MASS MEDICAL AFFAIRS STRATEGIC SUMMIT EAST

Develop a unified scientific voice and ultimately help position your medical affairs group as a strategic, customer-facing function

APRIL 9–11, 2018 | HYATT REGENCY NEW BRUNSWICK | NEW JERSEY

THREE TRACKS | ONE LOCATION | ALL ACCESS

MEDICAL AFFAIRS EXECUTIVE STRATEGY

MSL BEST PRACTICES

RESEARCH COLLABORATION AND INVESTIGATOR-INITIATED TRIALS

Featured Speakers

Kirk V. Shepard, M.D., *Senior Vice President, Head of Global Medical Affairs OBG,* **EISAI**

Mary Voehl Hirsch, M.Sc., *Senior Director, Head ISS Operations, Diabetes and Cardiovascular GBU,* **SANOFI**

Tehseen Salimi, *Head of Medical Affairs — Primary Care and Women's Health,* **MERCK**

Alan Wright, M.D., MPH, *Chief Medical Office,* **ROCHE DIAGNOSTICS**

Ruth du Moulin, Ph.D., *Vice President, Medical Affairs, Head of Medical Communications,* **TAKEDA ONCOLOGY**

Arthur Chan, Ph.D., MBA, *Head, MSL Capabilities, Development and Training,* **NOVARTIS**

Sonal Bhatia, M.D., *Vice President, North America Medical Lead, Rare Disease,* **PFIZER**

Bryan N. Bischel, Ph.D., MBA, *Senior Director, U.S. Field Medical Affairs,* **NOTAL VISION**

Cynthia Barbitsch, Pharm.D., *Director/Team Leader, Clinical and Research Collaborations, External Medical Communications,* **PFIZER**

Michael Steidle, Pharm.D., MBA, *National Director, Medical Science Liaison Team,* **MELINTA THERAPEUTICS**

Poushali Mukherjea, Ph.D., *Executive Director, Medical Affairs,* **BRISTOL-MYERS SQUIBB**

Peter Shaw, MBBS., DRCOG, *Senior Director, Medical Affairs — Orthopaedics,* **FERRING PHARMACEUTICALS**

Kelly Wimble Loughner, *Senior Associate Director, Site Enablement,* **BOEHRINGER INGELHEIM**

Kavitha Goyal, M.D., *Remicade Compound Development Team Leader,* **JANSSEN**

Marianne Gill, RN, M.S., *Vice President, Medical Affairs for MMS,* **BECTON DICKENSON**

Featuring

Presentations, Panel Discussions and Case Studies, Including:

- Panel: Explore Different Operating Models for Medical Affairs Groups and Discuss How an Organizational Structure Can Impact the Effectiveness of Your Activities
- The Role of MSLs in Today's Payer and Reimbursement Landscape
- Establish an Efficient and Compliant Process for Assessing the Fair Market Value (FMV) of IIT Budgets
- Effective Strategies and Models for Managing Contract MSL Teams
- Panel: Strategic Considerations for Converting an IIT to a Research Collaboration
- Industry Spotlight: The Evolving Role of Medical Affairs, MSLs and Investigator-Initiated Trials in the Medical Device and Pharmaceutical Industry

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The decline of the blockbuster model has forced pharmaceutical companies to rethink the focus of their R&D efforts and find ways to serve new populations. There are significant gaps in disease management, and it is important for organizations to identify opportunities to impact patient care. Medical affairs plays a pivotal role in communicating with external experts and clinicians and is key to identifying unmet medical needs, raising awareness with clinicians, and providing valuable feedback and insights that can better inform an organization's development strategy.

But the pharmaceutical industry isn't the only one undergoing a transformation. With the rise of educated stakeholders and empowered consumers, presenting the safety and efficacy of a product is simply not enough these days. Expectations have changed, and companies need to prove the value of a new therapeutic and its impact on patients. Investigator-sponsored research and postmarketing studies provide companies with additional sources of data that can help generate real-world evidence and link improved patient outcomes to the use of a product.

