



The Seventh Annual —
Pharmaceutical Regulatory and Compliance Congress
— *and Best Practices Forum*

Live Monitoring of Speaker Programs: Ways to Accomplish More During The Process

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Objectives

Discuss the following topics:

- ☐ What is speaker program monitoring?
- ☐ Speaker program monitoring trends
- ☐ How to maximize value
- ☐ Establishing a live monitoring program
 - Assessing compliance
 - Evaluating program value
- ☐ Compliance and Commercial relationship



What is Speaker Program Monitoring?

MONITOR: to watch, keep track of, or check, usually for a special purpose

- Ongoing real-time assessment of promotional speaker programs
 - Delivering the appropriate message
 - Compliance with company policy, industry standards, regulatory guidance, and applicable laws



Why Monitor Speaker Programs?

Increased Focus on Speaker Program Monitoring

➤ Regulatory Trend

- Recent Corporate Integrity Agreements (CIAs) include live monitoring requirements

➤ Industry Trend

- Identify risk proactively
- Implement real-time corrective actions



Why Monitor Speaker Programs?

Recent CIAs

- Six CIAs with speaker program monitoring requirements since August 2009

Pharmaceutical Manufacturer	CIA Effective Date	Number of Monitored Ride-Alongs Required	Number of Monitored Speaker Programs Required
Pfizer	8/31/2009	60	200
Astra-Zeneca	4/27/2010	75	250
Ortho-McNeil-Janssen	4/28/2010	30	40
Allergan	9/1/2010	30	75
Forest	9/15/2010	40	175
Novartis	9/29/2010	50	125

- ☒ Define monitoring
- ☒ Discuss trends
- ☐ Maximize value
- ☐ Establish a program
- ☐ Relationship with Commercial

Maximizing the Opportunity

Looking beyond Compliance

- Assess the value add of Speaker Programs
 - Speaker Effectiveness
 - Audience Reach
 - Program Costs
- Evaluate the third-party vendor
 - Program Management
 - Contract Compliance
- Connect with field staff
 - Raise awareness of compliance
 - Understand field staff perspective



Establishing a Live Monitoring Program

Considerations for establishing a live monitoring program

➤ First Steps

- Determine who will monitor the speaker programs
 - Compliance department, Internal Audit department, outside consultants, operations, or some combination of all
- Determine how many speaker programs to monitor
 - Design a sampling plan based upon scheduled speaker program events and current areas requiring special attention
- Determine source of project funding
 - Involve Commercial to create dialogue and synergy



Establishing a Live Monitoring Program

Forestalling operational challenges

- Enlist commercial side of the business
 - Get perspective on program effectiveness
 - Input on how to best communicate with field staff
- Anticipate administrative burden
 - Scheduling monitors
 - Contacting Sales Representatives
 - Ensuring all monitors have the appropriate documents and logistic details
 - Booking travel
 - Last minute changes and cancellations



Monitoring Compliance

Areas to consider before and during the event

- Pre-event review
 - Speaker training
 - Contracting
 - Enforcement of speaker caps
- Event review
 - Appropriateness of venue
 - Meals were in accordance with company policy
 - Approved materials were used
 - Off-label questions were handled appropriately
 - Necessary documents were distributed and collected



Monitoring Compliance

Areas to consider after the event

➤ Post-event review

- Expense reporting
 - Attendance is accurately reported
 - Program expenses are accurately reported
- Speaker honoraria and expenses
 - Fair Market Value compensation
 - Expenses are in line with company policies (i.e., no spouses, first class travel, extra hotel nights)
- Event cancellations



Assessing Program Value

Do programs fulfill a business need?

- Content - Relevant, current, accurate, interesting
- Speakers - Effective, engaging, and generally positive representations of the company
- Attendance
 - Relevance of audience
 - Number of attendees
- Venues
 - Conducive to presentations
 - Appropriately priced



Assessing Program Value

Assess Third Party Vendor effectiveness

- Identify gaps in communication, expectations, or documentation
 - Ensure the appropriate information was collected and provided to the company for state tracking and compliance, speaker effectiveness evaluation and documentation, and compliance issues resolution
- Observe how the company is represented
- Are you getting what your contract says?



Compliance and Commercial Relationship

Maintaining and Improving Existing Alliances

- Demonstrate Compliance's dedication to business objectives
 - Sales and Marketing management provide input on interacting with sales representatives before and during monitored events
 - Understand key company business objectives
 - Tie key objectives into the monitoring process
- Help to ensure sales force does not feel undue pressure
 - Communicate with sales managers prior to project start explaining program objectives and "what to expect"
 - Include Sales and Marketing management in planning stages
 - Explain what will be evaluated
 - Identify and address concerns



Compliance and Commercial Relationship

Maintaining and Improving Existing Alliances

- Foster open communication with sales force to create an education opportunity for all
 - Frame live speaker program monitoring as an industry reality
 - Understand what their frustrations are and take suggestions on ways to improve
- Use the personal interactions with the sales force as an opportunity to connect



Summary

Getting the most out of live speaker monitoring at your company

- Anticipate challenges - Plan for logistical complications
- Evaluate compliance - Consider pre-, during, and post-event
- Assess program value - Engage the commercial side of the business
- Connect with field representatives - Build trust and gain insight
- Develop and put plan in place - Begin planning now



Questions

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