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CLINICAL & MEDICAL  
AFFAIRS SERIES

VIRTUAL EVENT

DECEMBER 1-3, 2020

# Medical Affairs Congress



Expanded Access



Investigator Initiated  
Sponsored Research (IISR)



Publication Planning  
& Communications

**GAIN CRITICAL LEADERSHIP INSIGHTS FROM INDUSTRY THOUGHT-LEADERS**



Scott McConnell,  
Vice President, Medical Affairs,  
**Chiasma**



Raymond Mankoski,  
Vice President, Medical Affairs,  
**Blueprint Medicines**



Kathleen Long,  
Director, Medical Affairs Operations,  
**Alkermes**



Chirag Shah, PharmD,  
Head, Strategic Publications  
& Medical Education,  
**Neurocrine Biosciences**



Mary Hanson,  
Director, Scientific Affairs,  
**Merck & Co.**



Alex Halls,  
Director, U.S. Commercial & Global  
Medical Affairs Counsel – Complement,  
**Alexion Pharmaceuticals, Inc.**



Angela Sykes,  
Director, Team Leader,  
Publications Management Team,  
**Pfizer**



Elizabeth Dorn,  
Senior Medical Director,  
Medical Affairs,  
**Alkermes**



Katie Wade,  
Associate Director,  
Medical Research Operations,  
**Biogen**

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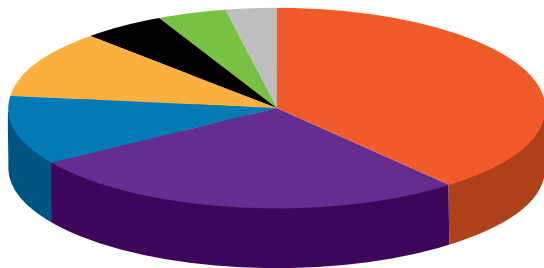


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# REDEFINING YOUR LEARNING EXPERIENCE

The **Medical Affairs Congress** provides a 360-degree view of the medical affairs landscape that brings together Investigator Initiated Sponsored Research (IISR), Expanded Access Programs (EAP) and Publication Planning & Communications. The Congress examines leading strategies to advance medical science communication, engage with KOLs compliantly, conduct effective investigator studies and so much more. This is an excellent opportunity to gain the strategies you need to ensure excellence throughout your medical affairs team.

## ANTICIPATED ATTENDEE PROFILE



- **39%** Medical Affairs
- **27%** Med Comm/Publications/Writing
- **11%** Research/IIS/Grants
- **11%** Clinical Affairs/Ops
- **5%** Legal/Compliance
- **4%** Commercial Affairs/Business Strategy
- **3%** Patient Access/Support



## UNIQUE BENEFITS OF THIS VIRTUAL EVENT:

- Convenient session scheduling for increased productivity
- On-demand access to content assets and topic resources
- Efficient and ROI-driven networking
- Interactive presentations/panels for reinforced learning
- Pointed problem-solving and solution sourcing
- Broader industry benchmarking
- Elevated and direct access to thought-leaders and experts



## DIGITAL CAPABILITIES AND FEATURES:

- Access to virtual environment
- Audience Q&A
- Live polling
- Expert-led problem-solving
- Virtual networking and partnering



## PARTNERING AND NETWORKING:

### Who's Who?

- Attendee and company profiles provide insight into the delegation and sponsoring organizations
- Advanced search capabilities to identify opportunities and potential partners

### When and How to Connect?

- Sophisticated and seamless scheduling tools to establish meeting times ahead of the event
- Ease-of-use technology to set small group meetings, via live chats or video conferencing

## ACCLAIM FOR THE MEDICAL AND CLINICAL CONFERENCE PORTFOLIO

"As someone who is new to the IISR space, I thought that this conference provided a comprehensive learning opportunity. Looking forward to the next one!"

– Clinical Research Manager, Takeda

"There are very few opportunities for making global connections in the IISR space. This CBI conference is invaluable."

– SWOG

"There are so many exciting and innovative ideas to take away from the meeting along with outstanding networking opportunities."

– Medical Science Liaison, Oncology, Ipsen

"This was a very relevant conference and the content was delivered well. Executed wonderfully."

– Medical Affairs Manager, Oxford Immunotec, Inc.

# LIVE CONTENT — YOUR TIME. REAL TIME.

During the Medical Affairs Congress there will be live presentations, interactive sessions and networking events. Any timeframe below that does not have a session listed is a great time to network and enjoy our on-demand sessions.

