

# Effective Field Monitoring: Essentials to Consider When Building a Successful Field Monitoring Program

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# NOTICE

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# Effective Field Monitoring Essentials: Agenda

- Overview
- Approach
- Types of monitoring typically done
- Interpersonal Dynamics
- Final Considerations

# Effective Field Monitoring Essentials - Overview

## Auditing vs. Monitoring – The Terms are not Synonymous

### Auditing

- Retrospective
- Formal, Systematic
- Measuring adherence to process, efficacy of controls against standard (Policy, SOP)
- Statistically relevant sampling up to 100%

### Monitoring

- Real Time
- Observational, risk-based, less structured
- Evaluating individual behaviors against standard (P&P training)
- Usually not statistically relevant

# Effective Field Monitoring Essentials - Overview

## Inspector or Partner – Define your Purpose

### Inspection

- Measures adherence to policy
- Checklist of rules
  - Followed? Yes or no.
- Emphasis on punitive response to infractions
- Maintain separation and strict objectivity
- Builds a culture of obedience

### Partnership

- Measures adherence to policy but also
  - Identifies gaps in awareness, knowledge, understanding and application of policy
  - Evaluates applicability of guidance to real situations
- Emphasis on root cause of infractions
- Establishes open lines of communication
- Builds a culture of Compliance

CIA's may require that you be more of an inspector than partner

# Effective Field Monitoring Essentials - Approach

- Determine Scope and Resources Available
  - How broad is your plan: Annual or multi-year?
  - How many Products, People and Processes will you need to monitor?
  - How many compliance resources are available?
    - Internal (qualified field monitors on staff) vs. External (contracted)
      - Pro's and Con's of each

# Effective Field Monitoring Essentials - Approach

- Proportional vs. Risk-based Plan
  - Proportional: % of total monitoring opportunities
    - Benefits: Higher chance of catching unexpected issues
    - Challenges: Higher resource requirements to get meaningful data
  - Risk-based: Identifying and targeting monitoring on higher risk areas
    - Benefits: Concentrates limited resources in a strategic manner
    - Challenges: May leave gaps and miss unanticipated issues
  - Hybrid:
    - Can you have the best of both worlds?

# Effective Field Monitoring Essentials - Approach

- Evaluating Areas of Risk: Meaningful risk quantification
  - Asking the right questions
  - Weighting the responses
- What to assess – Products, People, Processes
  - Product (product attributes, marketplace activities, promotional strategies)
  - People (experience, longevity and maturity of customer-facing teams)
  - Processes (specific types of customer-facing interactions you have identified as being a target for monitoring)
- When to assess – Periodic, Event triggered
  - Periodic (annual, semi-annual)
  - Events (important changes to the status quo)

# Effective Field Monitoring Essentials - Approach

- Developing a Plan
  - Be realistic!
  - Provide adequate justification
  - Apportion monitoring events based on priority/risk
    - Distribution across products, field teams, event types, geographies, etc.
  - Things to consider
    - Universe of potential monitoring opportunities available to pick from
    - When, where monitoring events may be concentrated
    - Potential for changes during the plan period

# Effective Field Monitoring Essentials - Approach

- Working the Plan – Identifying and Scheduling
  - Identifying the right opportunities
    - What are your sources for identifying monitoring opportunities?
    - Are they comprehensive, informative, accurate and up to date?
    - Is there a monitoring event opportunity that matches your plan (i.e. right product, right event type, right location, right team, etc.)?
    - Do you have a field monitor available to attend the event you have identified?
    - Can you combine multiple events in one trip for efficiency?
  - Scheduling the monitoring event
    - Advanced notice or not? Pro/Con of each...
    - Who needs to know and in what sequence?
    - Have you allowed for some last minute event cancellations?

# Effective Field Monitoring Essentials - Approach

- Working the Plan - Conducting Field Monitoring Events
  - Before
    - Gather essential documents, coordinate logistics, set appropriate expectations
  - During
    - Knowing what to look for, how to evaluate and how to respond
    - Identify infractions but also what was done correctly and well
  - After
    - Accurate documentation of observations, appropriate dissemination of findings and prompt follow-up on necessary corrective action

# Effective Field Monitoring Essentials - Approach

- Monitoring Observations
- What you are looking for: Adherence to policies and procedures, of course, but also...
  - Gaps in awareness, knowledge, understanding and/or correct application of policies and procedures
  - Individual's comfort level with doing things the right way
  - Situations which P&P does not adequately address
- Observed/Identified Violations of Policy
  - Random vs. for cause violations
  - Should you step in to prevent an imminent violation?
  - What do you do with potential/actual violations identified in discussions but not observation?

