

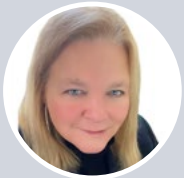
# 3<sup>RD</sup> TRANSPARENCY AND AGGREGATE SPEND

## SUMMIT

Collect, Analyze and Report HCP Spend Data Compliantly and Efficiently

June 3-4, 2024 | The Inn At Penn | Philadelphia, PA

### Benefit from The Collective Intelligence of Notable Speakers



**Co-Chair**

Kelly Tope  
Head of Compliance Monitoring and Reporting Operations  
**Takeda**



**Co-Chair**

Shane White  
Director HCP Engagement & Compliance  
**RLDatix Life Sciences**



Eileen Allen  
Senior Compliance Manager  
**Adaptive Biotechnologies**



Isha Arora  
Founder & CEO  
**INGEN**



Brian A. Bohnenkamp  
Partner, FDA & Life Sciences Practice  
**King & Spalding LLP**



Peter Christopoulos  
Global Senior Director, Transparency Reporting  
**Johnson & Johnson**



Nicole Colapietro  
Manager, HCP Engagement & Transparency Reporting  
**Arthrex, Inc.**



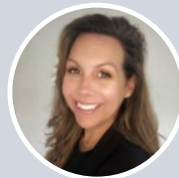
Jennifer Cosgrove  
Associate Director, Ethics and Compliance  
**Thea Pharma**



Lynn Cox  
Senior Manager, Global Transparency Reporting  
**Johnson & Johnson**



Paul-Henry Deveze  
Partner  
**Product Law Firm - Life Sciences & Healthcare**



Gina Dubois,  
Associate Director, Compliance,  
**Kiniksa Pharmaceuticals**



Bill Friedrich  
Associate Director, Compliance  
**Hikma**



Rawan Fusisi  
I&C Global Transparency Head  
**Indivior**



Patricia McKernan  
Senior Compliance Manager, Global Transparency  
**Stryker**



Lauren Miretsky  
Director, Global Spend Transparency  
**Vertex Pharmaceuticals**



Eric Saharig  
Senior Associate Director, Ethics & Compliance  
**Boehringer Ingelheim**



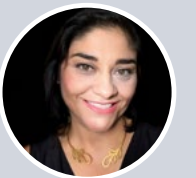
Ian Benjamin  
Schruben Compliance Auditor  
**Roche Diagnostics**



Bhupinder Singh  
Associate Director, Compliance  
**Karl Storz Endoscopy**



Inge Tham  
Senior Manager, HCP Reporting  
**Edwards Lifesciences**



Maria Villaneuva  
VP, Compliance  
**Radmed**

## WHY ATTEND

Recent changes in Open Payments, Global and State reporting requirements have added new layers of complexity for those managing transparency programs. CMS Open Payments audits, state requests for more detailed reporting and new regulations and guidelines in Italy and other regions around the world require an even more effective and efficient process for managing ethics, compliance and reporting.

To help you and your team keep up with the ever-evolving landscape, the 3rd Transparency and Aggregate Spend Summit gathers the perspectives of industry leaders who put the most challenging issues at the center of the conversation. Through collaborative learning and discussions that enhance your way of thinking and problem solving, you will gain a sharper focus on how others are navigating the waters and return to work with a network of next-level connections.

## WHO ATTENDS

Biopharmaceutical and medical device professionals working in:

- Transparency
- Compliance
- Global Transparency
- Global Compliance
- Aggregate Spend
- HCP Engagement
- Open Payments
- Data Analytics
- Compliance Monitoring and Auditing
- Ethics
- Legal
- General Counsel
- Systems/IT
- Finance
- Reporting
- Accounting
- Government
- Privacy

## Click Here to Register

Strengthen your transparency program and improve frameworks, processes and systems for collecting, analyzing and reporting HCP spend data compliantly and efficiently.

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## REACH KEY DECISION MAKERS

Are you an industry leader or looking to become one? Find out how to gain unparalleled exposure to top prospects in the biopharma/device industry.



Contact Joel Nunez at  
561-221-0752 or  
jnunez@dgeconfs.com

# DAY ONE

## MONDAY, JUNE 3, 2024

7:30 *Registration & Breakfast*

8:30 *Co-Chairperson's Opening Remarks*

*Kelly Tope, Head of Compliance Monitoring and Reporting Operations, TAKEDA*

8:45 **PANEL Prepare for and Survive the CMS Audit**

What can be gained from understanding the details around audits? This is an opportunity to discuss what CMS might leverage with regard to the range of audit findings and how to best prepare.

- Prepare for the audit by improving documentation and process management
- Ensure you have everything needed when requested
- Work with outside and inside counsel to potentially refine the scope of a request when appropriate

**PANELISTS:**

*Brian A. Bohnenkamp, Partner, FDA & Life Sciences Practice, KING & SPALDING LLP*

*Nicole Colapietro, Manager, HCP Engagement & Transparency Reporting, ARTHREX, INC.*

9:30 **PANEL Discover Ways to Improve Documentation of Decisions and Reasoning**

Documenting decisions regarding transfers of value and supportive reasoning is even more critical in an era of CMS Audits. Benefit from discussion on ways to improve documentation especially for changes in submission to Open Payments.