Tasked with leading data generation and dissemination, publication planning, and scientific exchanges, it is essential for medical affairs groups to develop innovative operating models and organizational structures that can help capture field insights, avoid operational inefficiencies and streamline communications across internal stakeholders.

The Medical Affairs Strategic Summit (MASS) East 2018 is an educational platform that provides a holistic view of medical affairs, allowing your organization to develop a unified scientific voice and ultimately help position your team as a strategic and credible customer-facing partner in the healthcare landscape. Attendees will have the option to attend sessions from any of the following three tracks for the duration of the conference:

- **Medical Affairs Executive Strategy**
- **MSL Best Practices**
- **Research Collaborations and Investigator-Initiated Trials**

This unique learning format provides the opportunity for teams to choose their own adventure and tailor their educational experience to the needs of an organization. In-depth presentations, interactive workshops, and peer-to-peer learning opportunities are balanced with networking breaks, allowing you to engage with 200+ medical affairs, MSLs and investigator-initiated trial professionals across this three-day event. Don't miss this opportunity to join the leading community of medical affairs professionals at MASS East 2018!

WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, biotechnology, and medical device organizations with responsibilities in the following areas:

- ✓ Medical Affairs/Field Medical Affairs
- ✓ Clinical/Scientific Affairs
- ✓ Medical Science Liaisons/MSLs
- ✓ Medical Strategy/Communications
- ✓ Medical/Clinical Operations
- ✓ KOL/Thought Leader Relations/ Engagement
- ✓ Investigator-Initiated Research (IIR)
- ✓ Investigator-Initiated Studies (IIS)
- ✓ Investigator-Initiated Trials (IIT)
- ✓ Investigator-Sponsored Trials (IST)
- ✓ Research Collaborations
- ✓ Medical/Scientific/Patient Communications
- ✓ Medical Information
- ✓ Medical Education
- ✓ Publication Planning
- ✓ Health Economics and Outcomes Research/HEOR
- ✓ Compliance/Legal
- ✓ Regulatory Affairs
- ✓ Research Grants
- ✓ Call Center Management
- ✓ Patient Services
- ✓ Clinical Outcomes and Publications

This conference is also designed for:

- ✓ KOL and Thought Leader Mapping Organizations
- ✓ Data Management Vendors
- ✓ Clinical Trial Service Providers
- ✓ Scientific and Technology Solutions Providers
- ✓ Medical Affairs Service Organizations
- ✓ Medical and Scientific Communication Vendors
- ✓ Talent Acquisition Service Providers
- ✓ Call Center Vendors
- ✓ Companion Diagnostics
- ✓ Data Management Solution Providers
- ✓ Clinical Outcomes and Publications

VENUE

HYATT REGENCY NEW BRUNSWICK

Two Albany Street
New Brunswick, NJ 08901

To make reservations, please call 800-233-1234 or the Wyndham 1-800 number at 1-800-996-3426 and request the negotiated rate for **ExL's Medical Affairs Strategic Summit (MASS) East 2018**. You may also make reservations online using the following weblink: http://bit.ly/2p83qGY. The group rate is available until **March 19, 2018**. Please book your room early, as rooms available at this rate are limited.

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MONDAY, APRIL 9, 2018 PRE-CONFERENCE WORKSHOPS

8:00 **Continental Breakfast**

9:15

WORKSHOP A: BUILDING A MEDICAL AFFAIRS LAUNCH POWERHOUSE

Across the core launch phases, medical affairs teams play a critical role in preparing the market for a successful product launch. Developing a compliant, strategic launch plan through high-impact scientific activities that harmonizes all levels of your medical and commercial groups is crucial for a successful product launch.

