissie Alemayehu, PhD, Vice President, Biostatistics, Pfizer Inc.

While the potential use of real-world evidence in regulatory decision making is well recognized, there are challenging fundamental issues that require careful attention. We discuss some of the commonly arising issues, along with the pros and cons of routinely used mitigation measures. Recent developments in the use of modern analytics to address confounding and high dimensionality are reviewed, and illustrations are provided using case studies from the pertinent literature.

8:55 Real-World Trial: The Role of RWD/RWE in Innovating Traditional Clinical Trial

Xia Wang, PhD, Head of RWE Early Solution, Global Real World Evidence and Digital Sciences, UCB

This talk presents the fast-emerging landscape of RWD/RWE in innovating traditional clinical trials, with a focus to communicate the vision, strategies, the best practice, the areas of success, and the challenges yet to conquer.

9:25 Time and Motion Studies: Generating Evidence to Improve Efficiencies in Healthcare Processes and Workflow

Sunning Tao, MA, MSc, Research Scientist, UBC

Time and motion study design is used in clinical and real world settings to generate evidence to improve efficiencies in healthcare processes and workflow. This presentation will discuss the evolution of this study design from its original industrial application to a valued tool for clinical research today. Topics include how ™ studies may differ in design depending on the intended clinical setting, real-world examples, regulatory and ethical procedures, and case studies.

9:40 CO-PRESENTATION: Using Real World Data to Minimize Patient Burden and Accelerate Oncology Clinical Trials

Liam Wood, SVP Product Management, ConcertAI

Jamie Powers, DrPH, Executive Director, Clinical Research Technology & AI Solutions, ConcertAI

Oncology clinical trials place a large burden on patients and researchers, such that only a small portion of cancer patients participate in research studies. Proximity to research centers, staffing requirements, and additional procedures limit the desirability of research participation. In this presentation, Real World Data sources (specifically Electronic Health Record systems) are discussed to reduce patient and research staff burden, while opening the door to accelerated studies with increased access.

10:10 An EHR to EDC Proof of Concept Observational Study: Implementation and Lessons Learned

Peter Payne, Vice President, Head, Digital Research Network, Optum

Optum partnered with three provider groups to streamline and automate clinical trials through their digitized solution, the Optum Digital Research Network. This approach to recruitment, data entry and PROs resulted in a more cost-effective, less burdensome process that could benefit practices interested in clinical trial participation and expand diversity of patient populations available for pragmatic trials in a real-world setting. This session will discuss the study methodology, results and participant perspectives.

10:40 Networking Coffee Break (Gatlin Foyer)

FRAMEWORK FOR RWD STUDIES

11:00 Study Automation – Framework and Tools to Conduct Common Real-World Data(RWD) Studies

Yeran Li, PhD, Associate Director, Real World Data Analytics & Innovation, CORE

We developed a framework and tools to conduct regular RWD studies. The objective is to improve operational efficiency and ensure reproducibility/repeatability/transparency. The framework provides best practice recommendations from data standardization to data visualization, and the tools include a suite of R packages to provide a user-friendly implementation.

11:30 Trials4Care: Leveraging Real World Data at Scale

Koenraad Batselier, Vice President, Life Sciences, Dedalus

Radical shifts are happening in the healthcare service delivery system. "Episode Centric" approach is changing to a "continuum of care" approach, with the consumer needs at the very center. Dedalus aims to enable such a revolutionary transformation with its innovative framework bridging the gap between various systems of record while generating contextually relevant insights, improving the clinician experience, and progressing study design and recruitment of more precise sub-populations of patient cohorts.

12:00 pm Transition to Shared Sessions or Brief Session Break

ROOM CHANGE: Gatlin E1

AI FOR REAL-WORLD AND TRIAL DESIGN APPLICATIONS

12:05 Multimodal Clinical Prediction Models in Research and Beyond

Patrick Schwab, PhD, Director, Artificial Intelligence and Machine Learning, GSK

Machine learning holds promise for integrating comprehensive, deep phenotypic patient profiles across time for (i) predicting outcomes, (ii) identifying patient subtypes and (iii) associated biomarkers. In this talk, we will outline opportunities and challenges for clinical prediction models built from deep phenotypic patient profiles in clinical research and beyond.

12:35 Case Studies for AI-Based Intelligent Automation in Pharmacovigilance

Neal Grabowski, Director, Safety Data Science, AbbVie, Inc.

Learn which AI-based technologies are in production for which ICSR process steps. Understand various considerations for planning,

implementation, and validation. Understand key learnings from early adopters of AI-based technologies within the ICSR process.

1:05 Transition to Lunch

SCOPE SEND-OFF LUNCHEON PRESENTATIONS

Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring

Nekzad Shroff, Vice President, Product Management, Saama Technologies

Aditya Gadiko, Director of Clinical Informatics, Saama Technologies

Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials

Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 SCOPE Summit 2022 Adjourns

Program Advisory Board

February 8-9, 2022 | All Tmes EST

Karina Bienfait, PhD,
Executive Director, Specimen Infrastructure & Informed Consent, Global Biospecimen & Imaging Management, Bristol-Myers Squibb

Michael Tanen,
Director, Clinical Biomarker Specimen Management, Merck & Co.

Lynn Wetherwax,
R&D Strategy and Operations, Amgen Inc.

Brenda Yanak,
Vice President, Global Biospecimen & Imaging Management, Bristol-Myers Squibb Co.

Mary Zuniga,
Consultant, Translational Science Immunology, Eli Lilly & Co.

MONDAY, FEBRUARY 7

8:00 am **SCOPE's Inaugural Masters of Clinical Research Golf Tournament**
Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 **Conference Registration Open (Gatlin Foyer)**

2:00 pm **User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)**
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

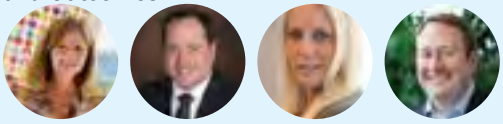
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 **Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants**
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

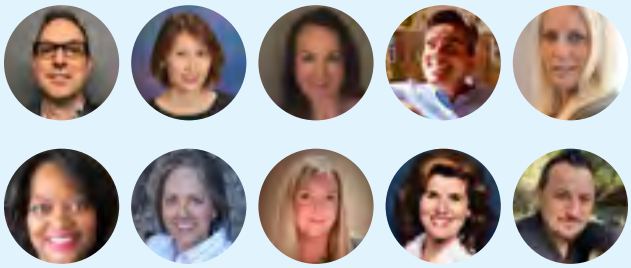
5:10 **Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes**



Moderator: Irfan Khan, MD, CEO, Circuit Clinical
Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

5:45 **SCOPE's 2022 Participant Engagement Awards Introduction**
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 **SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards**



Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions

& Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co., Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 **SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)**

7:45 **Close of Day**

TUESDAY, FEBRUARY 8

7:15 am **Registration Open (Gatlin Foyer)**

7:15 **Morning Coffee** *(Sponsorship Opportunity Available)*

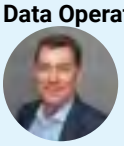
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 **Chairperson's Introduction**
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: **Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World**



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: **Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale**
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange, and clinical research? How do you do this at scale?

9:55 **Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E3

ENABLING BIOMARKER DRIVEN TRIALS

10:55 **Chairperson's Remarks**
Venugopal Mallarapu, Senior Director and Head of R&D Solutions, Life Sciences, Cognizant Technology Solutions

11:00 **Selecting, Developing and Validating Critical Path Clinical Assays for SARS-CoV-2 Vaccine Trials during a Global Pandemic**
Jean-Claude Marshall, PhD, Head of Clinical Biomarker, Moderna
In early 2020 the Moderna Clinical Biomarker team began considering the need for an unprecedented requirement, building clinical grade immunological and functional assays to support a vaccine trial for a novel virus. Over the next year the assays that were rapidly developed by academic, government and commercial partners were used for all phases of clinical development and eventual BLA. This talk will focus on the challenges of those assay developments.

11:30 **Exploiting Information to Innovate along the Specimen Lifecycle to Meet the Demands of Our Complex and Biomarker Rich Clinical Programs**
Michael Tanen, Director, Clinical Biomarker Specimen Management, Merck
Information has become the currency of our time. Information management and analytics are helping clinical teams advance insight-driven programs by helping to maximize information to deliver operational excellence, competitive agility, and overall efficiencies. Current clinical designs and complex biomarker-driven trials have pushed specimen management organizations to innovate old processes and tools to take advantage of advances in technology that can better manage data, improve intelligence, and shape strategies.

12:00 pm **Enabling Organization to Leverage Biospecimen Metadata for KPI and Metrics Assessment across Portfolio**
Dharmesh Patel, Lead, Biomarker Operations, Bristol-Myers Squibb Co.
Tumor tissue biopsies are critical biospecimens for endpoint and exploratory analysis in trials. The collection difficulty, burden to patient, and

inability for sites to evaluate prior to submitting samples, results in tumor tissue quality and quantity variability. BMS has created a Spotfire-based visualization of H&E pathology review and Pass/Fail rates. Integrating this biospecimen metadata with result's outcome and visualizing in Spotfire allows integration of 100 studies across programs and sites.

