

Speaker Programs Summit

**DELIVERED AS A
HYBRID EVENT:**

February 16-17, 2022
Philadelphia, PA

Align Speaker Programs Execution with PhRMA Code Updates and Increased OIG Scrutiny

Esteemed Conference Co-Chairs



JESSICA SEIFERT

Director, U.S. Commercial Compliance,
AbbVie



ELLEN FRIEDMAN

Senior Analyst, Commercial Effectiveness/Fleet,
Mallinckrodt Pharmaceuticals

Moderated Q&A: PhRMA Updates



JULIE RITCHIE WAGNER, JD

Senior Assistant General Counsel,
PhRMA

Featured Enforcement Panel: Explore Prosecutor Perspectives on the High-Risk Activities of Speaker Programs



RACHAEL HONIG

Acting U.S. Attorney,
U.S. Attorney's Office for
the District of New Jersey



CHARLENE FULLMER

Assistant United States Attorney
Deputy Chief, Affirmative Litigation,
U.S. Department of Justice



AMANDA P. M. STRACHAN

Deputy Chief, Criminal Division,
U.S. Attorney's Office for the
District of Massachusetts

ABOUT THE EVENT

Speaker Programs 2022 serves as the life sciences industry's ONLY educational forum focused solely on critical marketing, operations and compliance matters for sustaining speaker programs. Addressing the ever-evolving practices of speaker bureau management and development in a shifting enforcement landscape, this event provides valuable insights and best practices on the process of accurately and compliantly conducting speaker programs.

ALL ACCESS EXPERIENCE

- The In-Person Event February 16-17 in Philadelphia, PA
- 2 Jam-Packed Days of Content
- 3 Breakout Sessions
- Networking, Networking, Networking
- All Benefits Included in the Virtual Experience Pass

VIRTUAL EXPERIENCE

- Access to the Virtual Platform
- Live Streaming of the In-Person Event February 16-17
- Recorded Presentations from the In-Person Event, Available On-Demand for Two Weeks Beginning February 22
- The Full Attendee List with Video Chat, Instant Messaging and Meeting Request Functionalities
- Speaker Presentation Slides

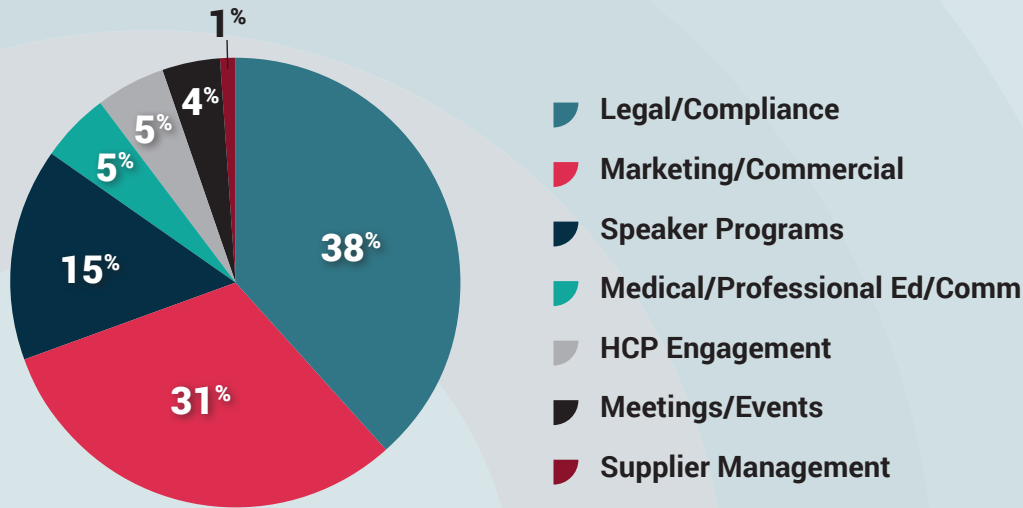
Impactful Discussions on Top Issues:

- Industry, policy and process shifts in response to PhRMA Code changes and the Special Fraud Alert
- Speaker bureau strategy regarding the speaker nomination process, faculty sizing and FMV contracting in a shifting enforcement landscape
- The staying power of virtual speaker programs post-pandemic
- Compliance risk in the return to F2F by ensuring vendor alignment with your organization's policy and process changes
- Approaches for determining the right number and mix of virtual, hybrid and F2F speaker programs
- Speaker training best practices to better prepare HCPs for evolving program formats