- Hear different approaches to assumptions documents
- Gain tips for writing annual year end summaries that serve as an internal highlight reel
- Record contextualization of clinical research information for teaching hospitals

**PANELISTS:**

*Kelly Tope, Head of Compliance Monitoring and Reporting Operations, TAKEDA*

*Bhupinder Singh, Associate Director Compliance, KARL STORZ ENDOSCOPY*

10:15 *Networking Break*

10:45 **PANEL Review Methods for Effective Reporting to Open Payments**

Contextualizing clinical research payments, improving provider data matching and ensuring accurate capture of HCP payments in the virtual environment are just a few of the ongoing challenges with Open Payment submissions. Gain tips to strengthen and improve the accuracy and efficiency of your Open Payments compliance reporting program.

- Capture lessons learned from reporting on NPS and Pas and solve potential roadblocks with data matching
- Respond to inquiries about the data which may require revisions and resubmissions
- Identify techniques to capture complete and accurate HCP payment data in the virtual environment

- Improve detail and contextualization around clinical research data capture

**PANELISTS:**

*Rawan Fusisi, I&C Global Transparency Head, INDIVIOR*

*Peter Christopolous, Global Senior Director Transparency Reporting, JOHNSON & JOHNSON*

*Eileen Allen, Senior Compliance Manager, ADAPTIVE BIOTECHNOLOGIES*

11:30 **Enhance Knowledge of State Transparency Reporting Requirements**

The uptick in state transparency reporting requirements like those in Connecticut has added a new layer of challenges. Hear an update on increasingly complex state reporting requirements and strategies for compliance.

- Envision how to respond to more complex data requirements
- Overcome the challenge of managing compliance with standards that are not uniform state to state
- Determine responsibilities across government affairs, commercial ops and transparency teams since there are elements of HCP payment, samples, sales call volume and length of calls

*Brian A. Bohnenkamp, Partner, FDA & Life Sciences Practice, KING & SPALDING LLP*

12:15 *Networking Luncheon*

1:30 **Operationalize Sub Certification and Know Your Data**

While seemingly rudimentary, creating a tree illustrating exactly who has responsibility for education items, rep meals, REMS programs, clinical trials and contracts with doctors on particular products and categories is fundamental to the success of your transparency program. Benefit from examples of how peers are successfully managing sub certification.

- Identify which business units are working with which vendors/customers/third parties
- Educate the organization on how transfers of value may tie into pre-approved categories
- Get certification from internal business units so your business partners can help resolve customer disputes

*Bill Friedrich, Associate Director Compliance, HIKMA*

2:15 **PANEL Examine Trends in Dispute Resolution**

It's always important to consider how disputes are currently trending across industry. Here is an excellent opportunity to deliberate examples of both commonplace as well as unique disputes and approaches to resolving them.

- Discuss difficulties with disputes related to debt forgiveness
- Review commercial agreements and work with teams to provide context
- Activate pre-notification for customers who dispute everything
- Assess situations where you need to change data after a dispute and CMS questions the change

**PANELISTS:**

*Bhupinder Singh, Associate Director Compliance,*

*KARL STORZ ENDOSCOPY*

3:00 *Networking and Refreshment Break*

3:30 **INTERACTIVE DISCUSSION GROUPS**  
 Optimize peer-to-peer learning by crowdsourcing solutions to common challenges surrounding Open Payments reporting. The connections you make will become a valuable takeaway.

GROUP 1  
**Overcome Challenges with Global Transparency Reporting**

GROUP 2  
**Best Practices for Medical Device Transparency Reporting**

CO-FACILITATORS:  
*Patricia McKernan, Senior Compliance Manager Global Transparency, STRYKER*  
*Inge Tham, Senior Manager HCP Reporting, EDWARDS LIFESCIENCES*

GROUP 3  
**Collecting HCP Identifying Information to Improve Acceptance Rates on Submissions**

FACILITATOR: *Lynn Cox, Senior Manager, Global Transparency Reporting, JOHNSON & JOHNSON*

4:15 **PANEL Ensure Compliance for Speaker Program Reporting**  
 Getting accurate reports and reconciling attendees with outsourced coordinators of speaker programs is only one of the many challenges for ensuring reporting compliance. Gain tips for compliant reporting and risk management.