12:30 CO-PRESENTATION: Innovative Biomarker Strategies for Clinical Research: Challenges and Opportunities

Venugopal Mallarapu, Senior Director and Head of R&D Solutions, Life Sciences, Cognizant Technology Solutions

Avi Kulkarni, Ph.D., SVP & Global Markets Head, Life Sciences, Cognizant Technology Solutions

While biomarker-based segmentation is becoming more mainstream in clinical trials, there are many challenges in designing the right strategies. Considerations include validated biomarkers vs. biomarkers of interest, iterative loops between biomarkers, and incorporating imaging, lab and longitudinal (outcomes) data. Innovative solutions include leveraging AI and identifying the right sites and PIs to integrate new testing approaches. This session will explore the challenges and opportunities around building innovative clinical research biomarker strategies.

1:00 Enjoy Lunch on Your Own

1:35 Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)

GLOBAL BIOMARKER OPERATIONS

2:30 Chairperson's Remarks

Dan O'Connell, Head of US Sales, eClinical Solutions

2:35 Strategies for Operationalizing the Collection of Biospecimens and Execution of Biomarker Research in China

Karina Bienfait, PhD, Executive Director, Specimen Infrastructure & Informed Consent, Global Biospecimen & Imaging Management, Bristol-Myers Squibb Co.

The inclusion of China in global clinical trials brings unique challenges to the biospecimen/biomarker space due to requirements of the 2019 Regulations of Management of Human Genetic Resources of the People's Republic of China (HRAC). This presentation will discuss the application process through the HGRAC, including navigating data and intellectual property sharing as well as sample and data management activities, with emphasis on ensuring compliance and oversight of the process.

3:05 Overcoming the Challenges of Assay and Diagnostic Development in China

Yixin Wang, Bristol-Myers Squibb Co.

Multinational pharmaceutical companies conducting clinical trials in China have been facing new challenges in regulation, quality, and operations. The presentation will discuss the learnings in development of biomarker and diagnostic assays for China clinical studies.

3:35 Overview of China's Human Genetic Resources Regulation

Katherine Wang, Partner, China Life Sciences, Ropes & Gray LLP

China's 2019 Human Genetic Resources Regulations regulate the collection, preservation, utilization, and provision to third parties including the export of Chinese human genetic resources. The HGRAC creates significant challenges to conducting clinical research in China. This session will provide an over o the HGRAC regulation and implications to biospecimen and biomarker operations.

4:05 External Lab Sample Tracking and Visualization with an Integrated Platform Approach

Lorenzo Balsamo, Associate Director of Clinical Informatics, Jounce Therapeutics

This case study session demonstrates how Jounce Therapeutics used a platform approach and the elluminate Clinical Data Cloud to aggregate external sample inventories and clinical operational data from disparate sources. By integrating sample data and providing self-service visualization access, the Jounce team enabled real-time insights and greater efficiency via the automation of manual processes. Learn about the analytics and outcomes of this new approach to biomarker sample and patient data tracking.

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 Find Your Table and Meet Your Moderators

4:40 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)

6:40 Close of Day

WEDNESDAY, FEBRUARY 9

7:15 am Registration Open (Gatlin Foyer)

BREAKFAST PRESENTATIONS

Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 Practical Approaches for Operationalizing DCTs Room Location: Gatlin A1

Kyle Hogan, President, Datacubed Health

Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2

Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS

Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+

healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin E3

ADVANCING BIOMARKER, BIOSPECIMENS AND IMAGE MANAGEMENT

8:25 Sample Reconciliation and Tracking: Can We Advance to the 21st Century?

Lynne Krajkovich, Global Head, Biomarker & Imaging Operations, Novartis Global Development Operations

Despite the advanced technological world we are living in today, the reconciliation and tracking of clinical trial samples has remained a mostly manual task. Companies have built in-house systems, piloted external systems, or used a combination of different approaches, but no one has yet to completely master the automation of this process. We are looking at a new approach, one that may change a traditional clinical trial activity.

8:55 Panel Discussion: Innovations in Biomarker and Biospecimen Management

Moderator: Karina Bienfait, PhD, Executive Director, Specimen Infrastructure & Informed Consent, Global Biospecimen & Imaging Management, Bristol-Myers Squibb Co.

The advancement of precision medicine depends critically upon the accessibility and quality of biomarkers and biospecimens, requiring effective biomarker and biospecimens collection and management. Join our expert panel as they discuss novel solutions to overcome the many operational challenges of biomarker and biospecimens management.

Panelists:

Michael Tanen, Director, Clinical Biomarker Specimen Management, Merck

Brenda Yanak, Vice President, Global Biospecimen & Imaging Management, Bristol-Myers Squibb Co.

Lynn Wetherwax, Director, R&D Strategy and Operations, Amgen

Lynne Krajkovich, Global Head, Biomarker & Imaging Operations, Novartis Global Development Operations

Mary Zuniga, Consultant, Translational Science Immunology, Eli Lilly & Co.

9:25 CO-PRESENTATION: Creating a Comprehensive Development Image Management Strategy for the Capture, Analysis, Transformation and Access of Scientific Images and Image Data

Bob O'Hara, Managing Partner, ResultWorks LLC

David Witt, IT Business Partner, Translational Medicine Imaging, Bristol Myers Squibb

The decentralization of image management has limited the access and sharing of imaging information, as well as created the consequential duplication of systems, and inefficient processes and data flow, resulting in poor investment returns. This presentation summarizes the results and lessons learned from a recent initiative at BMS to develop a comprehensive strategy for image management across the R&D organization.

9:55 30 Days to an Annotated Virtual Repository -- Without Changing DTAs

Michael Waters, Vice President, Sales, QuartzBio, part of Precision for Medicine

By linking biospecimen metadata, informed consent, and biomarker data across multiple LIMS and inventories, you can create an annotated virtual biorepository. Join our presentation to learn how cross-functional teams are using technology-enabled solutions on study, across studies, and across their entire portfolio, to:

- Address site performance, data quality, and query resolution
- Ensure regulatory compliance
- Save resources using stored samples to advance research beyond current study

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

11:25 CO-PRESENTATION: ROUNDTABLE DISCUSSION: Technologies and Partnerships to Streamline Sample/Biomarker Management in Clinical Trials

Lynne Krajkovich, Global Head, Biomarker & Imaging Operations, Novartis Global Development Operations

Yvonne Beasley, Senior Director, Laboratory Operations, Specimen Processing, Q2 Lab Solutions

COVID altered biomarker and biospecimen operations: should some of the changes stay beyond the pandemic (#nogoingback)?; Advanced informatics for biospecimen management & Central and reference labs: building the relationship; Informed consent and data sharing

11:55 Transition to Lunch

12:00 pm LUNCHEON PRESENTATION: Accelerating Biomarker Trial Enrollment by Closing the Patient-to-Subject Gap with Real-Time Data Access

Colleen Hoke, President & Chief Executive Officer, ObjectiveHealth

Why is the execution of biomarker clinical research so challenging? For a relatively straight forward trial, with qualifying patients readily available, the difficulty is in connecting study resources with the right patients, at the point of care, at the right time. We will examine EHR integration methodologies, risk stratification, similarity scoring, resource alerts, built-to-suit user-interface tools, and business models that deliver consistent results, that are 5-fold the typical enrollment expectations.

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

1:30 Close of Part A Conference. Join Plenary Keynotes and stay

on for Part B of SCOPE Summit!*

**Separate registration required for access to Part B conferences, upgrade to Best Value Package.*

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 **Welcome Remarks from CHI and the SCOPE Team**

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

Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: **Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative**

Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:00 **Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership**




Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative

What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.

Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

*Don't forget Part B Conferences begin at 3:45pm**Separate registration required, upgrade to Best Value package.*

Program Advisory Board

February 9-10, 2022 | All Tmes EST

WEDNESDAY, FEBRUARY 9

ROOM LOCATION: Gatlin E3

BRIDGING LUNCHEON PRESENTATION

12:00 pm **Bridging Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 **Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)**

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 **Welcome Remarks from CHI and the SCOPE Team**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

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Panelists:
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Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E3

IMPLEMENTATION OF NEW BIOMARKER TECHNOLOGIES

3:45 **Chairperson's Remarks**
Yvonne Beasley, Senior Director, Laboratory Operations, Specimen Processing, Q2 Lab Solutions

3:50 **Biomarker Operations Strategies for Managing Outsourced Biospecimen Lifecycles**
Lynn Wetherwax, Director, R&D Strategy and Operations, Amgen
The key to a successful outsourcing model is understanding your current and future biospecimen management needs. Biospecimens may be collected for study endpoints or they may be stored until that moment when scientific discovery hinges on biomarker investigation. This presentation will provide an overview of specimen lifecycle strategies that will support a cost-effective outsourced model in a manner that enables flexibility and speed in getting biomarker biospecimens to analytical laboratories.

4:20 **Biobank: Future Use Application of Biospecimen and Consent**
Yvonne Beasley, Senior Director, Laboratory Operations, Specimen Processing, Q2 Lab Solutions
Sample-level consent management is a critical component of clinical trials, especially follow-on and translational research. Best practice recommendations suggest that sponsors should use a configurable system to define a flexible and manageable set of attributes at the study, country and site levels that can be applied to all samples collected over the duration of the trial.

