

NAVIGANT

LIFE SCIENCES

16th Annual
Pharmaceutical Regulatory and
Compliance Congress

**Incorporating Effective Record
Reviews in your Auditing and
Monitoring Plan**

October 21, 2015



Agenda

It's Elemental - Record Reviews

Field Force Monitoring

Incorporating Record Reviews

Investigations and Corrective Actions

Reporting

It's Elemental Record Reviews

It's Elemental - Record Reviews



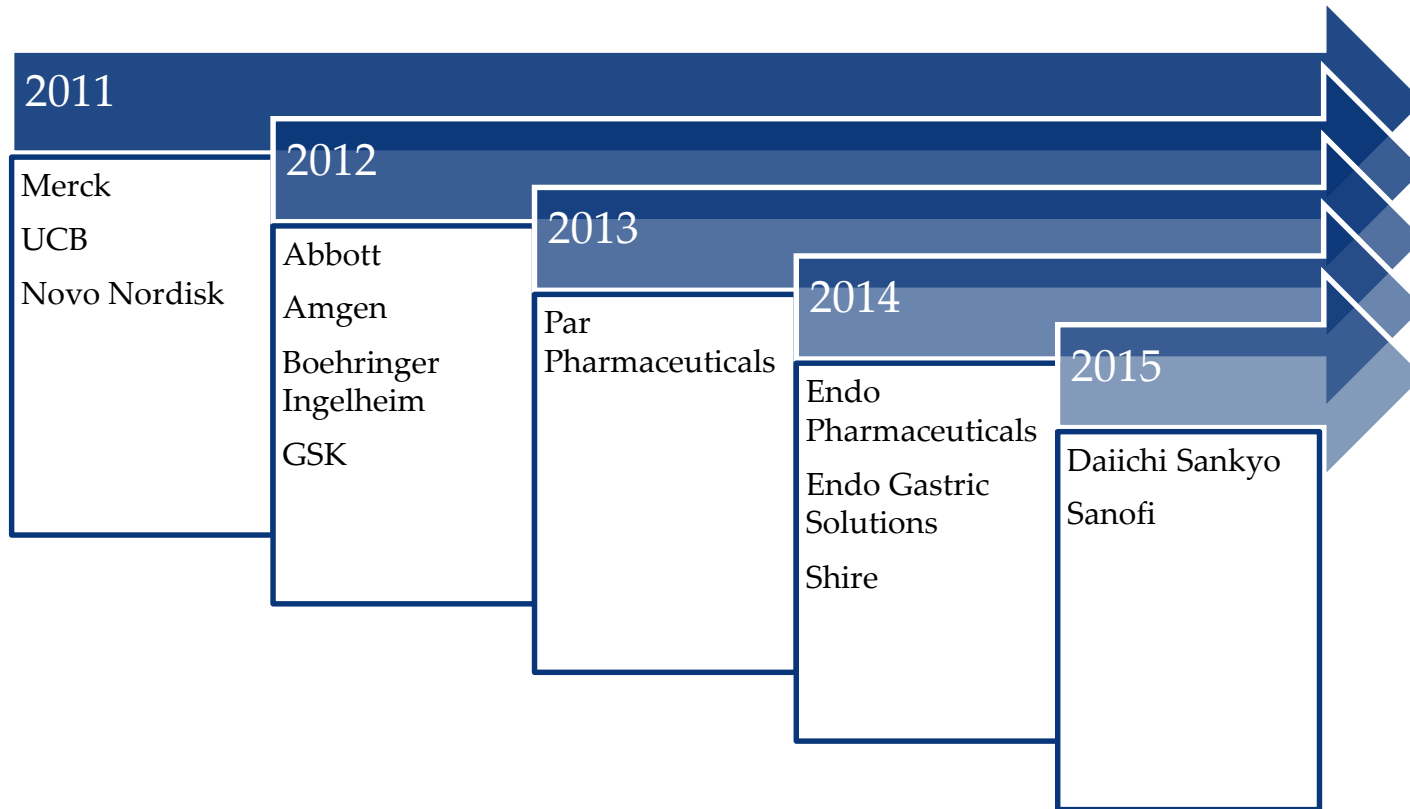
It's Elemental - Record Reviews

- The product promotional environment faces business and compliance risks related to the False Claims Act and the Anti-Kickback Statute.
- Corporate Integrity Agreements (CIAs) are incorporating