## DAY ONE: TUESDAY, DECEMBER 1, 2020

*\*Please note all times are EST*

10:30 – 10:45am

### Informa Connect and Chairman's Welcoming Remarks

*Katie Laquidara, Conference Producer, Informa Connect*  
*Scott McConnell, Vice President, Medical Affairs, Chiasma*

10:45 – 11:30am

### **LIVE** KEYNOTE PANEL

#### Does Your Medical Plan Align with Your Goals? — The Role of Planning Ahead in a Changing Healthcare Landscape

##### PANELISTS:

*Scott McConnell, Vice President, Medical Affairs, Chiasma*  
*Raymond Mankoski, Vice President, Medical Affairs, Blueprint Medicines*

11:30am – 12:00pm

### **LIVE** Coloring Within the Lines — Compliance and Regulation Pitfalls and Opportunities

*Alex Halls, Associate Director, US Commercial & Global Medical Affairs Counsel – Metabolics, Alexion Pharmaceuticals, Inc.*



## TAKE TIME FOR NETWORKING VIRTUALLY AND VIEWING ON-DEMAND CONTENT



## Expanded Access

2:00 – 2:30pm

### **LIVE** Align Mission and Vision in Expanded Access — Opportunities for Growth and Useable Data

*Gretchen Randlett, Consultant CT Comm Product Strategy & Process, Eli Lilly & Co.*

2:30 – 3:00pm

### **LIVE** Patient Advocacy and Right to Try Ethics — The Role of the Patient

*Peter Pitts, President, Center for Medicine in the Public Interest*

3:00 – 3:30pm

### **LIVE** Expanded Access — Best Practice Sharing Roundtable Discussion

Interested in IISR or  
Publication Planning &  
Communication content?  
Check out the on-demand  
sessions!



## DAY TWO: WEDNESDAY, DECEMBER 2, 2020

*\*Please note all times are EST*

10:30 – 10:35am	<b>Day 2 Kick-Off</b>
10:35 – 11:10am	<b>LIVE</b> <b>A Strategic Approach to Data and Technology to Fuel the Future of Medical Affairs</b> <i>Natasha Eslami, Manager, Commercial Strategy, Health Sciences &amp; Wellness Sector, Ernst &amp; Young LLP</i> <i>Susan Garfield, Commercial Lead, Health Sciences &amp; Wellness Sector, Ernst &amp; Young LLP</i>
11:10 – 11:55am	<b>LIVE</b> <b>The Goldilocks Approach — Building Successful Medical Affairs Teams</b> <i>Dawn-Marie Sullivan, L.E., Clinical Development &amp; Medical Affairs Consultant, Dawn Sullivan Consulting</i>



**TAKE TIME FOR NETWORKING VIRTUALLY AND VIEWING ON-DEMAND CONTENT**



### Investigator Initiated Sponsored Research (IISR)

Interested in Expanded Access or Publication Planning & Communication content? Check out the on-demand sessions!

2:00 – 2:45pm	<b>LIVE</b> <b>Strategize and Report the Value Proposition — Building a Successful IISR Initiative</b> <i>Kathleen Long, Director, Grants, Medical Affairs, Alkermes, Inc.</i> <i>Katie Wade, Associate Director Global Medical Research Operations, Biogen</i>
2:45 – 3:30pm	<b>LIVE</b> <b>Achieving Optimal Value — Norms and Outliers of FMV</b> <i>Andrea Molliver, Senior Principal Clinical Contract Analyst, Medtronic</i> <i>Cherie-Lynn Schwartz, Senior Clinical Contract Analyst, Medtronic</i>
3:30 – 4:00pm	<b>LIVE</b> <b>IISR — Best Practice Sharing Roundtable Discussion</b>

## DAY THREE: THURSDAY, DECEMBER 3, 2020

*\*Please note all times are EST*

10:30 – 10:35am	<b>Day 3 Kick-Off</b>
10:35 – 11:05am	<b>LIVE</b> <b>This is Not a Trend: Why Patient-Centered Clinical Research Will Continue to Change the Research Paradigms of the Past</b> <i>Behdash Bahador, Associate Director, Relationship Management and Development, Center for Information &amp; Study on Clinical Research Participation (CISCRP)</i>
11:05 – 11:35am	<b>LIVE</b> <b>The World Stage — Collaborating Through Global Teamwork</b> <i>Ivan Gonzalez Gomez, Independent; Former, Publications and MSL Manager, UCB</i>



## TAKE TIME FOR NETWORKING VIRTUALLY AND VIEWING ON-DEMAND CONTENT



### Publication Planning & Communications

Interested in  
Expanded Access or  
IISR content? Check out the  
on-demand sessions!

