

A large, stylized sunburst graphic composed of numerous triangular rays emanating from a central point at the bottom. The rays are light blue and white, set against a solid blue background.

# **Use of Outside Vendors in Monitoring Compliance Programs**

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# Field Interactions Inherently Pose Off Label Risks Which Is Magnified By The Volume Of Interactions Each Year

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## Food for Thought...

- **Most HCP interactions occur in the field**
- **A company with 500 sales reps will have approximately 1 million interactions with HCPs in a given year**
- **Each one of these interactions is both:**
  - **An opportunity for education and scientific exchange**
  - **A potential opportunity for off label promotion**

# Scaling And Execution Of Monitoring Programs Remains A Challenge

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## Use Of Vendors

### Program Design

- Identify monitoring tools to be incorporated in plan
- Recommend volumes and sampling approaches

### Program Execution

- Supplementing internal staff for field monitoring
- Provide resources for record reviews

### Reporting & Effectiveness

- Data integration and Dashboards
- Compliance effectiveness measures

# Companies Increasingly Using Vendors To Assist In Live Monitoring Activities (Ride-alongs, Speaker Programs)

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**Live field monitoring is a significant burden on already overworked compliance groups**

**Other internal resources rarely provide same level of effective monitoring as compliance/legal team**

## **Vendor Considerations**

### **Selection Considerations**

- Similar compliance knowledge to company's internal monitoring resources
- Consistency in interpreting criteria and observations across monitoring staff

### **Cost Consideration**

- Maximize reps/event monitored in the same location
- Two monitoring events a day substantially reduces costs (staff time and travel expenses)

# Even Small Scale Monitoring Efforts Can Have Substantial Benefits

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## “What Matters Gets Measured”

What is the message to the field organization if we do not monitor?  
What is the message if we do monitor but the field does not know?

### Building Culture of Compliance

**Monitoring programs can be powerful tools for supporting a culture of compliance**

- Monitoring tells an organization that compliance is important
- Monitoring informs and improves training programs
- Monitoring generates data that can be used in organization wide communications

### Awareness vs. Scale of Monitor Effort

**Broad awareness of a monitoring program can be more important than the scale of the monitoring program**

- Combined with call and email reviews a significant number of Reps/MSLs can still be monitored
- Important to publicize program and findings

# Demonstrating Compliance Effectiveness Remains Elusive

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➤ **Companies have data on action steps taken**

- Number of trainings conducted
- Number of ride-a-longs conducted
- Number of programs monitored
- Number of actions taken

➤ **Companies can discuss the kinds of observations being made in audits and monitoring programs**

➤ **Still difficult to identify trends and determine if behaviors are getting better or worse?**

- Too often data cannot be readily aggregated
- Other data (disciplinary actions etc) may be more a function of compliance effort and not underlying behavior in the field

# Given Importance of Field Monitoring And Reality Of Budget Constraints, Documenting Effectiveness Is Critical

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- **Need to get beyond a list of actions**
- **Need to focus on what was learned from monitoring**
- **Need to set an objective benchmark for measuring behavior**
- **Need to compare benchmark performance over time**

***“Did We Move The Bar?”***



## Polaris Contact Information

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| Name                         | Email  | Phone  |
|------------------------------|--|--|
| <b>Fred Eaton</b><br>Partner | <a href="mailto:featon@polarismanagement.com">featon@polarismanagement.com</a> | <b>Office: 212.502.1873</b><br><b>Mobile: 914.329.3777</b> |



[www.polarismanagement.com](http://www.polarismanagement.com)

666 Third Avenue • 27<sup>th</sup> Floor • New York NY 10017

212.502.1870