*“Within 120 days after the Effective Date, Company shall establish a **comprehensive** Field Force Monitoring Program (FFMP) to evaluate and monitor its sales representatives’ interactions regarding Government Reimbursed Products with HCPs and HCIs. The FFMP shall be a **formalized** process designed to directly and indirectly **observe** the appropriateness of sales representatives’ interactions with HCPs and HCIs and to **identify** potential improper promotional activities or other improper conduct. As described in more detail below, the FFMP shall include:*

- 1) a Speaker Monitoring Program;*
- 2) direct field observations (Observations) of sales representatives; and*
- 3) the monitoring and review of other records relating to sales representatives’ interactions with HCPs and HCIs (Records Reviews)*

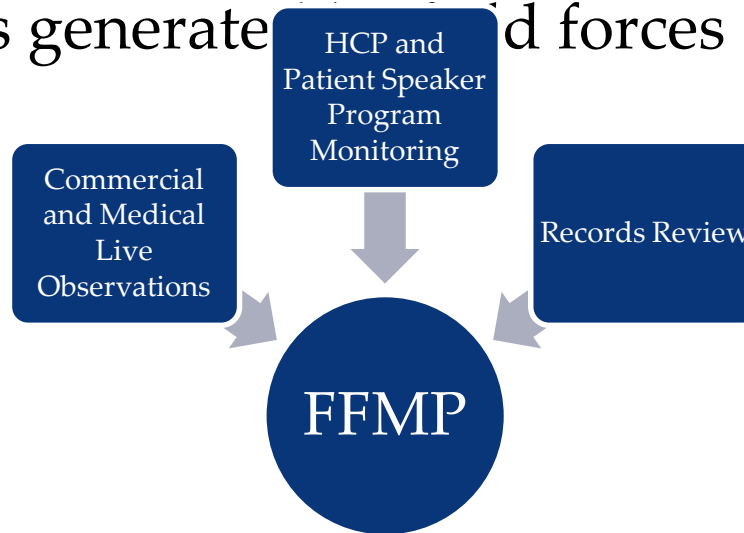
CIAs



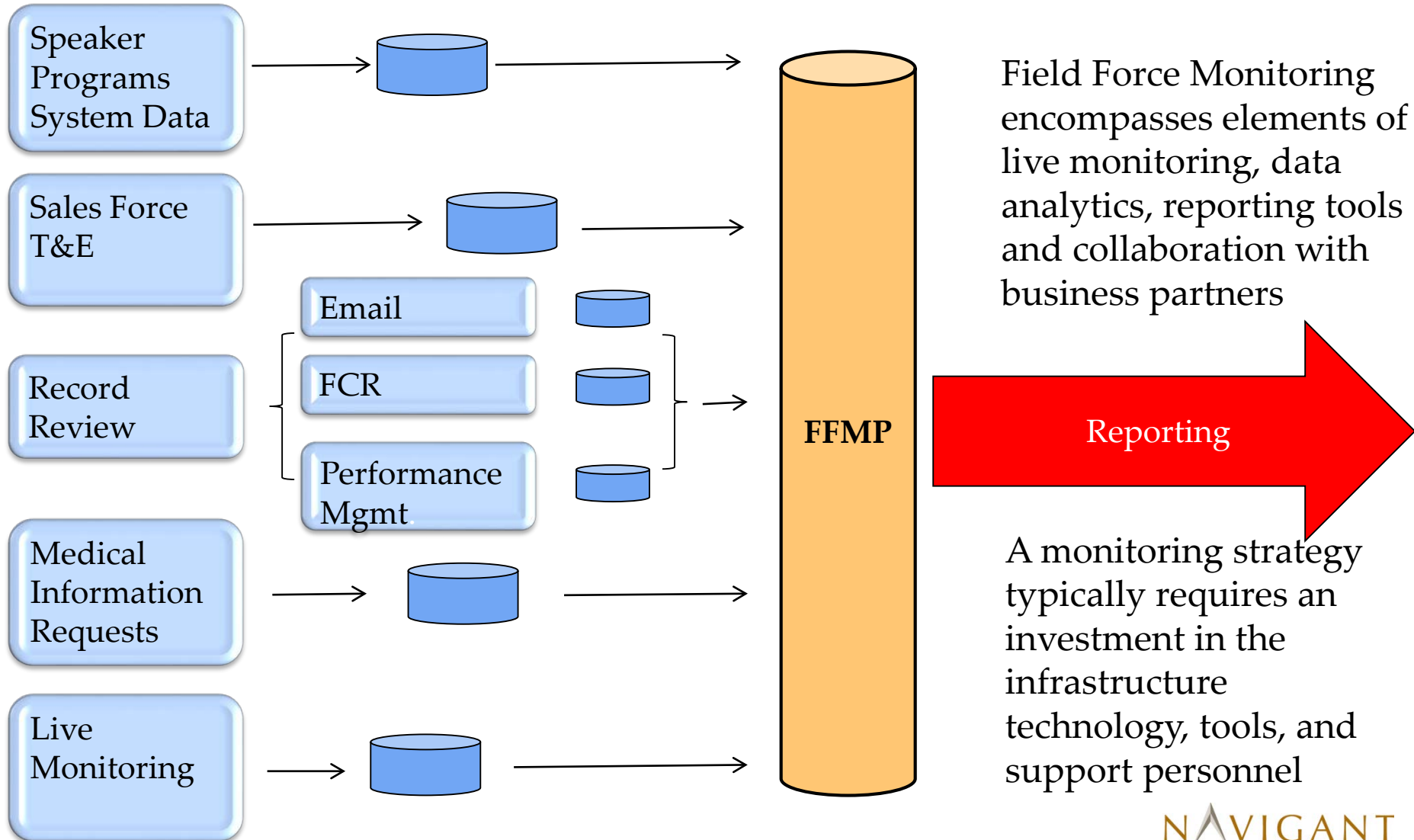
Field Force Monitoring Program (FFMP)