- Create a medical strategic and tactical launch plan that aligns with your organization's business objectives
- Develop a meaningful scientific communication platform to communicate and differentiate the medical and scientific value clearly
- Develop a comprehensive and actionable stakeholder (KOLs, clinicians, payers, advocacy groups, policy makers, etc.) engagement plan in a compliant way
- Set clear strategy for data generation activities through identifying unmet medical needs and insights from stakeholders
- Leverage medical information to educate healthcare practitioners

Ramin Farhood, Pharm.D., MBA, *Vice President, Head of Global Medical Affairs,* **AVEXIS**
**This session contains a 30-minute networking break*

WORKSHOP B: THE ROLE OF AN MSL ACROSS THE DIFFERENT PHASES OF A PRODUCT'S LIFE CYCLE

Depending on the therapeutic complexity and specific product being developed, there can be a range of activities in which an MSL can engage. This workshop will identify key activities across product life cycles that will help inform your organization of valuable field insights and prepare your team for market introduction

- Understand the MSL role as part of global medical affairs, in clinical trials, and during the FDA pre-approval phase
- Design your annual operating plan to prioritize activities and develop a strategy to work within budget constraints
- Understand what interactions are permissible with sales and marketing
- Explore best practices for MSLs in pharmaceutical and medical device industries and examine some key differences
- IIT Spotlight: Review the various types, functions, and interactions with clinical affairs; protocol submissions; and how MSLs can help solve current unmet needs
- Patient Advocacy Integration

Luchy Hidalgo, M.D., *Senior Medical Science Liaison — Nephrology/Transplant,* **HANSA MEDICAL**
**This session contains a 30-minute networking break*

12:15 **Luncheon**

1:30

WORKSHOP C: ENSURE COMPLIANT COMMUNICATIONS DURING SCIENTIFIC EXCHANGE AND OFF-LABEL DATA DISSEMINATION

Regulatory bodies recognize the value of truthful and non-misleading scientific or medical publications on unapproved new uses of a product. However, the major challenges with off-label communications are being able to provide accurate scientific data and protecting the patient, all while extending the market for a particular product.

- Explore the distinction between solicited and unsolicited queries and discuss regulatory expectations for medical affairs teams
- Clarify how to provide scientific research and medical findings that are clearly non-promotional
- Develop tools and techniques to provide ethical, accurate and balanced off-label data, while adding patient value in a compliant manner

Davida White, *Head, Medical Excellence and Education,* **INDIVIOR**
**This session contains a 30-minute networking break*

WORKSHOP D: EXAMINE HOW TO BEST DEVELOP YOUR IIT TEAM AND PROCESSES TO ENSURE EFFECTIVE MANAGEMENT AND CONTRACTING

When developing an IIT program, how you align your resources, staff the team, and develop your processes can greatly affect how quickly you can finalize any contracting necessary to support IIT trials. This workshop will discuss two overarching areas that affect contracting: 1) Processes such as IIT portals and hands-off IIT submission processes versus relationship-based models; 2) Staffing such as fully insourced IIT teams, outsourced or IIT teams staffed by Flexible Staffing providers, and IIT teams with set contracts.

- Weigh the pros and cons of the different types of submission processes that pharmaceutical companies use to support their IIT program and discuss how they are looked at by a site contract and budget team
- Review different staffing models and why companies may choose to use a specific model for their IIT program
- Discuss how the different models may affect your contracting timelines

Earl Knight, Esq., *Director, Contracting Sponsored Program Services,* **PURDUE UNIVERSITY**
**This session contains a 30-minute networking break*

4:30 **Workshops Concludes**

TUESDAY, APRIL 10, 2018 MAIN CONFERENCE DAY ONE

PLENARY SESSIONS

7:30 **Main Conference Registration and Continental Breakfast**

8:30

CHAIRPERSON'S OPENING REMARKS

Kirk V. Shepard, M.D., *Senior Vice President, Head of Global Medical Affairs OBG,* **EISAI**

8:45

THE ROLE OF MEDICAL AFFAIRS FROM PRELAUNCH TO LAUNCH

- Provide an overview of crucial activities during the prelaunch period
- Use clinical narratives and supporting evidence to develop a strong scientific platform
- Gain valuable input from the different disciplines to develop a scientific lexicon for a brand that is consistent and aligned across various stakeholder groups

Kirk V. Shepard, M.D., *Senior Vice President, Head of Global Medical Affairs OBG,* **EISAI**