4:50 **Panel Discussion: Central Lab Experts Speak: Insights on Best Practices, Operational Models, Processes and Technology**
Moderator: Brenda Yanak, Vice President, Global Biospecimen & Imaging

Management, Bristol-Myers Squibb Co.
Effectively partnering with CROs and central labs is a key component to successful clinical biomarker and biospecimens management. Gain insight from SME experts in the vendor community best practices in biospecimens collection and management, and processes and infrastructure to ensure access to high-quality specimens. What lessons can we take from COVID-19 and what innovations are on the horizon to advance precision medicine.

Panelists:
Lynn Wetherwax, Director, R&D Strategy and Operations, Amgen
Leanne Flye-Blakemore, Lead Scientist, Advanced Cytometric Applications, Labcorp
Kathi Shea, Senior Director, Repository Innovation, Azenta Life Sciences
Tia Parker, Director, ATL Central Lab Operations, Q2 Solutions
Stephanie Weber, Vice President of SampleGISTICS, LabConnect

5:50 Close of Day

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast (Gatlin Foyer)

ROOM LOCATION: Gatlin E3

BIOMARKER SERVICES IN CLINICAL TRIALS FOR NOVEL THERAPEUTICS

8:20 Chairperson's Remarks
Devon Kelly, Associate Director Biorepository, Clinical Operations, CRISPR Therapeutics

8:25 Operationalizing Gene Therapy Trials: A Clinical Sample Management Perspective
Devon Kelly, Associate Director Biorepository, Clinical Operations, CRISPR Therapeutics
Effective management of gene therapy trials often requires innovative operational approaches. Being able to pivot activities based on current operational needs, rather than conventional clinical trial practices, is key to succeeding in these types of trials. Aligning expectations with vendors and sites throughout the trial is essential to accomplishing this. Presenters will share experiences and insights from a clinical sample management perspective of operational challenges within immune-oncology trials.

8:55 Operationalizing Single Cell RNA Sequencing in Clinical Trials
Mary Zuniga, Consultant, Translational Science Immunology, Eli Lilly & Co.
Genomic and genetic testing in clinical trials bring up a set of specific challenges. This presentation will feature some operational and logistical solutions for scRNAseq in clinical trials, starting from sample collection all the way to the data analysis and storage.

9:25 Sponsored Presentation *(Opportunity Available)*

9:40 Operationalizing ctDNA
Andrew Albright, PhD, Program Manager, Molecular Profiling, Merck & Co., Inc.
For decades, tumor biopsies have been used to diagnose and guide treatment; however, we are entering a new era where circulating tumor DNA (ctDNA) in the blood may provide a substrate for replacing long standing tissue-based assays. But, operational obstacles remain if we are to incorporate ctDNA testing in clinical trials as the field moves from exploratory/RUO testing to using ctDNA as a CDx assay, for enrollment, and stratification.

10:10 Minimize sample loss in advanced therapy trials with proactive logistical planning and new technologies
Stephanie Weber, Vice President, SampleGISTICS, SampleGISTICS, LabConnect
Labconnect continues to lead the industry in clinical trial virtual sample management. The difficulties of sample collection/logistics in advanced therapy studies require a detailed sample management plan. Topics will include key solutions for today's logistical challenges, leveraging technology and people to reduce risk of sample loss, understanding the criticality of early planning in logistics with an emphasis on involving key experts in sample management for site selection and protocol design.

10:40 Networking Coffee Break (Gatlin Foyer)

BIOMARKER SERVICES IN CLINICAL TRIALS FOR NOVEL THERAPEUTICS (CONT.)

10:55 Chairperson's Remarks
Devon Kelly, Associate Director Biorepository, Clinical Operations, CRISPR Therapeutics

11:00 CO-PRESENTATION: Addressing T Cell Tracking Challenges in Cell Therapy Clinical Trials
Bob O'Hara, Managing Partner, ResultWorks LLC
August Zepka, Senior Director IT Business Systems, Adaptimmune
The personalized nature of cell therapies means that organizations are required by regulators to demonstrate end-to-end visibility across the product supply chain, ensuring chain of custody, identity, and condition. This presentation is based on a program at Adaptimmune to standup a T cell tracking environment. It illuminates some of the unique challenges and approaches in tracking T cells throughout their lifecycle from patient collection to manufacturing to treatment.

11:30 Focused Sample Management to Accelerate Clinical Trials
Jun Luo, Director, Sample Repository, Life Science - Services & Informatics Management, Azenta Life Sciences
What You'll Learn: Getting the right sample to the right researcher at the right time is paramount in meeting clinical research timelines. Doing so while decreasing overall cost, protecting valuable inventories, and increasing sample utilization is key to comprehensive clinical sample management. Learn how focused sample storage and management can help you achieve these goals and accelerate your clinical research.

12:00 pm Transition to Shared Sessions or Brief Session Break

ROOM CHANGE: Gatlin A2

TOKENIZATION OF CLINICAL TRIAL PARTICIPANTS

12:05 Panel Discussion: Introducing Unique, Anonymized Identifiers (Tokens) in Clinical Research to Link Participants to Real-World Data
Moderator: Kyle Holen, Head, Development Design Center, AbbVie, Inc.

This panel discussion will feature use cases and address the key questions regarding clinical trial participant's tokenization such as Why tokens? What are potential pitfalls? When will this be global?

1:05 Transition to Lunch

SCOPE SEND OFF LUNCHEON PRESENTATIONS

Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring

Nekzad Shroff, Vice President, Product Management, Saama Technologies

Aditya Gadiko, Director of Clinical Informatics, Saama Technologies

Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials

Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 SCOPE Summit 2022 Adjourns

Program Advisory Board

February 8-9, 2022 | All Tmes EST

Laura Galuchie,
TransCelerate Program Lead, Oversight Committee, Merck

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

Michael Walega,
Head, Centralized Monitoring, Bristol-Myers Squib

MONDAY, FEBRUARY 7

8:00 am SCOPE's Inaugural Masters of Clinical Research Golf Tournament
Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 Conference Registration Open (Gatlin Foyer)

2:00 pm User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)
Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

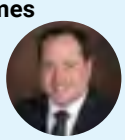
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

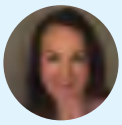



Moderator: Irfan Khan, MD, CEO, Circuit Clinical
Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.
Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

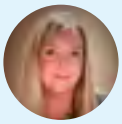
5:45 SCOPE's 2022 Participant Engagement Awards Introduction
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC
Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award
Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co.,

Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 **SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)**

7:45 **Close of Day**

TUESDAY, FEBRUARY 8

7:15 am **Registration Open (Gatlin Foyer)**

7:15 **Morning Coffee** *(Sponsorship Opportunity Available)*

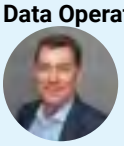
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 **Chairperson's Introduction**
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: **Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World**



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: **Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale**
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange, and clinical research? How do you do this at scale?

9:55 **Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E4

CASE STUDIES AND LESSONS LEARNED IMPLEMENTING AND EVOLVING RBQM

10:55 **Chairperson's Remarks**
Sheila Gwizdak, VP, Organizational & Quality Solutions, Halloran Consulting Group

11:00 **GCP Renovation: What Sponsors Need, Not Always What They Want**
Andy Lawton, Director & Consultant, Risk Based Approach Ltd.
What will ICH E6 R3 and ICH E8 R1 bring as benefits to sponsors and bring as changes in working practices. This presentation takes a holistic view of the changes as well as the benefits that everyone involved with pharmaceutical development (sponsors and CROs) will receive.

11:30 **Spotlighting Two Strategic Enablers of a Culture of Quality: Critical Thinking and Open Dialog**
Michael Torok, PhD, Senior Director, Clinical Quality Assurance, Process Improvement Operational Excellence & Audit, Astellas Pharma US, Inc.
Is your organization prepared to meet the new ICH E8(R1) regulation for a culture of quality? Is your organization clear on what is meant by critical thinking and open dialog? Join industry expert Michael Torok, who will provide a foundational summary of a culture of quality and discuss how the critical thinking and open dialog strategic enablers can be improved to create a high performing culture of quality.

12:00 pm **CO-PRESENTATION: A Call to Action: Evolving Your Risk-Based Quality Management Methodology during a Pandemic**
Katherine Taylor, Head, Risk Evaluation & Adaptive Integrated Monitoring, Merck & Co., Inc.
Natalie Blake, Director, Global Clinical Trials - Project Management Office, Merck
Gain insight into Merck's process to establish and maintain effective study and site quality management, to ensure inspection readiness and focus on what matters the most. A risk-based approach and tools are used to evaluate risk, detect systematic errors, and optimize inspection readiness. Innovation ensures of a holistic, end-to-end approach to exacting a RBQM methodology. Mock inspections and tactics for demonstrating data integrity and patient safety are utilized.

12:30 **Delivering Successful Decentralized Trials - How RBQM and Centralized Monitoring can Maximize**

Data Quality
John Hall, Senior Vice President, Europe and AsiaPac, CluePoints
The shift to decentralized research can present new challenges in ensuring patient safety and data quality.

By leveraging RBQM and central statistical monitoring tools, it enables pharma companies and CROs to evaluate new dimensions of risk and sources of variability in decentralized trial designs, maintain effective oversight of key risks, and ensure quality for patient-generated digital data.