1:00 - 1:45pm

#### **LIVE** Medical Affairs Strategy Integration — Planning Around Uncertainty

*Elizabeth Dorn, Senior Medical Director, Medical Affairs, **Alkermes***

*Chirag Shah, PharmD, Head, Strategic Publications & Medical Education, **Neurocrine Biosciences***

1:50 - 2:35pm

#### **LIVE** Writing to Audience — Diverse Perspectives on Planning for Unique Information Delivery

##### PANELISTS:

*Mary Hanson, Director, Scientific Affairs, Infectious Diseases & Vaccines, Global Scientific & Medical Publications, **Merck & Co.***

*Angela Sykes, Director, Team Leader, Publications Management Team, **Pfizer***

*Isabelle Lousada, CEO & President, **Amyloidosis Research Consortium***

2:40 - 3:10pm

#### **LIVE** Publication Planning & Communication — Best Practice Sharing Roundtable Discussion

3:10pm

#### Close of Conference



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# IN-DEPTH, ON-DEMAND SESSIONS — WHAT YOU WANT. WHEN YOU WANT IT.



There is much to experience and meet about at the Medical Affairs Congress.  
On-Demand content is available anytime, to accommodate your needs and schedule.



## Medical Affairs Excellence

**Achieving MSL Excellence — Best Practices for Optimal Training and Collaboration**

**FDA and Expanded Access — A Deep Dive into Project Facilitate**

**Best Practices for Cooperative Groups vs. Investigator Initiated Sponsored Studies in the Age of Large Platform Trials**

*Dana Sparks, Director of Operations and Protocols, SWOG*

**The Impact of Regulations on Medical Affairs — A Response to Historical Litigation**

*Howard Dorfman, Founder, H.L Dorfman Pharmaceutical Consulting, LLC*



## Expanded Access

**Financial and Strategic Considerations for Expanded Access Program Development and Managements**

*Michael Martineau, Associate Director, Global Medical Operations, Sanofi-Genzyme*

*Christopher Robertson, Associate Dean for Research and Innovation, James E. Rogers College of Law, University of Arizona*

**Policy and Strategy — A Layered Discussion of Expanded Access** *Naomi Lopez, Director of Healthcare Policy, Goldwater Institute*



## Investigator Initiated Sponsored Research (IISR)

**Managing Interactions with Investigators — Compliant Collaboration**

**Liability, IP and Data Issues — A True IISR Case Study** *Marlon Rajakaruna, Principal, Kingsgate Legal*



## Publication Planning & Communication

**Leveraging Online Discussion Platforms to Accelerate KOL Insights**

**The Publication Management Juggling Act** *Pia Graham, Associate Director, Publication Management, Merck & Co.*

# LEARN MORE ABOUT THE CONFERENCE CONTENT

## Does Your Medical Plan Align with Your Goals? — The Role of Planning Ahead in a Changing Healthcare Landscape

- Illustrate the evolving role of the medical affairs department from expanded access, IISR and publication planning perspectives
- Delineate best practices to report appropriate and relevant KPIs to stakeholders
- Examine the role of advisory boards and KOL management, and how to utilize them in the overall strategic plan

Scott McConnell, Vice President, Medical Affairs, **Chiasma**

Raymond Mankoski, Vice President, Medical Affairs, **Blueprint Medicines**

## Coloring Within the Lines — Compliance and Regulation Pitfalls and Opportunities

- Discuss the latest trends in regulation and accompanying compliance challenges
- Review the evolution of the False Claims Act and its impact on the efficacy of the medical affairs department
- Evaluate the intersection of medical affairs and commercial partners with accepted collaboration and potential sticking points
- Describe ideal KOL engagement to become compliance partners

Alex Halls, Director, U.S. Commercial & Global Medical Affairs Counsel –

Complement, **Alexion Pharmaceuticals, Inc.**

## Align Mission and Vision in Expanded Access — Opportunities for Growth and Useable Data

- Assess the role of R&D in shaping the expanded access program
- Include the necessary discussions of operational logistics required for successful expanded access plans
- Examine the unique challenges for working in global teams, including integrating with publication planning

