Clinical Outsourcing Group New England

Boston Marriott Burlington, MA

April 29th & 30th 2025

Phill Gallacher – SVP, Clinical Operations & Program Mgmt. **– Cullinan Therapeutics**
Bonnie Bain – President/CEO, Global Healthcare **– Ipsos**
Joan Chambers – Senior Consultant **– Tufts Center for the Study of Drug Development**
Jennifer Bentsen Gordon – Vice President, Head of Clinical Operations **– Editas Medicine**
Matthew Weinberg – Director, Clinical Outsourcing and Alliance Management **– Intellia Therapeutics**
Dennis Goldberg – CEO **– Senex Biotechnology**
Kristine Bernard – Vice President, Head of Clinical Operations – **Astria Therapeutics**
Ingrid Abrahamsen – Senior Director, Clinical Operations – **Editas Medicine**
Meredith Frank-Molnia – Vice President Clinical Affairs – **Vericel Corporation**
Adrienne Gaggi – Director of Innovative Patient Recruitment – **AstraZeneca**
Doris Sanchez – **Drug Development Consultant**
Jason Campagna – CMO – **Q32 Bio**
David Rodman – CMO – **Mineralys Therapeutics**
Frank Stout – Senior Director, Global Development Operations – **EMD Serono**
Cheryl R. Blanchard – President & CEO – **Anika Therapeutics**
Scott Megaffin – CEO – **Adiso Therapeutics**
Andrew Sternlicht – CEO – **AISA Pharma**
Jeffrey Bornstein – CMO – **Mediar Therapeutics**
Christina Weng – CMO – **Pelage Pharma**
Stan Russell – VP of Quality – **COUR Pharmaceuticals**
Page Gill – Global Project Lead, Early Development Outsourcing - **Sanofi**
Michael Wieczerzak – Associate Director, Clinical Quality Management Lead – **EMD Serono**
Uday Harle – Asst. Vice President/ Global Head Clinical Development – **Kashiv Biosciences**
Mohammed Asmal – CMO – **Prime Medicines**
Allison Kemner – SVP, Clinical Operations – **BoCo Bio Inc**
David Sherris – CEO – **Attivare Therapeutics**
Jeff Sabados – CEO – **Hubble Therapeutics**
Pete Bastedo – CEO & Co-Founder – **Zymewire (a division of Lumerate)**
Sofia Zhidro – Senior Director, Quality – **Vigil Neuroscience**
Abigail A. Flower – Director, Applied AI – **GSK**
Michael Tolentino – Co-Founder, Chief Innovation Officer **– Aviceda Therapeutics**
Alex Sverdlov – Senior Director, Statistical Scientist **– Novartis**
George Naumov – Chief Operations Officer & Chief Business Officer – **RS Oncology**
Giovanni Abbadessa – CMO – **ModeX Therapeutics**
Lois Kelly – VP Clinical Operations – **LuMind IDSC**
Kerry Culm – Chief Development Officer – **ModeX Therapeutics**
Karen Carroll – SVP, Clinical Development Operations – **Curevo Vaccine**
Mary Jo Lamberti – Director and Research Associate Professor – **Tufts Center for the Study of Drug Development**
Jennifer Burg – SVP, Clinical Development Operations **– Axonis Therapeutics**
Douglas Meyer – Senior Director Global Clinical Supply Chain Operations, Vendor Management and Centralized Ancillary Support **– Takeda**
Robert Andtbacka – CMO – **HiFiBiO Therapeutics**
Ami B Bhatt – Chief Innovation Officer – **American College of Cardiology**

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Todd Luckritz – Associate Director, Clinical Trial Patient Solutions – **Myonex**
Doug Rains – Chief Scientific Officer **– Quantigen, Part of Versiti Clinical Trials**
Ernest Odame – Director, Value Management Lead, R&D Data, Digital, and Technology – **Takeda**
Quan Doan – VP, Technology Solutions – **SDC**
Stacey Lasser – Senior Project Manager – **Mednet**

