



# Mini-Summit II: Advanced Issues in Monitoring

15<sup>TH</sup> PHARMACEUTICAL COMPLIANCE CONGRESS AND  
BEST PRACTICES FORUM

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# Evolution of monitoring

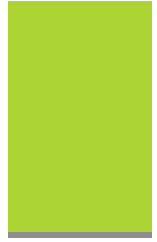
Focus has changed from

- ▶ Promotional to all interactions with healthcare professionals
  - ▶ 2009 - First CIA with speaker program and field force monitoring
  - ▶ 2014 - Research and publication activity monitoring common CIA requirement
  - ▶ Reintroduction of medical education grant oversight through monitoring
- ▶ US-centric to global
  - ▶ Increased anti-bribery/anti-corruption (ABAC) enforcement
  - ▶ Global transparency laws give direct access to potential ABAC violations
- ▶ Paper-based to big data analytics
  - ▶ Greater availability of data allows real time, total population monitoring
  - ▶ Better opportunities for standardizing monitoring across countries

# Agenda

- ▶ Advanced techniques to communicate monitoring results
- ▶ Using data to identify positive and negative trends to inform risk
- ▶ Driving ownership and accountability of monitoring outcomes
- ▶ Coordination of auditing and monitoring teams
- ▶ Risk based monitoring

Advanced  
techniques to  
communicate  
monitoring results





*Audience Poll:*

How evolved is your global compliance monitoring program?

1. N/A - No global presence
2. Local compliance personnel develop and implement monitoring plan
3. Standardized global compliance monitoring program has been developed
4. Standardized global compliance monitoring program has been implemented
5. Standardized global compliance monitoring program has been successfully communicated to and adopted by local compliance departments in other countries

## Communicating Results

- ▶ Effective communication is critical for mediating identified risks
  - ▶ Director and employees at every level need to understand the risk, be aware of gaps, and be accountable for process improvement
- ▶ Communication strategy must be tailored to specific audiences
  - ▶ Board of Directors
  - ▶ Department heads
  - ▶ Managers and supervisors
  - ▶ Field-based employees



*Advanced techniques to communicate monitoring results:*  
Panel Questions

1. Please share with us some techniques you use for communicating monitoring results to the organization.
2. Who are you communicating to? Are there different techniques and messages for different audiences? (e.g. commercial operations, sales/marketing, Audit Committee, etc.)
3. How does compliance demonstrate that they are a partner, not an impediment, to business. (i.e. How do you communicate the value proposition of monitoring?)
4. How have communication strategies changed over the years?
5. How has the reception from the business changed over the years?
6. How do you think communication with stakeholders will change/evolve in the future?

Using data to  
identify positive  
and negative  
trends to inform risk







*Audience Poll:*

Are you using physician payment data in your compliance monitoring efforts?

1. No. We are manually capturing data for state and federal reporting, but do not further analyze it.
2. Yes. We monitor distinct data sources for compliance with specific policies, such as meal cost limits or cumulative annual spend per HCP
3. Yes. We monitor aggregate data to identify overall risk level by country, region, or territory.

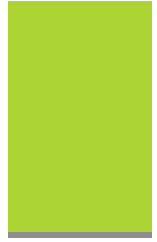
## Data analytics and dashboarding

- ▶ As companies prepare for greater external reporting, they must start thinking now how to use global data (e.g. compliance monitoring)
- ▶ The difficult part is linking data from different global systems to enable aggregate analysis in real time
  - ▶ As an example, Open Payments data is useful for compliance audits but lag time makes it less useful for ongoing monitoring

*Using data to identify positive and negative trends to inform risk*  
Panel Questions

- ▶ What datasets are you using for monitoring and where does that data come from (e.g. Business Meals to Consulting Fees to inclusion on non-financial data)?
- ▶ What kinds of data analytics are you doing?
- ▶ What are some ways we can utilize trending to inform future business decisions?
- ▶ Do you utilize dashboarding/visualization tools to present analyses?
  - ▶ How is it helpful?

Driving ownership  
and accountability  
of monitoring  
outcomes





*Audience Poll:*

How is compliance monitoring perceived by business partners in your organization and affiliates?

1. A necessary evil with little real value
2. An important activity for detecting and preventing issues
3. Something in between

## Driving ownership and accountability of monitoring outcomes

- ▶ Ownership of compliance by department heads
- ▶ Manager responsibility for demonstrating and reinforcing compliant behavior
- ▶ Use of embedded compliance champions
- ▶ Tying compliance goals to performance and compensation



*Driving ownership and accountability of monitoring outcomes*

Panel Questions

- ▶ What are some of the ways to hold individuals accountable for monitoring outcomes?
- ▶ What is the remediation and corrective action plan associated with noncompliant outcomes?
- ▶ There is typically a subset of monitoring data where you are expecting certain results and then you also have a subset of outliers that you analyze to see what's going on. But what if things start shifting in the expected set of data? What does that tell you about your organization?

Coordination of  
auditing and  
monitoring teams





*Audience poll:*

To what extent does Internal Audit incorporate compliance measures in their reviews?

1. None. Compliance is responsible for all compliance monitoring
2. Mix. For example, IA conducts specific testing measure for transactional monitoring while Compliance conducts live monitoring
3. All. We use IA monitors to complete all compliance monitoring

# Coordination of Auditing and Monitoring Teams

- ▶ Auditing is a retrospective look at what occurred during a review period for specific activities conducted by the organization
  - ▶ Typically includes:
    - ▶ Policies and Procedure review
    - ▶ Process assessments (i.e. Systems Review)
    - ▶ Transaction Testing (i.e. document based review)
    - ▶ Corrective Action Plans
  - ▶ Typically answers the question: What occurred?
- ▶ Monitoring is a “real time” assessment of programs being conducted by the organization
  - ▶ Typically includes:
    - ▶ Live monitoring of speaker programs, conferences/exhibits, medical education programs, advisory boards and conducting field ride alongs
  - ▶ Typically answers the question: Why did this occur? (i.e. provides context of what occurred)



## *Coordination of Auditing and Monitoring Teams* Panel Questions

- ▶ What are your definitions of auditing vs. monitoring?
  - ▶ Is there a difference?
  - ▶ What are the key differences/pros and cons of each?
- ▶ How do you combine the outcomes of your monitoring activities and your auditing activities?
  - ▶ What insights can each provide to the overall compliance environment?
- ▶ How are both efforts taken into consideration when developing your annual compliance plan?
- ▶ How do Product Risk Assessments (e.g. Pfizer's RAMP, GSK's TRACER, BTG BPREP) inform customized auditing and monitoring plans?

Risk based  
monitoring





*Audience poll:*

How often do you conduct an enterprise wide compliance risk assessment?

- ▶ Never
- ▶ Every two to three years
- ▶ Annually
- ▶ More than once per year

## The benefit of risk-based monitoring

- ▶ High level view of overall compliance risk
- ▶ Effective prioritization of monitoring activity
- ▶ Resources management

*Risk based monitoring*  
Panel Questions

- ▶ What are some of the inputs for a risk based monitoring approach?
- ▶ What are some techniques for rolling out this approach?