9:30

PANEL: EXPLORE DIFFERENT OPERATING MODELS FOR MEDICAL AFFAIRS GROUPS AND DISCUSS HOW AN ORGANIZATIONAL STRUCTURE CAN IMPACT THE EFFECTIVENESS OF YOUR ACTIVITIES

- Review some traditional and innovative operating models for medical affairs across big pharmaceutical and biotech companies
- Highlight different groups and areas of focus that can be impacted based on the reporting and budgetary structure for a medical affairs group
- Discuss the difference of expectations and challenges faced by medical and cross-functional leadership and how that can affect a team's ability to do their job well

Alan Wright, M.D., MPH, *Chief Medical Officer,* **ROCHE DIAGNOSTICS**

Ruth du Moulin, Ph.D., *Vice President, Medical Affairs, Head of Medical Communications,* **TAKEDA ONCOLOGY**

Tehseen Salimi, *Head of Medical Affairs — Primary Care and Women's Health,* **MERCK**

Kirk V. Shepard, M.D., *Senior Vice President, Head of Global Medical Affairs OBG,* **EISAI**

10:15

LEVERAGING ONLINE DISCUSSION PLATFORMS FOR OPTIMAL STAKEHOLDER ENGAGEMENT

- Identify the logistical and resource barriers to domestic and global stakeholder engagement
- Learn about innovative communication solutions that leading organizations utilize to overcome these challenges
- Discuss how to use these solutions to deliver improved engagement outcomes while maintaining regulatory compliance

Lance Hill, *CEO,* **WITHIN3**

10:45 **Networking Break**

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MEDICAL AFFAIRS EXECUTIVE STRATEGY

11:30 Track Chair's Opening Remarks

Jason Bradt, *Executive Medical Director, Oncology, Americas Medical Affairs, Consultant,* **ASTELLAS PHARMA**

11:45 CASE STUDY: How to Develop a Cutting Edge Medical Plan That Is Tailored to the Needs of Your Organization

- Consider how medical strategies can vary based on the size of a company and its governance structure
- Examine traditional versus electronic impact factors and make sure your communications plan is aligned with your overall medical strategy
- Integrate your medical strategy across regions in a complex organizational structure and measure success across different channels

Ruth du Moulin, Ph.D., *Vice President, Medical Affairs, Head of Medical Communications,* **TAKEDA ONCOLOGY**

12:30 Luncheon

1:30 Navigate Medical Affairs in the World of Alliance Partnerships and Co-Promotions

- Review the different types of alliances and partnerships
- Establish a model to manage medical affairs through the alliance
- Discuss the various challenges with respect to compliance, thought leader initiatives, and organizational structures
- Build trust with your alliance partners and minimize the overlap of team members from the same function on every project workstream

Poushali Mukherjea, Ph.D., *Executive Director, Medical Affairs,* **BRISTOL-MYERS SQUIBB**

2:15 PANEL: Explore Different Models for Managing Medical Affairs Activities in Co-Promotion Agreements, Strategic Alliances and Acquisitions

- Review the different kinds of scenarios that require you to partner with another organization
- Determine what sort of arrangement best serves your business needs
- Analyze the impact of this arrangement on the development and execution of medical activities
- Hear case examples and shared learnings from real-world scenarios

Poushali Mukherjea, Ph.D., *Executive Director, Medical Affairs,* **BRISTOL-MYERS SQUIBB**

MSL BEST PRACTICES

Track Chair's Opening Remarks

Davida White, *Head, Medical Excellence and Education,* **INDIVIOR**

The Smartest and Most Effective MSL Teams Need Innovative Training and Tools

- Hear how to leverage technology when training MSLs
- Achieve simplicity: less is more with customer tools
- Learn peer-based coaching and onboarding best practices
- Ensure retention through fun continued education
- Don't forget the soft skills: Upskilling the team

Arthur Chan, Ph.D., MBA, *Head, MSL Capabilities, Development and Training,* **NOVARTIS**