AUDIENCE PROFILE

2021 AUDIENCE BREAKDOWN BY TITLE



TOP 3 CHALLENGES FOR 2022



Navigating the evolving compliance landscape for speaker programs



Determining the right mix of live, virtual and hybrid meetings



Ensuring health and safety protocols for returning to face-to-face meetings

INSIGHTS SHARED FROM THE 2021 BENCHMARKING REPORT:

PRE-PANDEMIC

65% of surveyed individuals said less than 10% of their programs were virtual

79% of surveyed individuals said less than 10% of their programs were hybrid

POST-PANDEMIC

57% of surveyed individuals said greater than 50% of their programs will be virtual

42% of surveyed individuals said between 25-50% of their programs will be hybrid



DISTINGUISHED FACULTY DRIVING THE DISCUSSIONS

David Amendola, Global Compliance Risk Evaluation and Management, **ConvaTec**

Audrey Caporaletti, Manager, U.S. Commercial Compliance and Ethics, **Teva Pharmaceuticals**

Isabella Carini, Director, Strategic & Executional Excellence, Office of Ethics & Compliance Operations, **AbbVie**

Susan Cholakian, Manager, Speaker Program Operations, **Astellas Pharma US, Inc.**

Tracy Doyle, Managing Partner, **eNova**

Diane Evans, Marketing Manager, Dermatology, **AbbVie**

Ellen Friedman, Senior Analyst, Commercial Effectiveness/Fleet, **Mallinckrodt Pharmaceuticals**

Charlene Fullmer, Assistant United States Attorney Deputy Chief, Affirmative Litigation, **U.S. Department of Justice**

Rachael Honig, Acting U.S. Attorney, **U.S. Attorney's Office for the District of New Jersey**

Laura Konwinski, JD, Senior Director, Global Compliance, **BCD Meetings & Events**

Seth H. Lundy, Partner, **King & Spalding**

Joseph Mack, Senior Assistant General Counsel, Compliance and Investigations, **Bayer U.S. LLC**

Brian S. McCarthy, Director, U.S. Compliance Business Partner, **TG Therapeutics**

Brenda Neal, Senior Director, Marketing Operations, **Urovant Sciences, Inc**

Kelly Pitt, Vice President, U.S. General Counsel, **MorphoSys U.S. Inc.**

Tim Reasoner, Director, U.S. Faculty Administration and Marketing Supplier Management, **Lilly USA**

Kara Ryan, Director, Compliance & Privacy, **Blueprint Medicines**

Mike Saraceno, Corporate Compliance Lead, **Spark Therapeutics, Inc.**

Jessica Seifert, Director, Commercial Compliance Operations, **AbbVie**

Brian P. Sharkey, Director, U.S. Compliance and Ethics, **Teva Pharmaceuticals**

Amanda P. M. Strachan, Deputy Chief, Criminal Division, **U.S. Attorney's Office for the District of Massachusetts**

Michael Varlotta, Senior Director, Marketing Operations, **Janssen Biotech, Inc.**

David Verica, Operations and Events Management, Sales Force Operations, **AstraZeneca**

Julie Ritchie Wagner, JD, Senior Assistant General Counsel, **PhRMA**

Stacey Wodarski, Senior Manager, Professional Strategy, **Bausch Health**

Lisa M. Young, Associate Director, Commercial Event Planning and Operations, **Blueprint Medicines**

2022 ADVISORY COMMITTEE

A sincere thank you to the Advisory Committee Members for their support and guidance in assisting in the development of the robust program agenda aimed at addressing industry's most pressing challenges.



Julie Berliet, MPH,
Manager, Medical Education,
Allergan



Isabella Carini, Director, Strategic &
Executional Excellence, Office of Ethics
& Compliance Operations, **AbbVie**



Ellen Friedman, Senior Analyst,
Commercial Effectiveness/Fleet,
Mallinckrodt Pharmaceuticals



Brenda Neal,
Senior Director, Marketing Operations,
Urovant Sciences, Inc



Jessica Seifert, Director,
Commercial Compliance Operations,
AbbVie



Jenny Shire, Director, Travel,
Professional Programs and Operations,
Daiichi Sankyo



Michael Varlotta, Senior Director,
Marketing Operations,
Janssen Biotech, Inc.