Day 1: April 29th 2025

7:45	**Registration & Morning Refreshments**
8:20	**Organizer's Welcome Address** **Alexander O'Leary** – Director – **PBC Group**
8:25	**Chair's Welcome Address** **Bonnie Bain** – President/CEO, Global Healthcare – **Ipsos**
8:30	CMO Keynote Interactive Panel **Putting Patients First: Driving Patient-Centricity in Clinical Trials** *In the rapidly evolving landscape of clinical trials, patient-centricity has become not just a priority, but an absolute necessity for biopharmaceutical companies. This panel brings together a group of distinguished New England Chief Medical Officers to discuss why patient-centric approaches are critical for optimizing study designs, meeting regulatory timelines, and achieving patient recruitment and retention imperatives.* *Facilitator:* *Panellists:* **Christina Weng** – CMO – **Pelage Pharma** **David Rodman** – CMO – **Mineralys Therapeutics** **Jason Campagna** – CMO – **Q32 Bio** **Jeffrey Bornstein** – CMO – **Mediar Therapeutics** **Robert Andtbacka** – CMO – **HiFiBiO Therapeutics**
9:10	Keynote **Enhancing Clinical Supply and Logistics to Advance Patient-Centric Care and DEI in Clinical Trials** *Clinical trials are critical to advancing medical innovation and improving patient outcomes by providing rigorous scientific evidence about the safety and efficacy of new treatments, devices, and interventions before they become widely available to the public.* In this session Todd will provide insights into optimizing supply chain and logistics to improve the patient experience, emphasizing patient-centric approaches that align with the goals of DEI. **Todd Luckritz** – Associate Director, Clinical Trial Patient Solutions – **Myonex**
9:40	Keynote Fireside Chat **Rare Disease Trial Focus: Strategies for Finding, Recruiting & Retaining Your Patient Population**

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Rare disease clinical trials present many obstacles to patient recruitment and retention. Rare diseases, by definition, affect a small number of patients. This poses unique challenges when it comes to identifying patients, getting them involved early and keeping them engaged, especially given the complex needs of these patients and the specialized nature of the trials.

In this session, Phill will focus on best practices for site activation, identifying rare disease patient populations, designing and executing trials, and addressing key considerations unique to rare disease studies.

Phill Gallacher – SVP, Clinical Operations & Program Mgmt. – **Cullinan Therapeutics**
Facilitator: **David Jones –** Head of Content **– The PBC Group**

10:00 Keynote

Securing AI-Enabled Support: Best Practices for Vendor Assessment in Clinical Outsourcing

The rapid integration of AI into clinical operations presents enormous opportunities—and significant risks. But when it comes to outsourcing, selecting the right vendor for AI-enabled support is critical.

In this session, we'll delve into how to rigorously assess potential vendors to ensure they employ secure, compliant AI solutions. Designed specifically for outsourcing teams, this session offers actionable strategies to evaluate vendor security, mitigate risks, and drive operational efficiency through trusted AI partnerships.

Quan Doan – VP, Technology Solutions – **SDC**

10:30 **Coffee Break**

	Stream A	Stream B
	Clinical Outsourcing Confusion *Chair: David Jones – Head of Content – The PBC Group*	**Supply, Sites & Technology** *Chair: Bonnie Bain – President/CEO, Global Healthcare – Ipsos*
11:05	Interactive Debate: **Implementing a Functional Service Provider vs a Fully Outsourced Model from a Small Company Perspective** *There is a growing shift towards FSP models for outsourcing, allowing sponsors to take advantage of best-fit solutions to optimise their study. However, is the FSP model a realistic option for smaller biopharma without the infrastructure required to manage multiple suppliers?* The 'For' side of the debate will argue the FSP model can be successfully implemented into smaller companies, allowing sponsors to tap into their specialized experience. The 'Against' side of the debate will argue smaller companies struggle	Interactive Panel: **Opportunities and Obstacles with AI in Clinical Trials: How Do We Grabble with AI as a Trial Sponsor?** *Whilst AI often appears all singing all dancing, this isn't always the case in the real world. Can AI streamline clinical trials by accelerating patient recruitment, and enhancing trial efficiency? What are the obstacles with implementing it and is it a realistic opportunity for all trial sponsors?* This interactive panel will address the ClinOps and Data Management perspectives of introducing AI into a study. Our panellists will also discuss the challenges with of implementing AI in clinical trials,