# Effective Field Monitoring Essentials - Approach

- Documentation of Monitoring Observations
  - Monitor checklist against existing policies or guidelines
    - Yes/no questions, True/false statements
  - Open-ended questions
    - Free text descriptions of events, observations, coaching, etc.
    - Remember: Be factual, be clear, be relevant
- Document both observations and responses
  - Your response to the representatives words/actions (interceding or coaching)
  - Company Representative's response to your stated observations (acknowledgement, surprise, disagreement)

# Effective Field Monitoring Essentials - Types of Activities to Monitor

## Field Ride-Alongs

- Joining the representative on routine interactions with assigned HCPs and HCOs
- Sales Representative Ride-along
  - What are some key areas of focus?
- Managed Care Representative Ride-along
  - What are some unique aspects of this role?
- Medical Affairs Representative Ride-along
  - Including if there are any appropriate joint medical/commercial interactions (internal and external-facing)

# Effective Field Monitoring Essentials - Types of Activities to Monitor

## Speaker Programs

- The Company Representative(s)
- The Speaker(s)
- The Presentation/Discussion
- The Attendees
- The Venue

# Effective Field Monitoring Essentials - Types of Activities to Monitor

## Advisory Boards

### •Some factors to consider:

- Commercial or Medical focus
- Legitimate need established
- Appropriate services contractually defined, agreed to and provided
- Fee-for-service appropriately valued
- Modest and business-focused venue selected
- Transfers of value accurately tracked
- Most of the time spent actually working
- The majority of time dedicated to acquiring feedback
- Appropriate feedback being sought
- Feedback adequately captured
- Work product put to meaningful use

Many of these requirements of a compliant ad board could be confirmed by a live monitor

# Effective Field Monitoring Essentials - Types of Activities to Monitor

## Medical Congresses

- Staffed exhibits on the commercial floor
  - (Commercial, Scientific, International, etc.)
- Company-controlled events/presentations
  - Receptions, Promotional presentations, Executive-level meetings, etc.
- Sponsorship Benefits
  - Advertising, signage, acknowledgments, displays, etc.
- Company Representative attendance at educational sessions
  - Avoiding any involvement or interference with CME

# Effective Field Monitoring Essentials - Types of Activities to Monitor

## Other Potential Areas for Monitoring

- Medical Affairs and R&D activities
  - Investigator meetings
  - Publications/presentations
  - Grant supported medical education
- Government Affairs activities
- Patient Advocacy activities
- Cross-border and Non-US based activities

# Effective Field Monitoring Essentials - Interpersonal Dynamics

- Considerations for the knowledge base of your field monitor
  - Broad experience in various positions within the industry
  - Ability to quickly absorb and retain complex information
  - Excellent observational, listening and questioning skills
  - Detail oriented, with good situational awareness
  - Demonstrated precision in written and verbal communication
  - Highly principled, self-confident, able to maintain objectivity
  - Calming demeanor, skilled at de-escalating stressful interactions

# Effective Field Monitoring Essentials - Interpersonal Dynamics

- Leadership of respective teams to be monitored
  - What is their perspective?
  - How do you gain alignment and buy-in?
- First-line Manager of individuals to be monitored
  - What is their perspective?
  - What is their level of involvement and participation?
- At the “to be monitored” employee level
  - What is their perspective?
  - How do you communicate to maximize benefit and minimize apprehension?

# Effective Field Monitoring Essentials - Final Considerations

- Never underestimate how labor-intensive proper field monitoring can be
  - Manage the scope of your program
  - Be realistic about what can be done with existing resources
  - Consider a multi-year plan
- Act upon observations
  - If you implement a field monitoring plan, make sure you have the resources to follow-up appropriately on the findings
- Assume there will be some push back along the way
  - It is never a convenient time for you to monitor an event
  - Be gracious in your communication but be careful to never ask permission to conduct monitoring

# Effective Field Monitoring Essentials

**Questions??**