Fundamental - Field Force Monitoring Program

- The Field Force Monitoring Program is charged with assessing field sales force representatives' adherence to company policies, procedures and federal healthcare laws
- The Records Review component of Corporate Integrity Agreements (CIAs) is a way to look wide and deep into the documents generated by field forces



The Environment - Record Reviews



The Environment - Record Reviews

“As a component of the FFMP, the company shall also review various types of records to assess sales representatives’ interactions with HCPs and HCIs in order to identify potential or actual compliance violations. For each Reporting Period, the company shall develop and implement a plan for conducting Records Reviews associated with at least five Government Reimbursed Products and a sampling of the representatives promoting those products in every separate region.”

- Email Records
- Performance Management Records
- Call Notes/Call Records
- Field Coaching Reports (FCR)
- Speaker Program Documentation
- Sample Distribution/Inventory Records
- Travel & Expense Reports and Documentation
- Educational Items/Gift Distribution
- Medical Information Request Repository
- Verbatims
- Message recall surveys

FFMP

Incorporating Record Reviews

Visionary Leadership

Who

- Identify Key Collaborations and Stakeholders

What

- Know what is required entering into Corporate Integrity Agreement (CIA)
- What you have and what you don't have

How

- Know the systems
- Understand the impact

Why

- CIAs focus on the individual behavior
- Trends and root cause analysis

Elements

Written Standards

- Guides overall process
- Ensures consistency across all reviews
- Defines scope and responsibilities
- Provides methodology for representative selection process

Record Capture

- Maintains Record Review Selections
- Identifies Themes and Trends
- Assigned Follow up and Ownership

Data Storage

- Central Point for Documents
- Policy Procedures
- Contacts
- Live Reports

Incident Management

- Tracking of identified incidents if a potential violation is uncovered through Records Reviews