Medical Affairs and Emotional Intelligence: Not a Contradiction

- Consider the importance of adaptability, both in the home office and the field
- Highlight interview questions to identify candidates with the emotional intelligence you need in your organization
- Discuss how emotional intelligence is essential for significant, lasting relationships with KOLs
- Shed light on self-awareness and how it can help both you and your team

Bryan N. Bischel, Ph.D., MBA, *Senior Director, U.S. Field Medical Affairs,* **NOTAL VISION**

Effective Strategies for Keeping Your Field Team Engaged

- Understand the potential motivations and reasons why an MSL considers the profession
- Consider opportunities that can be provided to field medical teams to further their professional development
- Examine the relationship between compensation levels and therapeutic areas
- Establish effective ways to communicate the value of an MSL to executive leadership and understand how that can impact the retention of field team members

Davida White, *Head, Medical Excellence and Education,* **INDIVIOR**

RESEARCH COLLABORATION AND INVESTIGATOR-INITIATED TRIALS

Track Chair's Opening Remarks

Shailesh Chavan, M.D., *Vice President Clinical Research, Drug Safety and Medical Affairs,* **BIOTEST PHARMACEUTICALS**

Best Practices for Managing Investigator-Sponsored Research Across Strategic Alliances

- Understand the motivations behind co-development deals and strategic alliances
- Clearly communicate research areas of interest from the start to align expectations
- Map out a plan to effectively manage the submission, review, and management of all IIT proposals and streamline operations

Mary Voehl Hirsch. M.Sc., *Senior Director, Head ISS Operations, Diabetes and Cardiovascular GBU,* **SANOFI**

The Perils and Pitfalls of Clinical Research Collaborations

- Consider the pros of a research collaboration and how it can be beneficial for a company
- Develop strategies and checklists for maintaining compliance and streamlined communications throughout the research life cycle
- Conduct the necessary diligence to avoid common challenges and pitfalls

Cynthia Barbitsch, Pharm.D., *Director/Team Leader, Clinical and Research Collaborations, External Medical Communications,* **PFIZER**

PANEL: Strategic Considerations for Converting an IIT to a Research Collaboration

- Examine the risks of working with new investigators
- Outline different scenarios that can prompt you to step in and collaborate with an investigator to save the study and trial data
- Leverage compliant contractual strategies that can help you transition the trial

Jennifer J. Gaskin, CCRP, CMQ-OE, *Director, Investigator Sponsored Trials,* **KARYOPHARM THERAPEUTICS**

MEDICAL AFFAIRS EXECUTIVE STRATEGY

MSL BEST PRACTICES

RESEARCH COLLABORATION AND INVESTIGATOR-INITIATED TRIALS

3:00

Technology as a Clinical Coach: Real World Engagement

- Discuss why and how clinical awareness and training should be delivered at "the point of need" to affect meaningful behavior change
- Realize how superior content without an effective interface can create health and regulatory risk and hear how to avoid this
- Understand how technology can be that data-driven, patient-centric, empathic coach patients and clinicians really want
- Hear case examples that highlight how MSLs can be learned intermediaries and a conduit for technology-enabled coaching

Michael W. Young, *Chief Marketing Officer,* **SCIENCEMEDIA, INC.**

Khawar Khokhar, *CEO,* **SAKS HEALTH LLC**

CASE STUDY: The Difficulties of Launching a Product, Even If It Is a Groundbreaking Treatment

- Hear an industry example about launching a hospital product that was approved for use in the ER or hospital setting
- Understand what needs to be in place, from a company perspective, prior to launch and how activities can be different based on therapeutic area, product, and company culture
- Utilizing medical insights from the field to address challenges that can arise, such as resourcing and cost issues

Alison McReynolds, Ph.D., *Director, Medical Science Liaisons — Sleep, Medical Affairs,* **JAZZ PHARMACEUTICALS**

Establish an Efficient and Compliant Process for Assessing the Fair Market Value (FMV) of IIT Budgets