1:00 **Transition to Lunch**

1:05 **LUNCHEON PRESENTATION: Risk-Based Quality Management When You Don't Know The Risks**
Cristin MacDonald, Vice President, Client Delivery, WCG Avoca
In today's world, amid the disruptions of a pandemic, adopting innovations to ensure clinical trial continuity has heightened the importance of robust risk-based quality management. The question then becomes, how do you conduct risk-based quality management without knowing where some of these risks are? In this session, we will share some of the most unique findings identified through our collaborative discussions, and highlight leading practices your organization can adopt.

1:35 **Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)**

BENEFITS OF AND APPROACHES TO RBQM IMPLEMENTATION IN CLINICAL TRIALS

2:30 **Chairperson's Remarks**
Amy Adams, MBA, PMP, Senior Director, Clinical Operations, Parexel

2:35 **CO-PRESENTATION: Beyond The Checkbox: Managing Study Risk from End to End**
Amy Adams, MBA, PMP, Senior Director, Clinical Operations, Parexel
Liz Gough, Ph.D., Associate Director, Project Management Processes, Integrated Delivery and Enablement Office, Parexel
This session will introduce a holistic approach to risk management from study start to finish. Identifying critical data and processes establishes core factors driving the study objective. What are the keys to success for this vital foundational activity? At the same time, expanded risk considerations take risk evaluation beyond column-fodder to deliver on the promise of RBQM. We'll explore the importance of critical thinking and supporting systems at each phase.

3:05 **CDER BIMO Perspectives on RBQM Systems**
David Burrow, PhD, Director, Office of Scientific Investigations, FDA Center for Drug Evaluation and Research (CDER)
In this session, David Burrow will discuss the CDER Bioresearch Monitoring (BIMO) perspective on the beneficial use of risk based quality management systems (RBQMS) in clinical research. Dr. Burrow serves as the Director of the Office of Scientific Investigations within FDA's CDER, Office of Compliance. He will be sharing his observations on adoption of RBQMS, including some potential opportunities for further evolution in the future.

3:35 **CO-PRESENTATION: Fireside Chat: The Evolution of Risk Based Quality Management**
Mike Walega, Head, Centralized Monitoring, Bristol-Myers Squibb Co.
Katherine Taylor, Head, Risk Evaluation & Adaptive Integrated Monitoring, Merck & Co., Inc.
David Burrow, PhD, Director, Office of Scientific Investigations, FDA Center for Drug Evaluation and Research (CDER)
Listen in as two seasoned quality and monitoring professionals discuss with Dr. Burrow the components needed to ensure quality is consistently maintained in a clinical trial and how organizations can improve the implementation of risk-based monitoring approaches. Discuss lessons learned navigating disruptions caused by the pandemic. Gain insights into FDA enforcement priorities, and guidance on how to ensure your organizations RBM strategy is in line with what the FDA guidance.

4:05 **Implementing Web-based Workflows for RBQM Compliance**
Kristin Stallcup, Senior Director, Xcellerate Customer Success, Informatics, Xcellerate Customer Success, Labcorp Drug Development
Risk-based quality management (RBQM) can contain numerous steps for study teams. How can study teams be certain they've completed the required steps? And, how can clinical operations executives easily know that their study teams are compliant or know if certain steps are problematic? This presentation shares how a web-based workflow can be developed and implemented successfully to promote the consistent application of RBQM methodology.

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 **Find Your Table and Meet Your Moderators**

4:40 **Interactive Discussions**
Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 **Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)**

6:40 **Close of Day**

WEDNESDAY, FEBRUARY 9

7:15 am **Registration Open (Gatlin Foyer)**

BREAKFAST PRESENTATIONS
Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 **Practical Approaches for Operationalizing DCTs**
Room Location: Gatlin A1
Kyle Hogan, President, Datacubed Health
Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2

Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS

Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin E4

RISK-BASED QUALITY MANAGEMENT: METRICS, QTLs AND KRIs

8:20 Chairperson's Remarks

Sheila Gwizdak, VP, Organizational & Quality Solutions, Halloran Consulting Group

8:25 Helping QTLs To Do What We Want – Detect Emerging Issues Early

Keith Dorricott, Ambassador, Metrics Champion Consortium

Discover the key recommendations of a multi-stakeholder team of experts–sponsors, CROs, vendors–who discussed lessons learned in implementing Quality Tolerance Limits (QTLs) and developed an approach to pragmatic implementation. The session will explore the use of leading KRIs as companion metrics to QTLs in order to obtain early signals. Earlier detection improves the chance of reducing impact on human subject protection and/or the reliability of trial results.

8:55 CO-PRESENTATION: Risk-Based Quality Management: Forging Your Path to Success

Rhonda Roberts, Manager & Data Scientist, Remarque Systems

Rob Staszewski, Sr. Manager, Clinical Systems & Informatics, United Therapeutics Corporation

Industry experts & regulators have embraced Risk-based Quality Management methodologies over the past decade but there's still slow uptake in drug development. This session will help companies start using RBQM, covering 4 essential elements: planning, stakeholder buy-in, right technology, & willingness to continuously adapt & evolve. We will identify organizational & technical factors as keys to developing a successful strategy and present a case study about a biotech's path to success.

9:25 Quality Tolerance Limits Determination – How the Historical Data Can Be Used

Marta Kozińska, Director Centralized Monitoring, AstraZeneca

Since the introduction of QTLs in ICH-E6 R2, sponsors should apply QTLs as one risk control in clinical trials. There has been a lot of work done to understand QTLs in the context of managing quality in pharmaceutical industry. However, doubts around QTLs values determination are still there. This presentation will focus on sources of information that can be used to properly set QTLs, with emphasis on historical information.

9:55 The Future of RBM – Advanced Analytics & Quality Compliance

Jon Hill, Clinical Operations Associate Director, Digital Strategy, Innovation, Analytics, IQVIA

As risked based approaches become the norm, quality compliance will increasingly be managed through Advanced Analytics & AI/ML Capabilities. Well defined processes and technologies are a must and will pave the way for predictive and proactive signal detection. Through case studies covering ML integration in monitoring learn how trends in advanced analytics and AI/ML are driving post pandemic remote focus.

10:10 Outlook for Risk Based Monitoring with ICH E6(R3) Arriving

Dario Lirio, Senior Director, Product Management Clinical, Product Management Clinical, ArisGlobal

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

11:25 Panel Discussion: Inspection Experiences and Outcomes for Studies Following a Risk-Based Approach

Moderator: Laura Galuchie, Senior Director, TransCelerate Program Lead, Oversight Committee, Merck

We applied RBQM and nothing broke! Our panel of experts will share their experiences and observations from inspections, audits and other feedback following application of RBQM principles. You may learn best practices and gain valuable insights to help your teams and suppliers to apply situation appropriate approaches.

Panelists:

Marion Wolfs, Head, Senior Director, Risk Management & Central Monitoring, Janssen Pharmaceutical Companies of Johnson & Johnson

Amy Neubauer, Director, Data Quality Oversight, Alkermes

Melissa Suprin, Head, Quality Risk Management, Clinical Development, Pfizer, Inc.

11:55 Transition to Lunch

12:00 pm LUNCHEON PRESENTATION: From CRFs to Sensors: Operationalizing Digital Data Oversight for Today's DCTs

Lisa Moneymaker, SVP, Clinical Operations Technologies, Medidata, a Dassault Systèmes Company

Digital capabilities including remote monitoring, electronic patient-reported outcomes, and wearable sensors, are enabling clinical trial decentralization at scale. Robust DCT execution requires proactive, scalable central monitoring strategies to interrogate data at point of capture, minimize study risk, and provide continuous oversight of data integration, flow, and quality. This session explores how DCTs have evolved and elevated RBQM strategies towards the new normal for clinical operations.

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

1:30 Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!*

****Separate registration required for access to Part B conferences, upgrade to Best Value Package.***

KEYNOTE LOCATION: Gatlin A1 & A2

BUILDING DIVERSITY, EQUITY AND INCLUSION (DE&I) INTO OUR TRIALS AND ENROLLMENT

1:30 Welcome Remarks from CHI and the SCOPE Team

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

Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative

Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:00 Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership




Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative

What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.

Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)

Don't forget Part B Conferences begin at 3:45pm**Separate registration required, upgrade to Best Value package.

Program Advisory Board

February 9-10, 2022 | All Tmes EST

Laura Galuchie,
TransCelerate Program Lead, Oversight Committee, Merck

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

Michael Walega,
Head, Centralized Monitoring, Bristol-Myers Squib

WEDNESDAY, FEBRUARY 9

ROOM LOCATION: Gatlin E4

BRIDGING LUNCHEON PRESENTATION

12:00 pm **LUNCHEON PRESENTATION: From CRFs to Sensors: Operationalizing Digital Data Oversight for Today's DCTs**
Lisa Moneymaker, SVP, Clinical Operations Technologies, Medidata, a Dassault Systèmes Company
Digital capabilities including remote monitoring, electronic patient-reported outcomes, and wearable sensors, are enabling clinical trial decentralization at scale. Robust DCT execution requires proactive, scalable central monitoring strategies to interrogate data at point of capture, minimize study risk, and provide continuous oversight of data integration, flow, and quality. This session explores how DCTs have evolved and elevated RBQM strategies towards the new normal for clinical operations.