Gretchen Randlett, Consultant CT Comm Product Strategy & Process,

**Eli Lilly & Co.**

## Patient Advocacy and Right to Try Ethics — The Role of the Patient

- Examine the patient of the future and address expectations in results-sharing
- Identify opportunities for improved trust and collaboration with patients and patient advocacy groups
- Delve into the complexities of specialty therapies and the ethics surrounding expensive treatments

Peter Pitts, President, **Center for Medicine in the Public Interest**

## A Strategic Approach to Data and Technology to Fuel the Future of Medical Affairs

- Assess how to transform into an innovative medical affairs function
- Consider the role of technology in knowledge management and customer engagement
- Examine a real-world case study of managing data and medical communications to support collaboration and deliver value
- Discuss how to leverage digital capabilities to deliver value to the organization and customers
- Review KPIs to track and benchmarking impact of assets and publications
- Track integration and aggregation of multiple sources of data and of data management into the overall medical plan

Natasha Eslami, Manager, Commercial Strategy, Health Sciences & Wellness

Sector, **Ernst & Young LLP**

Susan Garfield, Commercial Lead, Health Sciences & Wellness Sector,

**Ernst & Young LLP**

## The Goldilocks Approach — Building Successful Medical Affairs Teams

- Outline ideal team sizes and structure based on company-specific needs
- Align company mission with medical plan execution with an eye to planned training and hiring
- Structure interactions with R&D and commercial partners to maximize communication flow
- Discuss the impact of mergers and acquisitions on teams along with other external alliances, such as co-promotion and partnership opportunities

Dawn-Marie Sullivan, L.E., Clinical Development & Medical Affairs Consultant,

**Dawn Sullivan Consulting**

## Strategize and Report the Value Proposition — Building a Successful IISR Initiative

- Discuss the importance of “scientific ROI” and anticipated deliverables
- Review opportunities in program-based evaluations
- Develop strategies to address gaps, failures, time spent per project, financial support and special support for international trials and teams

Kathleen Long, Director, Grants, Medical Affairs, **Alkermes, Inc.**

Katie Wade, Associate Director Global Medical Research Operations, **Biogen**

## Achieving Optimal Value — Norms and Outliers of FMV

- Determine and review budget for fair market value
- Understand regional differences with regard to local regulations
- Assess publication, reporting requirements and more based on contracts
- Share lessons learned and practice tips

Andrea Molliver, Senior Principal Clinical Contract Analyst,

**Medtronic Core Clinical Solutions**

Cherie-Lynn Schwartz, Senior Clinical Contract Analyst,

**Medtronic Core Clinical Solutions**

## This is Not a Trend: Why Patient-Centered Clinical Research will Continue to Change the Research Paradigms of the Past

- Examine the current patient-centricity landscape, including recent developments in regulatory and global guidance
- Review industry initiatives that engage patients, the public and physicians to improve awareness and understanding of clinical research and participation opportunities
- Assess the role of multi-stakeholder collaborations and opportunities for beneficial collaboration for all

Behdash Bahador, Associate Director, Relationship Management and

Development, **Center for Information & Study on Clinical Research Participation (CISCRP)**

## The World Stage — Collaborating Through Global Teamwork

- Assess the future landscape of medical affairs teams with an eye towards remote teams
- Discuss strategies for stronger compliance while balancing commercial and non-commercial interactions with internal stakeholders
- Review the role of technology in the teams of the future and opportunities for growth

Ivan Gonzalez Gomez, Independent, Former, Publications and MSL Manager, **UCB**



# LEARN MORE ABOUT THE CONFERENCE CONTENT (CONTINUED)

## Medical Affairs Strategy Integration — Planning Around Uncertainty

- Design structured plans to incorporate IISR, expanded access and other data-gathering initiatives into the overall publication plan
- Organize systems for knowledge management
- Develop targeted initiatives based on audience needs
- Identify distinguished and trusted publication channels
- Calculate resource allocation in terms of financials, time, project management commitments and vendor management

*Elizabeth Dorn, Senior Medical Director, Medical Affairs, Alkermes*

*Chirag Shah, Strategic Publications & Medical Education Lead, Neurocrine Biosciences*

## Writing to Audience — Diverse Perspectives on Planning for Unique Information Delivery

- Compare expectations for meaningful publications, including the highly-debated plain language summaries
- Discuss the role of advancing media technology in the form of enhanced content and how changing audience demographics inform delivery method interactions
- Examine the role of patient authors in scientific publications