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	with FSP models due to resource constraints, lack of infrastructure, and the need for close oversight. Followed by thoughts for the future. *Facilitator:* **David Jones –** Head of Content **– The PBC Group** *Debate team:* **Matthew Weinberg** – Director, Clinical Outsourcing and Alliance Management – **Intellia Therapeutics** **Ingrid Abrahamsen** – Senior Director, Clinical Operations – **Editas Medicine** **Frank Stout** – Senior Director, Global Development Operations – **EMD Serono** **George Naumov** – Chief Operations Officer & Chief Business Officer – **RS Oncology** **Karen Carroll** – SVP, Clinical Development Operations – **Curevo Vaccine**	while asking the question: Are clinical sites and their staff also ready to embrace this technology? *Facilitator:* **Bonnie Bain** – President/CEO, Global Healthcare – **Ipsos** *Panellists:* **Phill Gallacher** – SVP, Clinical Operations & Program Mgmt. – **Cullinan Therapeutics** **Abigail A. Flower –** Director, Applied AI – **GSK** **Alex Sverdlov** – Senior Director, Statistical Scientist – **Novartis** **Mary Jo Lamberti** – Director and Research Associate Professor – **Tufts Center for the Study of Drug Development** **Jennifer Burg –** SVP, Clinical Development Operations – **Axonis Therapeutics**
11:45	*Session Reserved for IQVIA Biotech*	*Session To Come* **Stacey Lasser** – Senior Project Manager – **Mednet**
12:15	**How to Position Yourself as a Top Priority for the CRO and Maintain the A-Team Throughout** *Due to insufficient resources and training, sponsors often find themselves working with different CRO teams than those initially selected during the bid defence. This inconsistency is negatively affecting a huge number of trials across the US and causing costly delays.* In this session Jennifer will examine the problem from the beginning, assessing what should be put into the RPF, what to discuss with your CRO initially and how to set boundaries and expectations. She will also address how to handle situations when a team member is not pulling their weight. How can you encourage a more proactive work environment? **Jennifer Bentsen Gordon** – Vice President, Head of Clinical Operations – **Editas Medicine**	**Delving into Best Practices for Selecting, Managing and Overseeing Your Clinical Supply Vendors** *Overseeing clinical supply vendors is crucial to ensure the timely delivery of quality supplies, regulatory compliance, and cost efficiency, ultimately supporting the trial's success and patient safety.* In his session Douglas will delve into the vendor selection process; how best to build and manage vendor relationships; as well as best practices when establishing timelines and establishing oversight requirements. **Douglas Meyer** – Senior Director Global Clinical Supply Chain Operations, Vendor Management and Centralized Ancillary Support – **Takeda**
12:40	**Lunch**	

Stream A	Stream B
Outsourcing & Controlling Costs	**Supply, Sites & Technology**

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1:40	**Strategies to Inspire Your CRO Counterpart to be Equally Committed to Achieving Objectives as Internal Teams, While Fostering a More Streamlined Operational Workflow** *With CROs often managing multiple projects at one time and not always being as invested in the success of your trial, it is crucial to generate enthusiasm and engagement in the studies, ensuring CRO counterparts feel motivated to drive progress and deliver results.* Matthew will highlight strategies to encourage the CRO team to be more invested in your study, enabling earlier milestone achievements and reducing frustrations within your internal teams. **Matthew Weinberg –** Director, Clinical Outsourcing and Alliance Management **– Intellia Therapeutics**	**Clinical Trial Supply: Strategies for Vendor Selection and Effective Oversight** *Ensuring a robust and reliable clinical trial supply chain is crucial for the success of any clinical study. Selecting the right vendors and maintaining effective oversight can make the difference between a seamless trial and one plagued by delays and quality issues.* Alan will share real-world case studies, best practices, and lessons learned from their extensive experience in managing clinical trial supply chains. **Alan Jacks** – Alliance Program Manager – **TriSalus Life Sciences**
2:05	*Session Reserved for Aixial Group*	**Japan & Taiwan Development: Regulatory Changes and Effective Patient Recruitment** *Japan and Taiwan have emerged as powerhouses in clinical research, boasting remarkably high levels of patient recruitment and engagement. Exploring the unique landscape and incentives of clinical trials in these countries can accelerate your global development and open the Asian market.* In this session, Hiroki will share insights into the factors that enable on-time and often early patient recruitment in these markets. He will discuss why it is reasonable to consider including Japan and Taiwan in your clinical trials, and highlight recent regulatory changes that have made it easier for foreign biotech companies to engage with these regions. **Hiroki Matsushima – B**ranch Manager, US Boston Branch **– A2 Healthcare**
2:35	Tufts Spotlight: **Evolving Clinical Trial Investigative Site Models and Partnerships** *This new empirical study is looking at 'Mapping and Assessing the Utilization Strategies and Practices, their Impact and Long-term Viability*	Fireside Chat: **Revolutionizing Clinical Trials: How AI and Technology Enhance Design, Recruitment, and Regulatory Success**