12:30 **Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)**

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 **Welcome Remarks from CHI and the SCOPE Team**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

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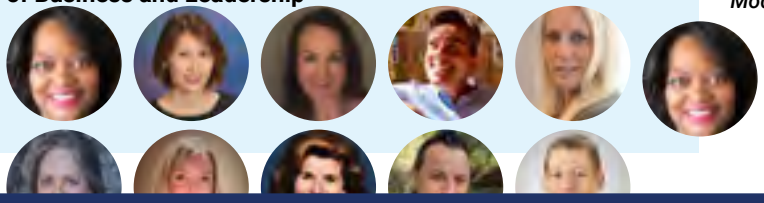

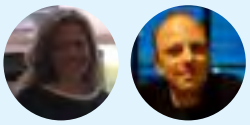

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Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co., Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
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Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E4

PEOPLE, PROCESSES AND TECHNOLOGY

3:45 **Chairperson's Remarks**
Jonathan Rowe, PhD, MS, MA, Principal, ZS

3:50 **Panel Discussion: GCP Quality Risk in Decentralized Trials – Pharma Quality Leaders Share Their Perspective**
Moderator: Jonathan Rowe, PhD, MS, MA, Principal, ZS
Ensuring the rights, safety and privacy of trial participants, along with the generation of credible data, are the cornerstones of GCP Quality. Decentralized trials are moving the oversight of GCP outside of the traditional realm of the investigative site and are bringing new processes, people and technology into trial execution. This panel will

discuss perspectives, misconceptions and truths about GCP risk across common decentralized trial modalities.

Panelists:

Federico Feldstein, Vice President, Head of R&D Quality & Compliance, Johnson & Johnson

Grace Crawford, Executive Director, Clinical Quality & Compliance, AstraZeneca

Patty Donnelly, Vice President, Global Quality - Research and Development, Eli Lilly and Company

4:20 Case Study of an Implementation of a Clinical Trial Risk Management Solution

Mike Walega, Head, Centralized Monitoring, Bristol-Myers Squibb Co.

Recently Bristol-Myers Squibb has undertaken a project to enhance its Clinical Trial Risk Management (CTRM) capabilities. As the journey continues, it was thought that sharing of the steps along the journey could be valuable to others who are also considering or already on a similar path. Reflections on the process, from initiation to current state, including some lessons learned, will be provided.

4:50 Case Study: How a Top 3 Pharma Scaled Remote Monitoring to 60+ Studies and 2,800+ Sites in 2021

Blake Adams, SVP, Marketing, Florence

In 2020, a top-three pharma company successfully implemented a remote monitoring and source data verification program for their COVID vaccine studies. This program made remote access available for 60 active studies across 2,800 sites in just one year. During our presentation, we'll show you how the organization implemented their remote strategy, what the strategy currently looks like, and how it's helped their business.

5:05 Predictive Factors for Patient Discontinuation: A Clinical Intelligence Case Study

Rohit Nambisan, President, Lokavant, Inc.

Lokavant is a clinical trial intelligence company, capturing emergent insights for sponsors and CROs through its integrated product platform. Our scientists mined data from > 2,000 trials to identify factors that predict patient discontinuation. Discontinuation poses a major challenge for trials because patients may be non-evaluable – reducing power on endpoints and leading to longer, more expensive trials. Join us for a tour through our research and what we do at Lokavant!

5:20 CO-PRESENTATION: Optimizing Data Integration for RBQM

Olivia Feiro, Associate Director, Central Monitoring, CSL Behring

Marquita Moore, Associate Director, eClinical Operations, CSL Behring

Data is our most valuable asset, but how well we integrate our data has a significant impact on our ability to perform central monitoring and analytics. Data integration becomes even more critical when utilizing multiple data sources and vendors across our clinical trials. We will discuss advantages to integrating all data sources within a clinical data warehouse prior to sending the data to a RBQM software partner.

5:50 Close of Day

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast (Gatlin Foyer)

ROOM LOCATION: Gatlin E4

RISK MANAGEMENT, MONITORING AND VENDOR OVERSIGHT

8:20 Chairperson's Remarks

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

8:25 Decentralized Trials' Impact on Central Monitoring: Leveraging RBM as a Quality Monitoring Tool for New Processes

Marion Wolfs, Head, Senior Director, Risk Management & Central Monitoring, Janssen Pharmaceutical Companies of Johnson & Johnson

Although risk-based monitoring is no longer considered a new way of working, it continues to stay an area that is constantly evolving. Changes in landscape due to the pandemic are accelerating this evolution. During this session we will share how risk management and data analytics can be leveraged to monitor quality and patient safety in clinical trials where innovative solutions and processes are being used.

8:55 RBQM Implementation in an Outsourced Model – Risk Assessment and Centralized and Site Monitoring Oversight

Linda Sullivan, MBA, Executive Director, WCG-Metrics Champion Consortium

Your organization outsources centralized, remote and onsite monitoring to your CRO… how do you oversee the new monitoring process? Who selects the KRIs? Are they the right KRIs? Are identified risks becoming actual issues? Are monitors focusing on the most important risks and issues? Are site issues being addressed? A multi-stakeholder group has been exploring these questions. Come hear about new monitoring metrics developed by the consortium.

9:40 How Do You Recruit and Nurture a Top Class RBQM/ Centralized Monitoring Team?

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

In many organizations specialized roles and teams to facilitate Risk-based Quality Management are created. I will summarize 10 years of my experience in creation, recruitment, and development of CM/RbQM teams. I will share examples of recruitment process tasks and cases aiming to confirm the desired skills and we will look at an exercise aiming to "brake" the simplest trial ever designed.

10:10 Next-Gen Clinical Risk Mitigation

Garrett Manasco, Solutions Lead, RBQM, Saama Technologies

As clinical trials become more complex, the importance of managing quality from study startup to submission cannot be overstated. In this session, you'll learn how to leverage artificial intelligence and machine learning for more efficient, effective, and transparent remote monitoring, risk detection, Source Data Review, and Source Data Verification

10:40 Networking Coffee Break (Gatlin Foyer)

RISK MANAGEMENT, MONITORING AND VENDOR OVERSIGHT

10:55 Chairperson's Remarks
Marcin Makowski, PhD, Head, Centralized Monitoring & Data Analytics, GlaxoSmithKline

11:00 An Alkermes Case Study: How a Mid-Sized Biotech Designs Its RBM Processes
Amy Neubauer, Director, Data Quality Oversight, Alkermes
As a mid-sized sponsor company grows, how can one start to build systems and processes for risk-based study execution that are right-sized for the organization but can adapt and flex for future growth? This session will take a look at the systems, roles, and CRO partnership model(s) that Alkermes' Clinical Data Operations team are building from the ground up to position the organization for current and continued success.

11:30 Proper Selection of Healthcare Providers for Remote Patient Visits Improves Data Integrity and Monitoring
Art Lazarus, Medical Director, Patient Primary, mdgroup
Highly trained HCPs are essential to ensuring the quality and integrity of data collected during in-home patient visits. By selecting HCPs who are appropriately medically trained, data will be more accurate, thus decreasing the time required to monitor the data - which will improve quality management and source data verification strategies for sponsors and CROs. This presentation will review important factors to consider when selecting HCPs for mobile health patient visits.

12:00 pm Transition to Shared Sessions or Brief Session Break

RISK MANAGEMENT, MONITORING AND VENDOR OVERSIGHT (CONT.)

12:05 Remote Monitoring: Coming up with a Plan
Krista Vermillion, Investigator Initiated Trials Division Manager, Vanderbilt University Medical Center
Remote monitoring in clinical trials has been an acceptable standard for several years now, but with the onset of the COVID-19 pandemic, the need to remotely monitor clinical data has become a necessity. When remote monitoring isn't a familiarity within your organization, how do you devise the appropriate steps to move forward? This talk will discuss steps taken to efficiently create a remote monitoring plan for your team.

12:35 New Trends and Innovations in Site Monitoring
Marina Malikova, PhD, Executive Director, Surgical Translational Research, Operations and Compliance, Boston University School of Medicine
This presentation will review applicable regulatory guidelines for monitoring of clinical trials in state of emergency, data integrity/quality expectations; provide an overview of FDA's remote inspections findings and review trends; share best practices for remote monitoring and alignment of policies/ procedures between stakeholders, and provide insights into contracts/ budgets amendments for remote versus on site monitoring.

1:05 Transition to Lunch

SCOPE SEND OFF LUNCHEON PRESENTATIONS
Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring
Nekzad Shroff, Vice President, Product Management, Saama Technologies
Aditya Gadiko, Director of Clinical Informatics, Saama Technologies
Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials
Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 SCOPE Summit 2022 Adjourns

Program Advisory Board

February 8-9, 2022 | All Tmes EST

MONDAY, FEBRUARY 7

8:00 am SCOPE's Inaugural Masters of Clinical Research Golf Tournament

Connect with your peers and colleagues at SCOPE's Inaugural Masters of Clinical Research Golf Tournament. For more information on participating or how you can get involved as a sponsor, please visit the SCOPE Summit website for further details.

