How to Develop Internal Monitoring Programs

SEVENTH ANNUAL PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS AND BEST PRACTICES FORUM

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The views of the presenters are their own and do not necessarily reflect the positions or actions of their respective organizations.
An Overview of the Issues in Development of Internal Monitoring Programs

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The Roadmap to an Effective Monitoring Program

- Identify areas for potential monitoring
- Development of areas of focus
- Budget support
- Written protocols
- Development and use of metrics
- Deployment of resources
- Utilization of technology
- Effectively communicating results
Potential Challenges to Developing an Effective Monitoring Function

- Data quality
- Systems integration
- Under-developed key performance indicators
- Financial resources
- Human resources/staffing
Potential Challenges in Deployment of Resources

- Personnel issues in performing monitoring
- Training of personnel
- Communicating event indicators
- Collaboration with HR/Legal
- Follow-on investigations
- Corrective Action
Potential Challenges in Utilization of Technology

- Real time monitoring
- Transition issues
- Dash Board Metrics
- System Development and Integration
- Vendor Performance
Potential Challenges in Communicating Results to Management

- Effective lines of communication between the compliance officer and senior management to communicate monitoring metrics and program performance
- Focus on key performance indicators
- Metrics and nature of the reporting will evolve over time based upon the evolution of the program in general and the sophistication of the monitoring function
A Closer Look: Developing Metrics and Approaches in Internal Monitoring Programs

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Part 1: Potential Areas to be Considered for Monitoring

- Government Price Reporting
- Engagement of Physicians (Consulting, Speaking Honoraria, Preceptorships)
- Clinical & Research Grants/Studies
- Continuing Medical Education
- Medical Affairs Guidelines
- Samples
- Free Goods
- Patient Assistance Program/Indigent Patient Programs
- Debt Forgiveness/Reduction
- Contractual Payments (Discounts, Rebates, Admin. Fees)
Potential Areas to be Considered for Monitoring (continued)

- Conventions/Symposia/Foundations
- Data Purchases
- Non-clinical Grants
- Value-Added Programs
- Gifts, Meals, And Entertainment
- Promotional Materials/Sales Aids
- Off-Label Promotion
- Privacy
- Data Integrity
- GXP/FDA Related Issues
- Publication of Clinical Data
Part 2: Development of Areas of Focus

- Risk matrix
- Use of surveys
- Internal assessments
- Government enforcement efforts
- Ability to monitor-technology and resources
Part 3: Budget Support and Allocation of Resources

- Priority of monitoring in the compliance context
- Allocation of resources
- Funding support
- Capital and operating commitments
Part 4: Written Protocols

- Develop written protocols for the monitor function.
- Training of staff on monitoring function
- Establish framework for assessment of monitor program operation
Part 5: Development of Metrics

- Within areas of focus identify key data needs
- Fashion approach based upon measurement capabilities
- Development of metrics is context specific
- Utilize metrics that can provide notice of the need for further review
- Utilize results to achieve compliance program goals
- Use results to communicate program activity
Possible Metrics to be Considered for Monitoring Dissemination of Scientific Information

- Requests or inquiries related to off-label uses of products
- Sales call notes
- Verbatims
- Drug sampling records
- Approved promotional materials
- Business/strategic plans
Possible Metrics to be Considered for Monitoring Engagement of Physicians

- Number of consultants retained per product
- Number of speakers retained per product
- Utilization of speakers who attend speaker training
- Direct payments to physicians
- Indirect (via vendor) payments to physicians
- Program design and content of advisory boards
Possible Metrics to be Considered for Sales Representative/MSL Monitoring

- Identifying potential off-label promotional activity by sales representatives/MSLs through observations of the interactions with Health Care Professionals.

- Conduct full-day, potentially random, direct inspections and observations of the messages and materials delivered by sales representatives/MSLs.
Possible Metrics to be Considered for Sales Representative/MSL Monitoring (cont’d)

- Number of inspections conducted proportional in number to the size of the sales force/MSLs
- Inspections conducted across all regions where the company operates.
- Inspection report prepared by compliance personnel to include:
  - the identify of the sales reps/MSLs;
  - the identity of the monitor;
  - the date and duration of the inspection;
  - the topics discussed during the inspection; and
  - identification of any potential off-label promotional activity by the sales rep/MSL.
Possible Metrics to be Considered for Monitoring and Review of Requests for Off-Label Information

- Analyze sales representative/MSL submitted off-label inquiries.
- Compile and provide information about all requests submitted to the Medical Information Unit by sales representatives/MSLs about products.
- Request information should be separated by therapy area and/or product.
- Data analyzed to identify those sales representatives/MSLs associated with the highest number of requests for information.
For each therapy area, review further the requests and resulting responses from a certain number of sales rep/MSLs with the largest number of requests.

Information related to the Medical Information requests for the top number of requestors in the therapy area is reviewed.

A formal investigation is conducted and disciplinary action undertaken where appropriate in the event that the analysis and review indicates that an MSL may have inappropriately caused the dissemination of off-label information or engaged in off-label promotion.
Possible Metrics: Message Recall Monitoring Program

- Message Recall Monitoring Program designed to identify potential off-label promotional activities by sales representatives/MSLs through the analysis of commercially available, non-company messages delivered by sales representatives/MSLs (Message Recall Studies)
- Obtain Message Recall Studies relating to several products
- Analyze the results of all Message Recall Studies to determine whether they reveal any indicators of potential off-label promotional activities
Total Spend Monitoring: the Holy Grail?

- Total spend requirements under State law evolving
- Changing standards and calculations
- Capturing data across the enterprise
- Quality of data
- Reporting timeliness
Other Metrics to be Considered

- Government Price Reporting
- Clinical & Research Grants/Studies
- Continuing Medical Education
- Samples
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- Patient Assistance Program/Indigent Patient Programs
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Questions/Discussion