IN-PERSON AGENDA

Wednesday, February 16, 2022

7:30-8:30 AM

Conference Registration and Networking Breakfast

8:30-8:45 AM

Co-Chair's Welcoming Remarks

Jessica Seifert, Director, US Commercial Compliance, **AbbVie**

EXAMINE TRENDS IN INDUSTRY SPEAKER PROGRAMS POLICY SHIFTS AND PROSECUTOR INSIGHTS ON TOP PRIORITIES

8:45-9:15 AM

MODERATED Q&A SESSION

PhRMA Updates

Julie Ritchie Wagner, JD, Senior Assistant General Counsel, **PhRMA**

Moderator: Jessica Seifert, Director, US Commercial Compliance, **AbbVie**

9:15-10:15 AM

BENCHMARKING SESSION

Examine Industry Policy and Process Shifts in Response to PhRMA Code Changes and the Special Fraud Alert

- Understand how aligned industry is regarding key code changes including: alcohol prohibition, in-office meals, in-office meals if rep and speaker are virtual, "high-end" restaurants as venues, addressing a bona fide educational need, repeat speaker attendance and commercial input into the speaker nomination process
- Discuss how companies may be modifying business models to address PhRMA Code changes

Mike Saraceno, Corporate Compliance Lead, **Spark Therapeutics, Inc.**

Joseph Mack, Senior Assistant General Counsel, Compliance and Investigations, **Bayer U.S. LLC**

Jessica Seifert, Director, US Commercial Compliance, **AbbVie**

Kelly Pitt, Vice President, U.S. General Counsel, **MorphoSys U.S. Inc.**

10:15-10:45 AM

Networking Break

10:45-11:45 AM

ENFORCEMENT PANEL

Explore Prosecutor Perspectives on the High-Risk Activities of Speaker Programs

- Review what the DOJ views as top priorities and high-risk areas around promotional programs post the OIG Special Fraud Alert and PhRMA Code updates
- Discuss the impact of PhRMA Code changes in addressing OIG risks outlined in the Special Fraud Alert
- Examine recent investigations on Anti-Kickback and False Claims Act cases and the implications for monitoring promotional programs

Rachael Honig, Acting U.S. Attorney, **U.S. Attorney's Office for the District of New Jersey**

Charlene Fullmer, Assistant United States Attorney Deputy Chief, Affirmative Litigation, **U.S. Department of Justice**

Amanda P.M. Strachan, Deputy Chief, Criminal Division, **U.S. Attorney's Office for the District of Massachusetts**

ENSURE ALIGNMENT OF HOW POLICY CHANGE IMPACTS ACROSS FUNCTIONS

11:45 AM-12:30 PM

Deploy a Collaborative Approach to Drive Adoption of New Policies and Procedures

- Examine effective approaches/examples of how compliance, legal and commercial/marketing operations have successfully partnered to roll out new policies and processes to address PhRMA Code changes
- Ensure that all key functions understand their roles and how their roles are affected
- Consider strategies for effectively monitoring and auditing to ensure compliance
- Discuss best practices to communicate, educate and inform internal stakeholders of the PhRMA Code updates, OIG SFA assertions and case investigations and why it is critical to maintain alignment across all functions of the organization