- Understand what fair market value is, how it is determined and when it is utilized in IITs
- Explore scenarios when deviations to the FMV would be considered and how the process works
- Learn how to avoid lengthy negotiations around budget requests, specifically those outside of the FMV

Kelly Wimble Loughner, *Senior Associate Director, Site Enablement,* **BOEHRINGER INGELHEIM**

3:45 Networking Break

4:15

Patient-Centricity in Rare Diseases: Opportunities for Real-World Evidence

- Patients as Key Partners in Drug Development — discuss potential framework to improve patient-centricity in drug development
- Role of Rea-World Evidence in Rare Diseases — discuss role and sources of Real-World Evidence
- Value of Registries in Rare Disease — pros and cons

Sonal Bhatia, M.D., *Vice President, North America Medical Lead, Rare Disease,* **PFIZER**

In-House Versus Contract MSL Teams – What is the Best Fit for Your Organization?

- Consider the uncertainty around product approval, the challenges of entering a new therapeutic area, and the difficult prospect of training new MSLs
- Weigh the benefits of turnkey and flex-schedule MSL teams, and the ability to mobilize experienced professionals right away
- Discuss the impact of working with third-party vendors and contract MSLs when you're trying to build a long-term field team

If you are interested in leading this session, please contact Eric Morrin at emorrin@exlevents.com or 212-400-6228.

Reconcile Your Data and Evidence Needs With Internal Stakeholder Expectations When Evaluating IITs

- Consider the internal struggle between supporting company-sponsored research and IITs
- Examine how areas of research are built, how they're refined and who the significant stakeholders are
- Discuss tactics to get internal stakeholders on board with the data needs of your product

Joe Kishel, Pharm.D., MBA, BCPS-ID, *Team Lead (East), ID Research Scientific Directors, Global Center for Scientific Affairs,* **MERCK RESEARCH LABS**

5:00

The World Is Flat: Enhancing Collaboration Between U.S., Global, and Regional Medical Affairs Teams

- Optimize organizational structure and committees to harmonize and simplify medical strategic planning across key geographies
- Create aligned strategic medical plans that support the needs of multiple key stakeholders
- Develop aligned tactical plans that have clear roles/responsibilities and timelines
- Implement processes for open communication between different geographies and medical functions

Robert Wright, Pharm.D., *Senior Director, Strategic Planning and Transversal Scientific Projects, Global Medical Affairs — Diabetes,* **SANOFI**

PANEL: Effective Strategies and Models for Managing Contract MSL Teams

- Explore different models for managing MSLs and field teams
- Discuss the pros and cons of strategy development, oversight of field activities, and HR related matters
- Learn innovative ways to improve communication between in-house management and contract/vendor companies

Jay Elliott, Ph.D., *Regional Deputy Director, Medical Science Liaisons,* **BAYER HEALTHCARE**

Ensure the Timeline for an IIT Meets the Needs of a Product and Clinicians in the Field

- Understand the needs of your organization's portfolio and conduct your due diligence on new proposals
- Hear how to structure your IIT process to improve its running time and ensure the new data will fall in line with a product's life cycle
- Discuss areas of optimization that can drastically impact the time of IITs such as patient recruitment, online submission portals, effective study milestones, and investigator payment methods

Peter Shaw, MBBS., DRCOG, *Senior Director, Medical Affairs — Orthopaedics,* **FERRING PHARMACEUTICALS**