Common Challenges

Resistance by
Business

“Big
Brother”/Fear

Internal
System
Support

Incomplete
Data during
reporting
period

Important Considerations

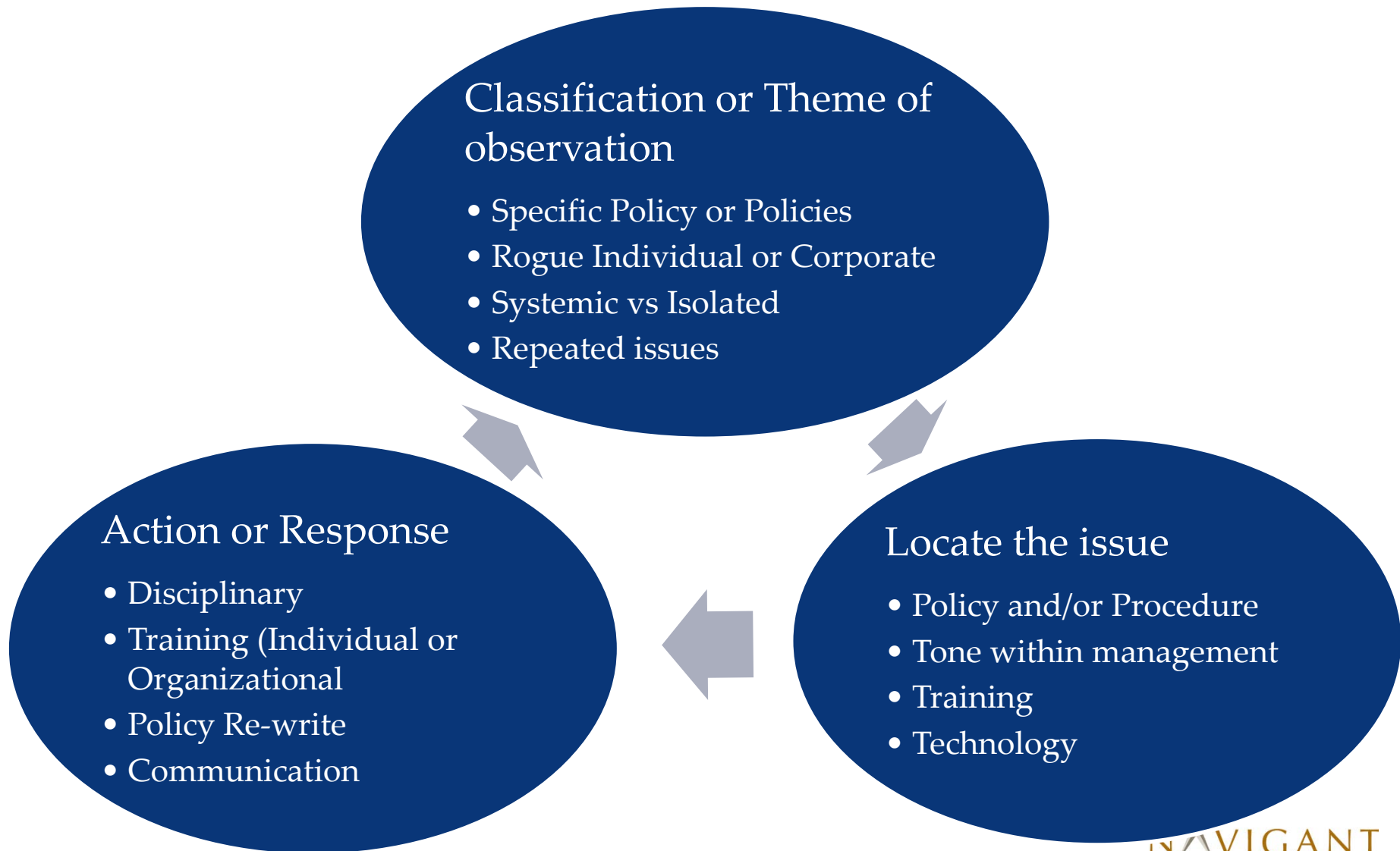
- Plan ahead of each monitoring period. Who will be your auditors?
- Do you require external resources outside of the compliance department? How will you leverage Subject Matter Experts
- Engage the business and gain business buy-in
- How will you ensure accuracy in your review?
- What will you do to document findings to allow for trending and analysis of findings?

Investigation and Corrective Actions

Investigations and Corrective Actions

- While conducting records reviews a Company is obligated to address and appropriately remediate potential compliance violations as necessary.
- Written Standards and having corrective action plans help Companies respond to instances of confirmed non-compliant behavior in a manner that is both appropriate for, and proportional to, the type of behavior surfaced by the records review.

Root Cause and Response



Reporting

Record Review Trends and/or Themes

Email

- Promotion through email
- Personal email
- Unapproved materials
- Management pressure

Record Review Trends and/or Themes

Call Notes

- Off-Label Promotion
- Email as a Call Note system
- Unapproved materials
- Excluded HCPs
- Performance Mgmt. Time Date Stamp

Record Review Trends and/or Themes Field Coaching Reports

- Missing or lack of Coaching Reports
- Off Label Promotion - Pressure
- Lack of Documentation
 - » Potential Compliance Activity
 - » Good Compliance

Record Review Trends and/or Themes Performance Reviews

- Collaborations with Medical

- Embellishment

- Inappropriate leverage of:
 - » Text books
 - » Journal articles
 - » Meals

Record Review Trends and/or Themes Speaker Program Documentation

- Inappropriate Attendees
- Incomplete Sign In Sheets
- Discrepancy between receipts and sign in sheets
- Discrepancy between sign in sheets and reporting systems
- Speaker non-compliance

Thank you!

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