- Document data gathering practices and get comfortable with the level of accuracy
- Flagging outliers and auditing for repeat attendees
- Managing risk in virtual programs

PANELISTS:  
*Maria Villaneuva, VP Compliance, RADMED*  
*Jennifer Cosgrove, Associate Director Ethics and Compliance, THEA PHARMA*

5:00 Day One Concludes

## DAY TWO TUESDAY, JUNE 4, 2024

8:00 *Networking Breakfast*

8:30 *Co-Chairperson's Remarks and Review Of Day One*  
*Shane White, Director HCP Engagement & Compliance, RLDATIX LIFE SCIENCES*

8:45 **Transform Your HCP and Transparency Processes and Systems to Enhance Performance & Anticipate Emerging Risks**  
*Shane White, Director HCP Engagement & Compliance, RLDATIX LIFE SCIENCES*

9:30 **PANEL Navigate the Global Transparency Reporting Arena**  
 Staying on top of evolving and varying country, regional and local requirements and codes is time consuming and complex. Learn more about best practices for ensuring data accuracy, overcoming challenges with global reporting systems and managing cross border spend.

- Understand the specifics of Italian Sunshine Law – what exactly is required to capture?
- Benchmark how peers are adapting to data collection to comply with Italian Sunshine
- Manage cross border spend accurately
- Benchmark how data can be reconciled globally and connect with regional teams

PANELISTS:  
*Lauren Miretsky, Director, Global Spend Transparency, VERTEX PHARMACEUTICALS*  
*Paul-Henry Deveze, Partner, PRODUCT LAW FIRM – LIFE SCIENCES & HEALTHCARE*  
*Gina Dubois, Associate Director Compliance, KINIKSA PHARMACEUTICALS*

10:15 *Break*

10:45 **Uncover Valuable Transparency Data Analytics and Risk Management**  
 Do you have questions about which analytics are most helpful for risk identification? This session is an opportunity to ensure your baseline analytics are helpful to the business and ways you can create meaningful and valuable dashboards for sharing with Chief Compliance Officers.

- Assess the need for and implementation of predictive metrics
- Pinpoint HCP engagement risks and avoid potential enforcement actions
- Use analytics to target auditing and monitoring activities
- Use analytics to target auditing and monitoring activities and translate data into informed business decisions

*Isha Arora, Founder & CEO, INGEN*

11:30 **Peer-to-Peer Benchmarking Session Via Live Polling + Discussion**

This session provides an opportunity to see and discuss industry trends first hand. Session facilitators have developed topical questions which pinpoint the issues most important for managing a successful transparency program. Based on the anonymous polling results, session facilitators help to identify trends, takeaways and best practices surrounding some of the most critical issues involved in compliant transparency reporting.

FACILITATOR:  
*Kelly Tope, Head of Compliance Monitoring and Reporting Operations, TAKEDA*

12:15 *Networking Luncheon*

1:30 **PANEL Optimize Compliance Monitoring Practices**

Your team must be up to date on the latest techniques for strengthening internal policies and processes for transaction monitoring and auditing activities is crucial to the success of your transparency program. Collect innovative practices to compliance monitoring including social media and field team monitoring.

- Use transparency data to inform and target compliance monitoring initiatives
- Improve frameworks for internal audits, existing reporting policies and data capture methods
- Examine recent enforcement efforts and investigations by OIG using transparency data

**PANELISTS:**

*Ian Benjamin Schruben, Compliance Auditor, ROCHE DIAGNOSTICS*

*Gina Dubois, Associate Director Compliance, KINIKSA PHARMACEUTICALS*

*Eric Saharig, Senior Associate Director, Ethics & Compliance, BOEHRINGER INGELHEIM*

2:15 **Examine Third Party Risk Management**

Take a deep dive into identifying and managing risk in third party data. Determine ways to make contracts airtight.

- Consider clauses in third party contracts which include availability of details from 3-4 years ago
- Examine risk related to asset and inventory management
- Understand the major risks while working with third parties and how to manage them

3:00 *Close of Conference*

**The 3<sup>rd</sup> Transparency and Aggregate Spend Summit is co-located with Artificial Intelligence in Life Sciences Compliance.**

This groundbreaking event discusses challenges and opportunities involved in safeguarding organizations and managing risks in the evolving era of AI.

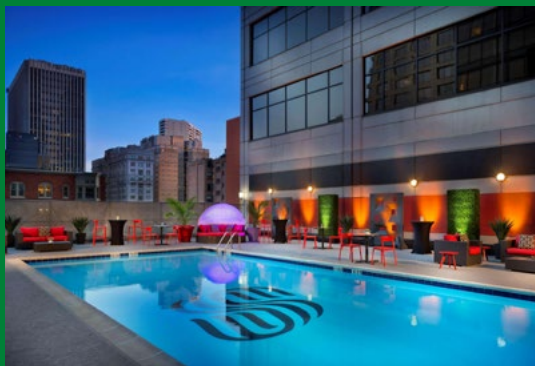


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# 3<sup>RD</sup> TRANSPARENCY AND AGGREGATE SPEND SUMMIT

June 3-4, 2024 | The Inn At Penn | Philadelphia, PA



**The Inn at Penn, a Hilton Hotel,**  
 Philadelphia 3600 Sansom Street Philadelphia, PA 19104  
 (215) 222-0200 |

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