9:00 Conference Registration Open (Gatlin Foyer)

2:00 pm User Group Meetings (ROOM LOCATIONS: St. John's 30 & 31 & St. John's 32)

Co-locate your User Group, a Workshop or even your company's Annual Meeting with SCOPE Summit. CHI will help market the event and manage logistical operations. We will co-market prospective attendees and extend your users a discount to attend the entire SCOPE conference. We are here to work with you. Use SCOPE as your gathering point! Learn more on the SCOPE Summit website.

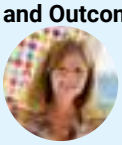
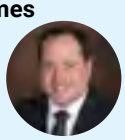
KEYNOTE LOCATION: Gatlin A1 & A2

EVENING KICK-OFF PLENARY KEYNOTE & PARTICIPANT ENGAGEMENT AWARDS

5:00 Organizer's Welcome Remarks
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

5:05 Chairperson's Introduction: Proven Technology and Services to Support a Seamless Clinical Trial Journey for Participants
Tarra Shingler, MS, Senior Vice President, Global Business Solutions, StudyKIK

5:10 Interactive Panel: Engaging and Understanding Patient Behavior to Improve Accessibility, Retention and Outcomes

Moderator: Irfan Khan, MD, CEO, Circuit Clinical

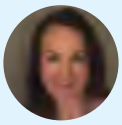
Patient-centric drug development that incorporates patient experience coupled with behavioral science and real-world evidence is evolving the way in which sponsors and regulators bring new medicines to the patients. This executive panel will discuss emerging trends along with case studies that demonstrate how understanding patient need, beliefs and their healthcare journeys influences participation in clinical trials and impacts outcomes.

Panelists:
Vicky DiBiaso, MPH, BScN, Global Head, Patient Informed Development & Health Value Translation, Sanofi
Brendan O'Neill, Senior Director Patient Recruitment Programs, Clinical Development & Operations & Global Product Development, Pfizer Inc.
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Thad Wolfram, President, Matrix Clinical Trials, Matrix Clinical Trials

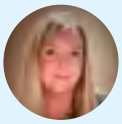
5:45 SCOPE's 2022 Participant Engagement Awards Introduction
David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

5:50 SCOPE's 2020 Participant Engagement Awards: SCOPE's 6th Annual Participant Engagement Awards










Moderator: David Sall, President & CEO, Marketing, Patient Enrollment Advisors LLC

Now in its 6th year, the Participant Engagement Award (PEA) recognizes innovation and change in how the industry communicates with participants in the fields of recruitment and retention in clinical trials. Submit your proposal!
www.SCOPEsummit.com/participant-engagement-award

Panelists:
Michelle Crouthamel, PhD, Head, Digital Sciences, AbbVie, Inc.
Kelly McKee, Vice President, Patient Recruitment and Registries, Medidata
Irfan Khan, CEO, Circuit Clinical
Gretchen Goller, Senior Director & Head, Patient Recruitment Solutions & Clinical Development Operations, Seagen, Inc.
Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
Alicia Staley, MBA, Trial Volunteer & Cancer Survivor; Vice President, Patient Engagement, Medidata
Angie Caprise, Senior Scientist, Global Trial Optimization, Merck & Co.,

Inc.
Melissa Jane Bime, CoFounder & CEO, Infiuss Health
Melissa Gebhardt, Senior Director Business Development & CDx, Guardant Health
Fabio Gatton, Co-Founder & CEO, THREAD Research (formerly inVine Labs)
Adam Kleger, Head, Client Solutions, inVibe Labs
Gwenn Oakes, Director, Global Trial Optimization, Merck
Jeff Smith
Ian Greenfield, CEO, Tryl

6:35 **SCOPE's Kick-Off Networking Happy Hour (Gatlin Terrace)**

7:45 **Close of Day**

TUESDAY, FEBRUARY 8

7:15 am **Registration Open (Gatlin Foyer)**

7:15 **Morning Coffee** *(Sponsorship Opportunity Available)*

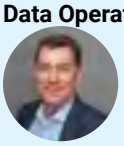
KEYNOTE LOCATION: Gatlin A1 & A2

NEW NORMAL IN PERI-PANDEMIC CLINICAL TRIALS & CONNECTED HEALTH AT SCALE

8:05 **Organizer's Welcome Remarks**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)

8:10 **Chairperson's Introduction**
Peyton Howell, Chief Commercial & Strategy Officer & President, Consulting, Parexel

8:15 KEYNOTE PRESENTATION: **Fireside Chat: Fit-for-Future Data Operations in a Post-Pandemic World**



Demetris Zambas, Vice President & Global Head, Data Monitoring & Management, Pfizer Inc.
Darren Weston, Senior Vice President, Integrated Data Analytics and Reporting (IDAR)and Janssen Clinical Innovation (JCI), Janssen Pharmaceuticals, Inc.
Cynthia Pan, RPh, Senior Director, Therapeutic Area Operations Leader, Global Clinical Operations, Regeneron
The new reality and the ongoing need for real-time data collection and consumption require new creative and live data flows. An additional ramification of this evolution has been a significant improvement in the level of collaboration required within our organizations and with our external partners. Let us discuss how we can cement this "New Normal" to not only maintain the momentum but to ensure these valuable innovations are sustainable.

9:10 KEYNOTE PRESENTATION: **Case Study: Moving Beyond the Promise of Connected Health, Learning from Implementation at Scale**
Adama Ibrahim, Director, Digital Solutions, Technology, Platforms, Data & Digital Global Drug Development, Novartis Pharma AG

Justin Wright, MD, Vice President, Global Head Connected Health, Novartis
This talk will focus on the real work that has been done as a collaboration to bring digital health tools to clinicians, patients, and to pharma research to improve access to trials. How do you give patients their own digital data so they can be engaged in their treatment plans? How can Connected Health improve clinical workflow, communication, data exchange, and clinical research? How do you do this at scale?

9:55 **Grand Opening Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E5

REGULATORY UPDATE

10:55 **Chairperson's Remarks**
Lucy Stone, Clinical Evaluation Specialist, Vascular Devices Team, BSI

11:00 **Overview of FDA Regulatory Science Tools for Advancing Medical Device Innovation**
Glenda Guest, Vice President, NCRA; President, Assured of Quality Consulting & Training
Technological advances continue to move faster than the science for evaluating the benefits and risks of new products. FDA's Center for Devices and Radiological Health (CDRH) is implementing strategic programs to streamline the medical device development and review process. This presentation provides an overview of FDA's Regulatory Science Tools, an update on progress of qualification of Medical Device Development Tools and provides helpful resources and tips for finding these tools.

11:30 **ISO 14155: Updates to Design, Conduct, Recording, and Reporting of Clinical Investigations**
Norbert Clemens, Director, Clinical Trial Management EMEA, HOYA Surgical Optics
ISO 14155 clinical investigation of medical devices for human subjects — GCP has been recently revised and substantially extended. This revision includes: Guidance for ethics committees, the reinforcement of risk management throughout the process of a clinical investigation, definition of different clinical development stages, and the inclusion of guidance on clinical investigation audits. The according impacts on design, conduct, recording, and reporting of clinical investigations will be presented.

12:00 pm **Common Deficiencies in MDR Clinical Evaluations: A Notified Body Perspective**
Lucy Stone, Clinical Evaluation Specialist, Vascular Devices Team, BSI
The notified body certification submission process, particularly for the clinical documentation, is complex and challenging. Based on experiences with vascular clinical evaluation (both MDD and MDR), gain valuable insight on common deficiencies found in applications, and best practices for submitting a file that is likely to proceed smoothly through the review process.

12:30 **Innovative Technologies are Driving Changes in** Deloitte.

Clinical Trials and Evidence Generation
Douglas Billings, Managing Director, MedTech Innovation and Product Development, Deloitte Consulting LLP
Regulators, patients, payers, and providers are increasingly requiring broader demonstrations of evidence across the medical product lifecycle often beyond what traditional clinical trials can provide. In this presentation, Deloitte will share its perspectives on the potential value, state of use and keys to success of adopting new technologies to enhance clinical trial and evidence generation effectiveness of medical technology in a changing regulatory environment.

1:00 Transition to Lunch

1:05 LUNCHEON PRESENTATION : The Next Generation CTMS (and Why the eTMF as We Know it Will Disappear)
Jens Thuesen, Founder and Member of the Executive Board, BSI Life Sciences
A CTMS is the backbone of clinical trials management and assures that sponsors, CRO and SMO have their clinical study execution under control. All major deliveries with their corresponding milestones are planned and closely tracked. Join this presentation to get an insight why the "standalone" eTMF, where all essential documents for conducting clinical trials are stored, will disappear and be an integrated component of the CTMS in the future.

1:35 Coffee and Dessert Break in the Exhibit Hall (Gatlin Ballroom BCD)

OPERATIONALIZING REGULATORY MANDATES

2:35 Cybersecurity Requirements for MDR/IVDR and FDA Submissions
Anura Fernando, Global Head of Medical Device Security, UL
Regulators recognize the risk of cyberattacks, and cybersecurity is becoming imperative for manufacturers. Requirements for cybersecurity are divided into the process tasks and product related tasks. In this talk we want to provide information on how develop medical device incorporating software or software as a medical device in compliance with cybersecurity requirements. We will touch on FDA requirements European requirements defined in MDR/IVDR considering respective guidance documents from MDCG.