### PANELISTS:

*Mary Hanson, Director, Scientific Affairs, Infectious Diseases & Vaccines, Global Scientific & Medical Publications, Merck & Co.*

*Angela Sykes, Director, Team Leader, Publications Management Team, Pfizer*

*Isabelle Lousada, CEO & President, Amyloidosis Research Consortium*

## Financial and Strategic Considerations for Expanded Access Program Development and Management

- Review regulatory considerations and implications
- Identify potential pitfalls and opportunities with key stakeholders, including product planning and financial considerations
- Consider strategies with external partnerships to facilitate contract negotiations

*Michael Martineau, Associate Director, Global Medical Operations, Sanofi-Genzyme*

*Christopher Robertson, Associate Dean for Research and Innovation, James E. Rogers College of Law, University of Arizona*

## Policy and Strategy — A Layered Discussion of Expanded Access

- Sketch potential pitfalls and opportunities relating to transparency and patient access
- Examine the outlier possibilities for product production, including reimbursement and access for gene therapies and specialty therapies
- Review off-label state legislation and challenging access opportunities on the administrative and legislative landscape

*Naomi Lopez, Director of Healthcare Policy, Goldwater Institute*

## Managing Interactions with Investigators — Compliant Collaboration

- Develop a logistics and operational plan for improved compliance in an IISR plan
- Discuss the sponsor's role and anticipated needs that offer additional support
- Examine benchmarking initiatives and strategic adjustments for more accurate expectations of scientific ROI

## Liability, IP and Data Issues — A True IISR Case Study

- Review contract challenges and examples of unfavorable outcomes
- Discuss possible resolutions of issues and opportunities for improvement
- Share lessons learned/practice tips

*Marlon Rajakaruna, Principal, Kingsgate Legal*

## Leveraging Online Discussion Platforms to Accelerate KOL Insights

- Examine the evolution from traditional methods to asynchronous communication platforms
- Discuss how medical affairs teams are leveraging online platforms to address strategic objectives
- Review benefits and outcomes of using online discussion platforms

## The Publication Management Juggling Act

- Apply the best of project management to publication planning, including strategy, tactical, budget and risk management
- Organize an internal and external publication calendar
- Discuss site of publication assistance and opportunities for better management of teams
- Assess opportunities with international teams in emerging markets to incorporate country publications into a global plan

- Explore the opportunities of digital publications and necessary steps for a smooth transition from more traditional publishing

*Pia Graham, Associate Director, Publication Management, Merck & Co.*

## Achieving MSL Excellence — Best Practices for Optimal Training and Collaboration

- Outline the best practices for becoming an MSL
- Review guided training and utilization of KOLs
- Discuss the roles of in-house vs. field MSLs and collaborative initiatives for improved communication

## FDA and Expanded Access — A Deep Dive into Project Facilitate

- Consider the role of assistance programs for oncology management from providers and regulatory professionals
- Assess eligibility for expanded access programs in the project
- Review collaborative opportunities for representation and access

## Best Practices for Cooperative Groups vs. Investigator Initiated Sponsored Studies in the Age of Large Platform Trials

- Discuss the intersection between IISR programs and cooperative groups
- Review strategies for collaborative work in clinical trials and studies relating to science and technology capability advancements
- Describe best practices for ongoing relationships with cooperative groups
- Consider the role of large platform trials and the evolving role of clinical trials

*Dana Sparks, Director of Operations and Protocols, SWOG*

## The Impact of Regulations on Medical Affairs — A Response to Historical Litigation

- Review lessons learned to drive more compliant interactions with regulators
- Discuss the intersection of sometimes isolated silos and improved communication of necessary collaboration
- Integrate clearer guidelines to match scheduled deliverables for more timely decisions

*Howard Dorfman, Founder, H.L Dorfman Pharmaceutical Consulting, LLC*



# EXPERIENCE ENHANCEMENT

Continue to Customize Your Virtual Conference Experience by Taking Advantage of the Below Activity:



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### LIVE CHAT

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## CONNECT WITH THE **MEDICAL AFFAIRS TEAM** FOR MORE INFORMATION!

### Program Development:



**Katie Laquidara**

[katie.laquidara@informa.com](mailto:katie.laquidara@informa.com)  
339-298-2219

### Sponsorship Opportunities:



**Karen Hanover**

[karen.hanover@informa.com](mailto:karen.hanover@informa.com)  
617-290-6113

### Registration Details:



**John Kuchinski**

[john.kuchinski@informa.com](mailto:john.kuchinski@informa.com)  
339-298-2112

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