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Given the Evolving Global Investigative Site Landscape.'

Many new clinical trial execution models have been introduced in the past decade including site staff embedded within clinical care settings, remote sites, retail pharmacies and urgent care facilities etc. The study findings will help industry stakeholders understand the strategic and structural growth of new trial sites and partnerships in bringing trials directly to local communities and integrating healthcare and clinical research to improve patient access to trials.

Joan Chambers – Senior Consultant – **Tufts Center for the Study of Drug Development**

AI and technology are transforming clinical trials by optimizing trial design, improving patient recruitment, and enhancing regulatory success.

This session Ami will explore how AI can enable more precise patient matching, adaptive study protocols, and real-time monitoring for better efficiency. Additionally, AI-powered tools streamline regulatory compliance by automating documentation and identifying potential risks early in the process.

Ami B Bhatt – Chief Innovation Officer – **American College of Cardiology**

3:00 **Coffee Break & Scavenger Hunt with Prizes!**

3:30 **From Volume to Value: The Future of Patient Recruitment Starts Now**

With trial saturation and tougher criteria, patient recruitment demands a smarter approach. Are we prioritizing the right trials? Are we focusing on the correct key performance metrics?

In this session Adrienne will discuss innovative methods to design data-driven, patient-centric recruitment strategies and how to measure their success. It's time to move from volume to value—by putting patients first.

Adrienne Gaggi – Director of Innovative Patient Recruitment **– AstraZeneca**

3:55 *Session Reserved for Harbor Clinical*

4:25 **Cell & Gene Therapy Trial Set Up and Execution**

Cell and gene therapy clinical trials face several unique challenges, particularly within ClinOps and Supply Chain.

In this session Ingrid will discuss the obstacles faced when setting up a gene therapy trial, and draw on their wealth of experience to share how to plan and collaborate to successfully implement the trial.

Ingrid Abrahamsen – Senior Director, Clinical Operations – **Editas Medicine**

4:50 *Reserved for Sponsor*

5:20 Keynote Interactive Panel

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Fuelling the Future: CEO Perspectives on Funding Clinical-Stage Biotechs

Securing sufficient investment remains challenging for biotech companies, whether they are seeking to enter clinical trials, or seeking investment to move to later stages. Clear communication of drug/device candidate potential, as well as possible creative funding/ equity models.

This CEO panel will bring together leaders of biotechs to discuss strategies for financing clinical pipelines. Topics will include international trends in venture capital, public markets, licensing deals, local government funding, and cross-border partnerships.

Facilitator: **Pete Bastedo** – CEO & Co-Founder – **Zymewire (a division of Lumerate)**
Panellists: **Dennis Goldberg** – CEO – **Senex Biotechnology**
Cheryl R. Blanchard – President & CEO – **Anika Therapeutics**
Scott Megaffin – CEO – **Adiso Therapeutics**
Andrew Sternlicht – CEO – **AISA Pharma**
Jeff Sabados – CEO – **Hubble Therapeutics**

6:00	**Chair's Day 1 Summary** **Bonnie Bain –** President/CEO, Global Healthcare **– Ipsos**
6:00	**Networking Drinks & Canapés Reception & Rapid-Fire Team Quiz with Prizes** ***(complementary admission to all conference participants)***