Stacey Wodarski, Senior Manager, Professional Strategy, **Bausch Health**

Brenda Neal, Senior Director, Marketing Operations, **Urovant Sciences, Inc.**

Kara Ryan, Director, Compliance & Privacy, **Blueprint Medicines**

12:30-1:30 PM	Networking Luncheon
1:30-2:30 PM	WORKING SESSION
	<p>Compliance Spotlight: Analysis of PhRMA Code Updates and Industry Response</p> <p>In facilitated breakout sessions, participants will have the opportunity to review each of the PhRMA Code changes, discuss the interpretations of the code, consider industry response, explore potential ramifications for compliance and for speaker programs effectiveness moving forward.</p> <p>CO-FACILITATORS: <i>Audrey Caporaletti, Manager, U.S. Commercial Compliance and Ethics, Teva Pharmaceuticals</i> <i>Brian S. McCarthy, Director, Compliance Business Partner, TG Therapeutics</i> <i>David Amendola, Global Compliance Risk & Evaluation Management, ConvaTec</i> <i>Isabella Carini, Director, Strategic & Executional Excellence, Office of Ethics & Compliance Operations, AbbVie</i></p>
2:30-3:15 PM	<p>Reassess Speaker Bureau Strategy in a Shifting Enforcement Landscape</p> <ul style="list-style-type: none"> • Review of the speaker nomination process • Discuss appropriate speaker faculty sizing considerations • Examine current contracting and FMV practices/policies <p><i>Kelly Pitt, Vice President, U.S. General Counsel, MorphoSys U.S. Inc.</i> <i>Michael Varlotta, Senior Director, Marketing Operations, Janssen Biotech, Inc</i></p>
3:15-3:45 PM	Networking Break
3:45-4:30 PM	<p>Fraud Alert Fallout: Assessing Compliance Risk on Meals and Alcohol for In-Person and Virtual Programming under the PhRMA/AdvaMed Codes</p> <p>Hear perspectives from a compliance officer, external compliance counsel, investigations defense counsel and a recent government prosecutor as they talk candidly about past cases and real-life scenarios, in which HCP activities involving meals and/or alcohol may raise compliance and enforcement risks in in-person and virtual settings. Through their varying viewpoints and extensive industry experience, you will have an opportunity to better understand how these risks could expand beyond speaker programs and consider the broader implications for managing compliance risk across all HCP interactions. Key takeaways include:</p> <ul style="list-style-type: none"> • Understanding how DOJ and OIG are likely to view HCP interactions involving meals and/or alcohol in the wake of recent guidance • Guidance on compliance measures that companies might consider to address the changing risks • Benchmarking on approaches that companies have taken and are considering <p><i>Seth H. Lundy, Partner, King & Spalding</i></p>
4:30-5:15 PM	<p>Managing Compliance Risk in the Return to F2F Meetings</p> <ul style="list-style-type: none"> • Ensure that vendors are in alignment with your organization's response to code changes • Garner additional data capture from vendors to monitor greatest areas of risk around PhRMA Code changes • Update auditing and monitoring procedures to ensure compliance with revised guardrails • Examine contract considerations for how industry is managing COVID safety protocols <p><i>Ellen Friedman, Senior Analyst, Commercial Effectiveness/Fleet, Mallinckrodt Pharmaceuticals</i> <i>Brian P. Sharkey, Director, U.S. Compliance and Ethics, Teva Pharmaceuticals</i> <i>Laura Konwinski, JD, Senior Director, Global Compliance, BCD Meetings & Events</i></p>
5:15-5:20 PM	<p>Day One Closing Remarks</p> <p><i>Jessica Seifert, Director, U.S. Commercial Compliance, AbbVie</i></p>
5:20-6:20 PM	Networking Reception