3:05 Pre- and Post-Market Studies: Use of Real-World Data (RWD)
Jen Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific
This presentation will outline the purpose of pre- and post-market studies and why multiple types are necessary. I will provide a comparison of requirements by study type and share how real-world data and experience (RWD/RWE) could be used in both pre- and post-market studies. This presentation will highlight a case study in embedding post-market studies in national registries.

3:35 Vendor Selection and Vendor Management Best Practices
Chris Cain, Clinical & Regulatory Affairs, Hyalex Orthopaedics
Outsourcing strategy and vendor selection in a key component to effectively setting up and running a successful clinical program. As more clinical trial activities are outsourced to CROs and other third-party vendors it is important to utilize a rigorous vendor selection and management strategy, implement the right KPIs and metrics for success, and ensure effective oversight and risk mitigation.

4:05 Next-Generation Clinical Data Management
Kimberly Tableman, Chief Clinical Development Officer, Castor
Unlocking the potential of the next generation of clinical trials will require transformative change in how we approach collecting and managing clinical data. As we move beyond CRFs and embrace eSource, committing to collecting structured data will be vital. With structured data, data ontologies can both increase the usefulness of the data collected, and reveal previously-hidden insights, but only if we are willing to make the investment.

INTERACTIVE BREAKOUT DISCUSSIONS

4:35 Find Your Table and Meet Your Moderators

4:40 Interactive Discussions
Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page on the conference website for a complete listing of topics and descriptions.

5:25 Welcome Reception in the Exhibit Hall (Gatlin Ballroom BCD)

6:40 Close of Day

WEDNESDAY, FEBRUARY 9

7:15 am Registration Open (Gatlin Foyer)

BREAKFAST PRESENTATIONS
Come enjoy a breakfast with your peers while listening to your choice of two compelling industry presentations.

7:45 Practical Approaches for Operationalizing DCTs Room Location: Gatlin A1
Kyle Hogan, President, Datacubed Health
Sponsors and CROs need more than change management to operationalize decentralized trials. In this session, Kyle Hogan will outline the approaches sponsors and CROs can take to build value in the decentralized trial participant journey, from pre-implementation to study launch and monitoring.

7:45 Optimizing Clinical Trial Site Selection Utilizing Real-World Data Room Location: Gatlin A2
Andrea Valencia Dremelj, Director BioPharma Business Operations, Biopharma, SOPHiA GENETICS
Delays in clinical trial patient enrollment are significant challenges for sponsors, especially for biomarker-targeted investigational therapies associated with rare genomic variants. Join us and discover the solutions offered by SOPHiA GENETICS, leveraging insights from multimodal datasets - including 770'000 genomic profiles - curated across 780+ healthcare institutions. We can better enable biomarker-driven clinical trials in oncology and inherited rare disorders to meet recruitment goals by identifying potential sites worldwide.

8:15 Session Break

ROOM LOCATION: Gatlin E5

STRATEGIES TO ALLOW INNOVATION WITHIN REGULATORY GUIDELINES

8:20 Chairperson's Remarks
Glenda Guest, Vice President, NCRA; President, Assured of Quality Consulting & Training

8:25 Panel Discussion: Perspectives on EU MDR - How Companies Are Approaching Compliance
Moderator: Glenda Guest, Vice President, NCRA; President, Assured of Quality Consulting & Training
The changes necessary to meet the impending EU MDR deadline are enormous and complex. The transition to EU MDR will result in potential changes to regulatory documents, processes, lifecycle requirements, technical documentation, and more. Join this interactive panel discussion to gain insight into how different companies are approaching achieving compliance and gaining EU MDR-certified body approval.
Panelists:
Christina Villar, Head Global Clinical Operations, Global Clinical Operations, Philips Healthcare
Jane M. Jacob, PhD, Vice President, Research & Clinical Affairs, Synergy Spine Solutions, Inc.
Norbert Clemens, Director, Clinical Trial Management EMEA, HOYA Surgical Optics
Jen Bolton, Senior Fellow, Regulatory Affairs, Boston Scientific

9:25 Development and Framework for AI in *in vitro* Diagnostic Devices
Patricia Connolly, Executive Vice President, Product Development, Renalytix AI plc
Leading edge technologies are being developed incorporating data science alongside clinico-biological science. Current product development and clinical trials require a flexible and open framework for innovative data approaches. Key to this framework is cross functional engagement to define requirements and evaluate performance of analytical, clinico-biological and data sciences. As innovators, we re-define the approach to development and clinical evaluation of IVDs coupled with AI to deliver advancements in specialty care.

9:55 Sponsored Presentation *(Opportunity Available)*

10:25 Coffee Break in the Exhibit Hall (Gatlin Ballroom BCD)

STRATEGIES TO ALLOW INNOVATION WITHIN REGULATORY GUIDELINES (CONT.)

11:20 Talk Title to be Announced
Glenda Guest, Vice President, NCRA; President, Assured of Quality Consulting & Training

11:25 Cybersecurity in CTAs and Vendor Agreements: Proactive Management vs. Cleaning Up the Mess
Katherine Leibowitz, JD, Lawyer, Leibowitz LLC
While cyber risk is not new, cybersecurity language in CTAs and remote monitoring agreements is. Security incidents can impact multiple parties, creating mutuality of risk. This session will discuss sample cybersecurity language from research institutions and pitfalls for sponsors. Hear about lessons learned from sponsor audits of their vendor agreements for compliance with CTA cybersecurity obligations. Common gaps make sponsor CTA obligations heavier. Learn about contract provisions that mitigate risk.

11:55 Transition to Lunch

12:00 pm BRIDGING LUNCHEON PRESENTATION: Achieving Operational Agility, Transparency, and Quality Outcomes for Dynamically Changing and Adaptive Clinical Trial Operations
Jeanette Pascuzzi-Heacock, R.Ph, CSSBB, CQA, Global Life Sciences Industry Practice Director, UiPath
The number of registered clinical trials underway has increase significantly. Clinical administration costs are also rising as Clinical trial workers are doing manual tasks as remote trials add greater regulatory reporting complexity. Automation with robotic process automation (RPA) at the core, has emerged as a pathway to agility, accurate and transparency for today's digitally forward providers. Clinical teams can now be empowered to perform the" higher valued-added work" of insights and risk mitigation, with the assurance that their "digital peers" can manage the redundant, manual, and repetitive work of data intake and administration. . This discussion and demonstration shares ways today's modern clinical trial programs might achieve happier teams, better quality results with speed at scale.

12:30 Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)

1:30 Close of Part A Conference. Join Plenary Keynotes and stay on for Part B of SCOPE Summit!*
****Separate registration required for access to Part B conferences, upgrade to Best Value Package.***

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 Welcome Remarks from CHI and the SCOPE Team
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative
Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

2:00 Panel Discussion: Implicit Bias Around Advocacy and Decision Making: Metrics of DE&I and Speaking the Language of Business and Leadership




Moderator: Kimberly Richardson, Research Advocate, Founder, Black Cancer Collaborative
What is the perspective of Black professionals and patient advocates as the medical and scientific industries grapple with effective ways to engage minority population? Where are their voices being heard and what can we learn from cultural experiences they weave into their research methodologies and daily practices? Panelists will share their perspectives on how the Black voice should be included in advocacy and public and private aspects of clinical research.
Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)
*Don't forget Part B Conferences begin at 3:45pm**Separate registration required, upgrade to Best Value package.*

SCOPE's 2020 Participant Engagement Awards

February 9-10, 2022 | All Tmes EST

Program Advisory Board

WEDNESDAY, FEBRUARY 9

ROOM LOCATION: Gatlin E5

BRIDGING LUNCHEON PRESENTATION

12:00 pm **Bridging Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 **Coffee and Dessert Break in the Exhibit Hall(Gatlin Ballroom BCD)**

KEYNOTE LOCATION: Gatlin A1 & A2

DIVERSITY, EQUITY & INCLUSION (DE&I) AND SPEAKING THE LANGUAGE OF BUSINESS AND LEADERSHIP

1:30 **Welcome Remarks from CHI and the SCOPE Team**
Micah Lieberman, Executive Director, Cambridge Healthtech Institute (CHI)
Thank you all for being here from the SCOPE team: Micah Lieberman, Dr. Marina Filshtinsky, Kaitlin Kelleher, Bridget Kotelly, Mary Ann Brown, Ilana Quigley, Patty Rose, Julie Kostas, and Tricia Michalovicz

1:35 KEYNOTE PRESENTATION: **Why Advancing Inclusive Research is a Moral, Scientific, and Business Imperative**
Meghan McKenzie, Principal, Inclusion, Patient Insights and Health Equity, Chief Diversity Office, Genentech

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Panelists:
Karriem Watson, PhD, Chief Engagement Officer, NIH
Monique Phillips, Global Diversity and Inclusion Lead, Bristol Myers Squibb Co.
Nikhil Wagle, MD, Assistant Professor, Harvard Medical School, Dana-Farber Cancer Institute

2:45 **Booth Crawl & Refreshment Break in the Exhibit Hall (Gatlin Ballroom BCD)**

ROOM LOCATION: Gatlin E5

SITE SELECTION, ENROLLMENT AND PROTOCOL DEVELOPMENT

3:50 **Development of a Clinical Investigational Plan Used to Study a Medical Device**
Teri Takle-Flach, Director, Clinical Operations, Boston Scientific Corp.
This presentation discusses key elements required in developing a high quality clinical investigational plan (or protocol) to collect data on a medical device. Whether your device is a new concept or already commercialized, any new study needs to weigh the risks to the patient participants against the potential benefits the results from the study may yield. The protocol is the roadmap defining the steps required to conduct a successful study.