5:45 Cocktail Reception

6:45 Day One Concludes

	MEDICAL AFFAIRS EXECUTIVE STRATEGY	MSL BEST PRACTICES	RESEARCH COLLABORATION AND INVESTIGATOR-INITIATED TRIALS
8:00	**Continental Breakfast**		
8:30	**Track Chair's Recap of Day One** **Jason Bradt,** *Executive Medical Director, Oncology, Americas Medical Affairs, Consultant,* **ASTELLAS PHARMA**	**Track Chair's Recap of Day One** **Davida White,** *Head, Medical Excellence and Education,* **INDIVIOR**	**Track Chair's Recap of Day One** **Shailesh Chavan, M.D.,** *Vice President Clinical Research, Drug Safety and Medical Affairs,* **BIOTEST PHARMACEUTICALS**
8:45	**The Role of Medical Affairs in a Fast-Paced, Innovative and Engaged Space** → Train and provide educational materials for marketing, sales and other functional stakeholders that will allow them to be better informed partners for medical affairs → Enhance the speed of execution and set yourself up for success when responding to the challenges and claims against your products → Garner scientific credibility within your company, as well as externally, through effective KOL engagement, advisory boards, scientific publications and interacting with regulatory authorities **Eric Pierre Guenin, Pharm.D., Ph.D., R.Ph.,** *Director of Medical Affairs,* **RECKITT BENCKISER**	**Effective Strategies for Collaboration With Medical Affairs When Executing Field Medical Activities** → Highlight the importance of having end-to-end vision of the overall medical strategy → Discuss successful approaches for home office and MSLs to collaborate across U.S. and ex-U.S. regions → Learn how to communicate more strategically and purposefully with medical affairs, as well as global teams **Riju Ray, Ph.D.,** *U.S. Medical Affairs Lead,* **GLAXOSMITHKLINE**	**Best Practices for Managing a Single Versus Multicenter Investigator-Sponsored Clinical Studies** → Discuss the regulatory requirements and interactions with the IRB when conducting single versus multicenter IITs → Learn how to efficiently secure financing, ensure study start-up time, train and monitor multicenter IITS, minimize risk, and promote accuracy and quality of the data collected → Hear logistical considerations for both scenarios and learn how to plan for the unexpected
9:30	**Professional Development in Medical Communications: What It Takes to Bring You and the Industry to the Next Level** → Building an individual development plan in medical communications and the impact to publication planning → Communication skills that help convey ideas laterally, downwards, and upwards → Skill set application for future career opportunities in the industry **Dheepa Chari,** *Senior Director/Team Leader, Global Medical Communications, Oncology,* **PFIZER**	**Optimizing Field Intelligence: Getting the Right Information to the Right People at the Right Time** → Find the balance between compliant push and pull of information with thought leaders → Leverage MSL insights to establish the team value proposition → Utilize strategic information collection and dissemination to inform pre- and post-launch planning **Jay Elliott, Ph.D.,** *Regional Deputy Director, Medical Science Liaisons,* **BAYER HEALTHCARE**	**Effective Strategies to Increase Sponsor and Site Collaboration During Investigator-Sponsored Studies** → Learn about specific challenges at sites/centers from those creating and conducting IITs, and about the role of good communication in successful projects → Understand how to work with the site and reduce key barriers that can threaten project success → Highlight how a poor understanding of logistics (e.g., a sponsor-center disconnect) can adversely affect protocol design, budget and schedule for a clinical trial **Earl Knight, Esq.,** *Director, Contracting Sponsored Program Services,* **PURDUE UNIVERSITY**
10:15	**Networking Break**		
10:45	**Strategies for Medical Affairs to Work Effectively With Commercial to Navigate the Compliance Landscape** → In this environment, how does MA come to the table and work with commercial? → How do you work proactively, reactively? How do sales teams communicate with MSLs? → How does marketing influence medical strategies? → How to let medical be medical so they can generate data, setting up an environment where physician barriers and challenges are effectively addressed **Leslie Meltzer,** *Vice President, Head of Medical Affairs,* **KERYX BIOPHARMACEUTICALS**	**The Role of MSLs in Today's Payer and Reimbursement Landscape** → Review the new operating model of medical affairs focused on end-to-end evidence, medical value and broad-based integrated stakeholder engagement → Gain an understanding of payer-centered evidentiary needs including real-world evidence, patient-centered outcomes and health economic data → Understand payer perspectives and what it takes to clearly communicate the value proposition of a product to payers and managed care organizations → Develop a two-way interface in the new medical affairs operating model; systematically bringing integrated external insights from both physicians and payers back to the medical affairs organization and effectively contributing to patient access and corporate strategy **Usman Iqbal,** *Senior Director, Medical and HEOR,* **TREVENA**	**Best Practices for Managing Large-Scale Global and Multicenter Investigator-Sponsored Trials With Limited Resources and Funding** → Discuss the regulatory requirements and interactions with the IRB when conducting single versus multicenter IITs → Learn how to efficiently secure financing, ensure study start-up time, train and monitor multicenter IITS, minimize risk, and promote accuracy and quality of the data collected → Hear logistical considerations for both scenarios and learn how to plan for the unexpected **Jennifer J. Gaskin, CCRP, CMQ-OE,** *Director, Investigator-Sponsored Trials,* **KARYOPHARM THERAPEUTICS**

