

# 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





# **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?

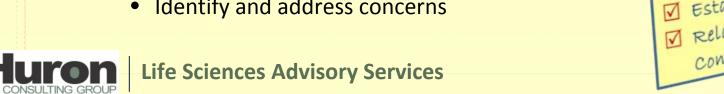




# **Compliance and Commercial Relationship**

## **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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