4:20 **Successful Site Selection for Investigational Medical Device Trials**
Kelly Van Schouwen, CEO and Director of Research, Research Source
Medical device trials are faced with challenges that can range from low/slow enrollment to site regulatory concerns. As with all investigational clinical trials, the success of the trial is directly related to successful sites. However, the traditional selection criteria utilized in drug trials often fail to produce high quality, high enrolling medical device sites. Here, we will discuss the selection criteria unique to successful investigational medical device sites.

4:50 **The Treasure in Real World Data and the Technologies That Deliver Transformational Patient Support**
spencer health solutions
Tom Rhoads, CEO, Spencer Health Solutions
Real-world data provides a new level of insights that help improve clinical trials. To harness these insights, trial sponsors must consider the quality and integrity of a host of data sources, including patient-reported outcomes. This presentation discusses approaches to capturing and evaluating patients' self-reported data on their health conditions and quality of life.

12:30 pm **Sponsored Presentation** *(Opportunity Available)*

5:20 The Role of Social Media in Patient Recruitment for Medical Device Trials

Jane M. Jacob, PhD, Vice President, Research & Clinical Affairs, Synergy Spine Solutions, Inc.

With the sudden, unexpected arrival of "the pandemic," sponsors were forced to think outside the box to enroll clinical trials. How can sites reach potential study patients with traditional office visits becoming telehealth visits? Social media – Facebook, Instagram, LinkedIn, TicTok and Twitter – was the obvious answer. In this talk, we will explore ways a sponsor can effectively use social media to recruit study patients while remaining regulatorily compliant.

5:50 Close of Day

THURSDAY, FEBRUARY 10

7:15 am Registration Open and Breakfast (Gatlin Foyer)

ROOM LOCATION: Gatlin E5

RISK BASED MONITORING IN MEDICAL DEVICE TRIALS

8:20 Chairperson's Remarks

Jane Myles, VP, Clinical Trial Innovation, Curebase

8:25 Remote Monitoring Data Quality Risk Assessment

Amy Jimmerson, RN, BSN, MSHCA, CCRA, Clinical Monitoring Director, Medtronic

This topic will focus on how one company developed and implemented a Remote Monitoring Quality Assessment tool and process post COVID-19. The discussion will focus on the process development aspect, why the process was necessary and the determinants/components used for developing the tool. The discussion will include factors to consider when determining if there is a difference in data quality between remote monitoring and on-site monitoring.

8:55 CO-PRESENTATION: Abbott's Risk-Based Monitoring Innovative Smart SDV Framework for Subject Sampling and Escalation

Krupa Rocks, Associate Director Clinical Data Systems, Medical Devices, Abbott Labs

Michelle Engler Sunga, Staff Clinical Engineer, Abbott

Abbott has been conducting monitoring visits using our customized Site Monitoring Application (SMA) since the early 2000's. We have recently enhanced SMA to include streamlined study risk assessment connecting study risk to statistical sampling inspection levels for patient selection. We have also implemented a standardized signal identification framework via threshold driven escalations and automatically documented risk mitigation measures. Come learn about Abbott's Smart SDV RBM Monitoring approach, process, and application.

9:25 Comparing Virtual and Traditional Sites in a Pivotal Medical Device Trial

Jane Myles, VP, Clinical Trial Innovation, Curebase

As the medical device clinical trial market is rapidly growing, so are the opportunities to augment traditional study designs with virtual trial sites and DCT solutions. However, there are a number of misconceptions about online patient recruitment, enrollment, and participation. In this session, we bust six of these "virtual site myths" using first-hand data from a gastroenterology digital therapeutics trial.

ROOM CHANGE: Gatlin E4

9:40 How Do You Recruit and Nurture a Top Class RBQM/ Centralized Monitoring Team?

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

In many organizations specialized roles and teams to facilitate Risk-based Quality Management are created. I will summarize 10 years of my experience in creation, recruitment, and development of CM/RbQM teams. I will share examples of recruitment process tasks and cases aiming to confirm the desired skills and we will look at an exercise aiming to "brake" the simplest trial ever designed.

10:10 Sponsored Presentation *(Opportunity Available)*

10:40 Networking Coffee Break (Gatlin Foyer)

ROOM CHANGE: Gatlin E5

RISK-BASED MONITORING IN MEDICAL DEVICE TRIALS (CONT)

10:55 Chairperson's Remarks

Jane Myles, VP, Clinical Trial Innovation, Curebase

11:00 Something to be Thankful for with COVID – Accelerating Our Adoption of Decentralized and Virtual Trials

Jane Hart, Senior Director, Clinical Affairs, Exact Sciences

One benefit to come from the pandemic is the way in which it forced us to embrace technology more, be open to new ways of operating and meaningfully make advances to bring clinical trials to the patients. During this session I will share with you how, during the pandemic, we implemented decentralized/virtual trial components into our studies and how it is helping us also have more diverse study populations.

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Transition to Shared Sessions or Brief Session Break

ROOM CHANGE: Gatlin E4

INNOVATION IN REMOTE MONITORINIG: IMPACTS OF COVID 19

12:05 Remote Monitoring: Coming up with a Plan

Krista Vermillion, Investigator Initiated Trials Division Manager, Vanderbilt University Medical Center

Remote monitoring in clinical trials has been an acceptable standard for several years now, but with the onset of the COVID-19 pandemic, the need to remotely monitor clinical data has become a necessity. When remote monitoring isn't a familiarity within your organization, how do you devise the appropriate steps to move forward? This talk will discuss steps taken to efficiently create a remote monitoring plan for your team.

12:35 New Trends and Innovations in Site Monitoring

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

This presentation will review applicable regulatory guidelines for monitoring of clinical trials in state of emergency, data integrity/quality expectations; provide an overview of FDA's remote inspections findings and review trends; share best practices for remote monitoring and alignment of policies/ procedures between stakeholders, and provide insights into contracts/ budgets amendments for remote versus on site monitoring.

1:05 Transition to Lunch

SCOPE SEND OFF LUNCHEON PRESENTATIONS

Come enjoy a luncheon with your peers while listening to your choice of two compelling industry presentations.

1:10 CO-PRESENTATION: Gatlin A1 LUNCHEON PRESENTATION: Finding the Needle in the Haystack: AI-Guided Medical Monitoring

Nekzad Shroff, Vice President, Product Management, Saama Technologies

Aditya Gadiko, Director of Clinical Informatics, Saama Technologies

Today's medical monitors are under tremendous pressure to quickly identify trends and signals that could impact patient safety and drug efficacy. This critical task is only getting more difficult as the volume of data–and the number of data sources–grows. This session will explore new approaches to medical monitoring, available now, that can simplify workflows and scale to meet the challenges posed by data volume, velocity, and variety.

1:10 Gatlin A2 SCOPE Send-Off Luncheon: How to Adjust Monitoring Plans to Accommodate Decentralized Trials

Nicole Stansbury, Vice President, Clinical Monitoring, Central Monitoring Services, Syneos Health

1:45 SCOPE Summit 2022 Adjourns

2022 Interactive 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.

INTERACTIVE BREAKOUT DISCUSSION GROUP TOPICS FOR SCOPE 2022

(co-moderators and discussion points coming soon):

1. **Rolling Protocols: Lessons Learned from Vaccine Studies**
2. **Integrating Early Patient and Site Insights in Protocol Development and Site Selection**
3. **Implementing a Data-Driven Site Selection Capability with RWD, Modelling and Analytics**
4. **Building Diversity, Equity and Inclusion (DE&I) into Trial Design and Ops**
5. **Strategies for Patient-Centric Trial Design and Digital Patient Engagement**
6. **Future State of Trials Due To COVID-19: Planning for and Enabling Smooth Start Up in Multi-Center, Hybrid and Decentralized Trials**
7. **Engaging and Understanding Patient Behavior and Behavioral Economics to Improve Accessibility, Retention and Outcomes**
8. **Budgeting for and Contracting with New Technology Companies: Strategies and Challenges**
9. **Re-Examining Outsourcing Models in the COVID Era and Beyond: FSP vs. Hybrid vs. Strategic Partnerships**
10. **Managing Resources and Proper Oversight for Outsourced Decentralized Clinical Trials**
11. **Developing Tools for Speeding Study Start-Up: Contracting, Budgeting, Capacity Planning**
12. **RWD To Accelerate Design and Execution of Clinical Trials**
13. **Data Management for the "New Normal"**
14. **Validating Digital Biomarkers and Endpoints**
15. **Decentralized and Hybrid Trials: The New Ecosystem**
16. **#NOGOINGBACK: Thriving for Sustainable Innovation**
17. **The Car is Ready, But No Fuel in the Tank: Overcoming Data Challenges of RBQM**
18. **Integrating Biomarkers in Global Trials**
19. **Medical Device Clinical Trial Design and Operations**
20. **Adopting Supply Chain Predictive Analytics to Shift from Reactive to Proactive Decision-Making**

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