Thursday, February 17, 2022

7:30-8:15 AM	BREAKFAST ROUNDTABLE DISCUSSION Examining DE&I in Speaker Bureau Management
7:30-8:15 AM	<i>Networking Breakfast</i>
8:15-8:30 AM	<i>Co-Chair's Opening Remarks</i> <i>Ellen Friedman, Senior Analyst, Commercial Effectiveness/Fleet, Mallinckrodt Pharmaceuticals</i>
GARNER CONSENSUS ON DEFINING HYBRID, MEASURING VIRTUAL PROGRAMMING IMPACT AND PREPARING SPEAKERS TO EXCEL IN MULTIPLE FORMATS	
8:30-9:30 AM	Evolve Standards, Definitions, and Execution of HCP Peer-to-Peer Engagement <ul style="list-style-type: none"> • Discuss criteria and industry standards around assessing the total number of F2F engagements with meals for launch and mature brands • Understand industry perspectives on how to determine the right mix and balance of F2F and virtual/hybrid speaker programs • Examine evolving approaches to and challenges to overcome related to extending in-person speaker programs • Case Study: An Orchestrated HCP Engagement Approach (Live, Hybrid/Virtual, Digital) <i>Tracy Doyle, Managing Partner, eNova</i> <i>David Verica, Director, Operations and Events Management, Sales Force Operations, AstraZeneca</i> <i>Michael Varlotta, Senior Director, Marketing Operations, Janssen Biotech, Inc</i> <i>Lisa M. Young, Associate Director, Commercial Event Planning and Operations, Blueprint Medicines</i> <i>Isabella Carini, Director, Strategic & Executional Excellence, Office of Ethics & Compliance Operations, AbbVie</i>
9:30-10:15 AM	Elevate Speaker and Audience Experiences in Virtual Speaker Programs <ul style="list-style-type: none"> • Understand speaker pain points in presenting to a virtual audience and how to remedy them • Integrate the latest technologies to enhance virtual interactions • Consider what to include in your virtual speaker programs toolkit to drive optimal engagement and collaboration • Examine best practices to garner attendee/speaker feedback and utilize these results to update how you execute virtual speaker programs <i>Tim Curry, SVP, Account Management, MedPoint Digital Inc.</i> <i>Susan Cholakian, Manager, Speaker Program Operations, Astellas Pharma, Inc.</i>
10:15-10:45 AM	<i>Networking Break</i>
10:45-11:30 AM	Assess the Staying Power of Virtual Meetings Post-Pandemic <ul style="list-style-type: none"> • Understand the true impact of virtual meetings • Review current measures/KPIs to determine impact • Consider specific criteria to determine what programs are best for a virtual format versus hybrid or F2F

11:30 AM-12:30 PM	CONCURRENT SESSIONS — PLEASE SELECT ONE	
	A. Speaker Programs Master Class During this working session, benchmark and brainstorm solutions to common challenges with your peers and industry leaders. Participants pre-submit discussion topics for the session and a summary of key learnings is distributed after the conference concludes. CO-FACILITATORS: <i>Tim Reasoner, Director, Faculty Administration and Third-Party Management Office, Lilly USA</i> <i>Michael Varlotta, Senior Director, Marketing Operations, Janssen Biotech, Inc</i>	B. Speaker Programs 101 <ul style="list-style-type: none"> • Review the critical steps in operationalizing and executing effective speaker programs • Examine key steps in effective speaker recruitment • Explore best practices for speaker training CO-FACILITATORS: <i>Brenda Neal, Senior Director, Marketing Operations, Urovant Sciences, Inc.</i> <i>Ellen Friedman, Senior Analyst, Commercial Effectiveness/Fleet, Mallinckrodt Pharmaceuticals</i> <i>Diane Evans, Marketing Manager, Dermatology, AbbVie</i>
12:30-1:30 PM	Networking Luncheon	
1:30-2:15 PM	NextGen Virtual Meetings: Innovating to Drive Engagement and Value Creation	
2:15-3:00 PM	Re-Engineering Speaker Training for Varied Meeting Formats <ul style="list-style-type: none"> • Review speaker concerns in meeting audience needs for virtual and hybrid meetings and understand what they see as top training needs • Explore speaker training best practices to better prepare HCPs for different program formats • Evolve speaker training to manage last minute shifts from in-person to virtual 	
3:00 PM	Co-Chair's Closing Remarks <i>Ellen Friedman, Senior Analyst, Commercial Effectiveness/Fleet, Mallinckrodt Pharmaceuticals</i>	

“I always find the Speaker Program conference to be an extremely valuable time to connect with my peers, understand industry-wide challenges, witness the evolution of operational approaches and solutions, and recognize opportunities to utilize new technology in a hybrid environment moving forward.”

BACK BY POPULAR DEMAND!

CONTINUE THE CONVERSATION WITH WEEKLY “TUESDAY TALKS!”

The conference portal will be open for you to view on-demand content, as well as sessions that aired live. In addition, join us for weekly “Tuesday Talks.” Each Tuesday at Noon (EST), you can participate in a live session on critical topics related to speaker programs management as the current landscape continues to evolve.