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11:30

The Use of Data Analytics in Medical Affairs

- Leverage new technologies and processes to build out a reporting tool to gather data
- Utilize this data to identify trends and patterns in content used by various user groups
- Understand how hard data can be more reliable than subjective insights
- Improve how you disseminate this information and report its value to internal stakeholders

Scott McConnell, Pharm.D., *Senior Director, Medical Affairs,* **ALKERMES**

Develop a Focused Field Strategy That Ties Into Your Overall Medical Brand Plan

- Build a medical brand plan that is fit for purpose
- Adapt the medical plan to ensure your field activities are evolving as time goes on
- Hear operational efficiencies that can help companies maximize their resources in the field

Michael Steidle, Pharm.D., MBA, *National Director, Medical Science Liaison Team,* **MELINTA THERAPEUTICS**

Effectively Demonstrate the Value of Investigator-Sponsored Research to Internal Leadership

- Pinpoint key metrics used to evaluate IITs and how that can differ from leadership's perspective
- Balance the use of qualitative and quantitative analysis for investigator-sponsored research operations
- Demonstrate value for both clinical and commercial goals within an organization

Jason Bradt, *Executive Medical Director, Oncology, Americas Medical Affairs, Consultant,* **ASTELLAS PHARMA**

12:15 **Luncheon**

INDUSTRY SPOTLIGHT: THE EVOLVING ROLE OF MEDICAL AFFAIRS, MSLS AND INVESTIGATOR-INITIATED TRIALS IN THE MEDICAL DEVICE AND PHARMACEUTICAL INDUSTRY

1:15 **NEW PRODUCT DEVELOPMENT**

- Obtaining and being the voice of the customer
- Fostering and growing relationships with clinical user boards and KOLs/thought leaders
- How to overcome "bring me a rock" leadership mentality
- Importance of involvement in key professional organizations and associations

2:15 **PANEL: EXPLORE HOW THE ROLE AND IMPACT OF MEDICAL AFFAIRS HAS EVOLVED AT MEDICAL DEVICE AND PHARMACEUTICAL COMPANIES**

- Discuss best practices from both industries that can be incorporated into your medical affairs organization's core activities
- Thought Leadership Initiatives for Market Development
- Medical Affairs and Human Factors collaboration: Impact on safety work flows, efficacy, and testing the product through usability and simulation
- Education and training through augmented/virtual reality and video/audio calling service
- Medical affairs role in unifying the development of a product with marketing, regulatory affairs, quality, research and development

Marianne Gill, *Vice President Medical Affairs,* **BD MEDICAL**

Idal Beer, *Vice President, Medical Affairs, Medication Management Solutions Office of Science, Medicine and Technology,* **BD MEDICAL**

Mark Hunter, *Manager, Medical Affairs,* **BD MEDICAL**

3:15 **Summit Concludes**

"I got good info in IIRs and heard the experience of others. The patient representative talk was a good idea." *—Global Grants Officer,* **PFIZER**

"Above and beyond! Excellent presenters with very informative presentations. Very nice, friendly environment." *—M.D.,* **PROVIDENCE HOSPITAL**

"Wow! Very eye opening. Good to know IIT process can be shared in different areas." *—Scientific Affairs Coordinator,* **BOSTON SCIENTIFIC**

"Really offered a different view of MA structure. Excellent." *–VP, Customer Strategy,* **TMAC**

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