Day 2: April 30th 2025

8:15	**Registration & Morning Refreshments**
8:45	**Chair's Day 2 Welcome Address** **Bonnie Bain –** President/CEO, Global Healthcare **– Ipsos**
8:50	Keynote Interactive Panel: **Revolutionizing Clinical Trials: Innovations in Trial Design for Faster, Smarter, and More Efficient Drug Development** *The landscape of clinical trials is evolving rapidly, driven by the need for faster, more efficient, and patient-centric drug development. This panel discussion will explore the latest innovations in clinical trial design, focusing on strategies that can accelerate timelines, improve data quality, and enhance patient engagement.* The panellists will explore adaptive trial designs, the integration of advanced technologies such as AI and machine learning, and the growing trend of decentralized and virtual trials. Sharing insights on the application of real-world evidence, innovative statistical approaches, and patient-reported outcomes to complement traditional randomized controlled trials. Discussing the regulatory landscape, and collaborative efforts to facilitate the adoption of innovative designs.

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Facilitator: **Giovanni Abbadessa –** CMO **– ModeX Therapeutics**
Panellists: **Joan Chambers** – Senior Consultant – **Tufts Center for the Study of Drug Development**
Doris Sanchez – Drug Development Consultant
Uday Harle – Asst. Vice President/ Global Head Clinical Development – **Kashiv Biosciences**

9:30 **Developing, Validating, and Deploying Infectious Disease Assays in Clinical Trials**

Accurate infectious disease testing is crucial for proper patient enrollment, stratification, and ongoing monitoring in many clinical trials. While FDA-approved diagnostics exist for many pathogens, some studies require novel assays that must be developed, validated, and deployed under strict regulatory oversight.

In this session Doug explore key technical and regulatory challenges in designing and implementing non-approved infectious disease assays for clinical trials. Attendees will gain insights into assay development and validation strategies, regulatory compliance considerations, and best practices for ensuring reliable infectious disease testing throughout a trial's lifecycle.

Doug Rains – Chief Scientific Officer **– Quantigen, Part of Versiti Clinical Trials**

10:00 **Data-Driven Clinical Trials: Accelerating Site Selection & Patient Recruitment, Reducing Costs, and Gaining More Control**

The current approach to clinical trials is plagued by slow processes, missed timelines, and excessive reliance on vendors for day-to-day operations, significantly delaying the delivery of new drugs to market. By leveraging data and technology, pharmaceutical companies can accelerate the clinical trial process, streamline site selection, and ultimately bring life-saving medications to patients more quickly and efficiently.

Ernest will explore the transformative power of data, technology, and field intelligence in modernizing and accelerating clinical trials. Discussing how leveraging advanced analytics can improve the accuracy of trial outcome predictions and optimize site and patient selection.

Ernest Odame – Director, Value Management Lead, R&D Data, Digital, and Technology – **Takeda**

10:25 **Clinical Outsourcing Strategy for Emerging Oncology Biotech: Optimizing Operations Through Strategic Partnerships**

Emerging biotechs must carefully balance internal expertise with external partnerships to maximize limited resources while maintaining strategic control over core development activities, ensuring essential in-house capabilities complement outsourced functions without creating organizational redundancy or gaps in oversight.

In this session Kerry will share ModeX Therapeutics' current outsourcing strategy, highlighting the their CRO partnership and strategic functional service providers. Arguing how strategic outsourcing decisions enable operational scaling while maintaining lean organizational structure. The session will include

critical clinical pharmacology for dose optimization, resource allocation strategies, and preparing for scaling up operations with external partnerships.

Kerry Culm – Chief Development Officer – **ModeX Therapeutics**

10:50 **Coffee Break**

11:20 Debate: **Building Effective Partnerships Between Clinical Operations and Site Management**

Strong partnerships between clinical operations and site management teams are crucial for efficient trial execution and quality outcomes. Aligning priorities and workflows enables successful site activation, patient recruitment, and data collection.

In this panel, we will examine best practices for building robust collaboration between clinical operations and site management functions. It will outline strategies to streamline site selection, initiation, and oversight processes while maintaining quality standards and regulatory compliance. The discussion will focus on practical approaches to enhance communication, optimize resource allocation, and drive operational excellence across the site management lifecycle.