**Mark Your
Calendars
in Advance**

Tuesday, February 22, 2022

Evolving Peer-to-Peer Programs to On-Demand Speaker Programs

- Discuss potential parameters for recording speaker programs and making them available to HCPs on-demand versus offering them live and virtually
- Consider the impact of having speaker programs memorialized
- Explore the fee structure for HCPs recording sessions for on-demand viewing versus live/virtual presentations — One-time payment versus a residual payment every time a video is viewed
- Examine compliance implications for on-demand programming options versus live speaker programs with meals

Tracy Doyle, Managing Partner, eNova

Tuesday, March 1, 2022

Best Practices in Operational Excellence for Hybrid Speaker Programs



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WHO SHOULD ATTEND

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Informa AllSecure


This event is produced to the Informa AllSecure Standard

Ten Priority Commitments at all Informa Events

Post COVID-19, all Informa events will be run in accordance with the AllSecure standard, applying the full range of recommendations wherever applicable and possible, but with a commitment to ten key priorities:

Cleaning and Hygiene


- 1**  **ENHANCED CLEANING:** All events will undertake enhanced, deep cleaning before, during and after our events, working with venue partners to ensure the highest standards of hygiene and cleanliness. This includes continuous sanitisation throughout the course of an event, with a focus on high-touch areas such as door handles, restrooms and food and beverage areas.


- 2**  **PERSONAL HYGIENE:** All events will provide additional hand washing facilities and hand sanitising stations throughout the event space, encouraging all participants to regularly wash and disinfect their hands.

Physical Distancing


- 3**  **NON-CONTACT REGISTRATION:** All events will employ a system that facilitates non-contact registration for participants, including the availability of online registration.


- 4**  **PHYSICAL CONTACT:** All events will request that participants avoid physical contact, such as hand shakes and embraces, promoting alternative ways to greet business partners. The exchange of printed materials, such as business cards and sales brochures, will also be discouraged, with digital alternatives recommended.


- 5**  **PHYSICAL DISTANCING:** All events will maintain a density of participants in line with local authority guidance. In the absence of local guidance, a minimum of 1-1.5 meters (or 3-4.5 feet) is recommended. This will be managed through one or more control measures such as pre-show communications to participants, a one-way traffic system around show floors, staggered entry times, on-site signage and floor markings and on-site social distance ambassadors.

- 6**  **FOOD AND BEVERAGE STATIONS:** All event teams will work closely with venue partners to employ the highest standard of food safety, minimising self-service buffets in favour of pre-packaged food options. If any queuing is anticipated, social distancing will be maintained through the use of floor markings and relevant signage.

Detect and Protect

- 7**  **PERSONAL PROTECTIVE EQUIPMENT (PPE):** Participants at all events will be asked to wear a face mask on entry. Further items of PPE, such as gloves and eye screens, will be used by participants and staff if appropriate, in line with local government and health authority advice.

- 8**  **FIRST AID:** All events will have access to a qualified first aider and a separate quarantine area if possible. Participants will be asked not to attend if they are feeling unwell, and teams will follow local health authority guidance on detecting and managing anyone who displays symptoms of COVID-19.

- 9**  **SCREENING:** All events will follow relevant health authority guidance on screening participants. This may include checking the temperatures of everyone on entry, through thermal scanning or other screening processes.

- 10**  **TRACE AND CONTACT:** Should it be necessary, we will work with local authorities to trace and contact participants at our events, subject to local privacy regulations.

REGISTRATION

REGISTRATION FEE		REGISTER BY 12/10/2021	STANDARD RATE
Life Sciences Companies	All Access Pass (In-Person + Virtual)	\$2299	\$2599
	Virtual-Only	\$1899	\$2199
Solution Providers/Consultants/Law Firms	All Access Pass (In-Person + Virtual)	\$2799	\$3099
	Virtual-Only	\$2399	\$2699

4 WAYS TO REGISTER NOW!



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PHONE

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LIVE CHAT

informaconnect.com/speaker-programs



EMAIL

juliet.nelson@informa.com

YOUR KEY POINTS OF CONTACT:



Content Development:

Tracey Kimball
tracey.kimball@informa.com
 781-606-2984



Sponsorship & Exhibits:

John Egan
john.egan@informa.com
 908-310-7683



Registration & Teams:

Juliet Nelson
juliet.nelson@informa.com
 339-298-2140

VENUE INFORMATION

Philadelphia, PA – Hotel Venue TBA

ACCOMMODATIONS

For hotel room availability and direct booking links, please visit the conference website and select the **Pricing & Venue** tab. Rooms are limited and the discounted rate will expire in advance of the meeting, so please book early. All travel arrangements are subject to availability.

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