Track III: Transparency and Third Party Compliance Requirements

Pharmaceutical Regulatory and Compliance Congress

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Your Co-Chairs

Eve Costopoulos
Vice President, Global Compliance, Schering-Plough Corporation

Kris Curry
Senior Director, Health Care Compliance Operations, Johnson & Johnson Pharmaceutical Research & Development

Greg Levine, Esq.
Partner, Ropes & Gray

Paul Silver
Managing Director, Practice Leader, Life Sciences Advisory Services, Huron Consulting Group

Day 1 Recap

Sunshine Act: Latest Developments and Industry Impact

- Legislative overview: House and Senate differences
- Preemption will set a floor not a ceiling
- Is there such a thing as a “de minimis” gift?
  - Pfizer CIA sets a $0 threshold
- Pfizer transparency initiative covering clinical trials (including investigator-initiated)
- Pfizer thinking on potential ramifications

Disclosure of Clinical Trial Results: Obligations and Best Practices

- Federal (FDAAA) and Maine law requirements
- International clinical trial registries proliferating, with inconsistent requirements
- Booz Allen report inconsistent with criticism of industry non-compliance with postmarket commitments
- Debate over lay summaries of clinical trials

Disclosure of Third-Party Data: Compliance and Beyond

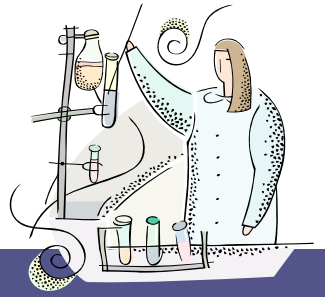
- Update on state laws limiting disclosure of prescriber information
- New need for data skills in Compliance
- Importance of due diligence on acquisition targets to identify data challenges
- Key decisions on website functionality (e.g., search, download) drive data format
- Third party data disclosure checklist

Third Party Data: How to Collect and Use It Effectively

- Building solutions to collect, analyze, and report third party data
- Importance of data governance and utility of third-party certifications
- Models for analyzing data to identify risks
- Increased functionality as more data are gathered
- Ability to use commercially available software

Our Sessions For Today

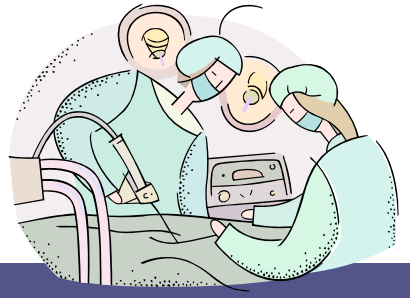
1:10 Session



Developing a Global Approach for Third-Party Due Diligence

- William R. Baker, III, Esq., Latham & Watkins LLP; Former Associate Director, Division of Enforcement, Securities and Exchange Commission
- Colleen A. Conry, Esq., Partner, Ropes & Gray LLP, Former Federal Prosecutor, Fraud Section, Criminal Division, Department of Justice

2:00 Session



Aggregate Spend & State Reporting: Do You Know Where Your Third Parties Are?

- Michael D. Bell, Esq., R-Squared Services and Solutions LLC
- Marci Juneau, Huron Consulting Group
- Eric Siegel, Chief Compliance Officer, EMD Serono, Inc.

2:45 Session

Harmonization of FMV Policies and Procedures Internally and with Your Third Party Vendors

- Jeffrey J. Brady, President, Advanced Health Media LLC
- Brian A. Dahl, Esq., Director of Compliance, Teva North America
- Meghan Davis, Manager, Life Sciences Advisory Services, Huron Consulting Group
- Paul J. Silver, Huron Consulting Group (Moderator)