Facilitator: **Bonnie Bain –** President/CEO, Global Healthcare **– Ipsos**
Debate Team: **Lois Kelly** – VP Clinical Operations – **LuMind IDSC**
Page Gill – Global Project Lead, Early Development Outsourcing - **Sanofi**

11:45 **Global Site Selection & Feasibility Study**

Getting site selection and feasibility studies right is crucial for getting access to the right patient population, and therefore, the success of a clinical trial. These foundational steps ensure appropriate geographic coverage, minimize recruitment challenges, and help establish realistic timelines and budgets for the study.

Michael will give an in-depth exploration of emerging trends and cutting-edge best practices in elevating clinical trial awareness and revolutionizing recruitment strategies.

Michael Tolentino – Co-Founder, Chief Innovation Officer **– Aviceda Therapeutics**

12:10 Interactive Panel: **Building Quality by Design (QbD) into Clinical Trials: Moving from Quality Control to Quality Assurance**

QbD principles are transforming how clinical trials are planned and executed, shifting focus from reactive monitoring to proactive quality assurance. However, successful implementation requires strategic planning and cross-functional collaboration.

In this session, the panel will discuss practical approaches to embedding quality principles throughout the clinical trial lifecycle. Key areas of discussion will include risk-based quality planning, critical-to-quality factor identification, quality tolerance limit setting, technology enablement strategies, and

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methods for measuring and improving quality performance across trial operations.

Facilitator: **Bonnie Bain –** President/CEO, Global Healthcare **– Ipsos**
Panellists: **Stan Russell** – VP of Quality – **COUR Pharmaceuticals**
Sofia Zhidro – Senior Director, Quality – **Vigil Neuroscience**
Michael Wieczerzak – Associate Director, Clinical Quality Management Lead – **EMD Serono**

12:40 **Lunch**

1:40 Keynote
Involving Patients in Clinical Trial Decision Making

Keeping patients at the heart of your clinical trial is vital for recruitment and engagement success. This involves incorporating patient input during trial design, simplifying protocols to reduce participant burden, and ensuring clear communication.

In this session Kristine will address how prioritizing patient-centric practices not only enhances trust and engagement but also improves trial outcomes by fostering greater adherence and retention.

Kristine Bernard – Vice President, Head of Clinical Operations – **Astria Therapeutics**

2:05 **Innovative Approaches in Immuno-Oncology: A Case Study**

Immuno-oncology (IO) drugs are one of the hottest areas in drug development, with checkpoint inhibitors being administered systemically to enhance the body's immune response against cancer.

The tumor microenvironment (TME) is the target of immunotherapy. Attivare specifically targets its IO drug to the TME, aiming to improve treatment efficacy. David will share key take-home thoughts regarding this approach will be discussed.

David Sherris – CEO **– Attivare Therapeutics**

2:30 Workshop: **RFP Focus Session: Comparing Apples to Apples**

RFPs are critical for finding the best CRO for your study. However, in the complicated world of outsourcing clinical trials, using RFPs to compare CROs can be incredibly challenging.

In this session, groups will work together to identify key elements to include in an RFP and develop a basic template. Each group should list 5-10 criteria that are essential for assessing vendor qualifications to ensure we are comparing apples to apples.

Host: **Meredith Frank-Molnia** – Vice President Clinical Affairs – **Vericel Corporation**

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2:55	**Implementing Diversity, Equity, and Inclusion Initiatives in Clinical Trials: A Patient Centric Approach** *Improving diversity, equity, and inclusion in clinical trials requires intentional strategies to address barriers to participation. This includes engaging underrepresented communities and ensuring trials are accessible to participants of all backgrounds. Partnering with Patient Advocacy Groups early on is critical for enhanced equity in clinical research.* In this session Allison will explore real life case studies and strategies for diversity, equity, and inclusion in patient recruitment and engagement. **Allison Kemner** – SVP, Clinical Operations – **BoCo Bio Inc**
3:20	**Chair's Day 2 Summary & Closing Remarks** **Bonnie Bain –** President/CEO, Global Healthcare **– Ipsos**

End of Conference