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# Compliance Risk Management



- **Today's discussion will focus on two of Pfizer's compliance risk management approaches**
  - Risk Assessment and Mitigation Planning (RAMP)
  - Promotional Quality Assurance (PQA)]
- **In addition to RAMP and PQA, Pfizer utilizes a multi-faceted compliance risk management framework managed by Corporate Compliance, Legal, and business colleagues**

- **Risk Assessment and Mitigation Planning (RAMP)**
- **Promotional Quality Assurance (PQA)**

## Objective

- Utilize a uniform approach to identifying and prioritizing product-specific risks
- Create uniform guidance for mitigating identified risks
- Share best practices across the product support legal team
- Support a risk-based approach to downstream compliance efforts



## Approach

- Develop a first-in-class online risk management software application (RAMP application) for use by product attorneys
- Mandate ongoing use of RAMP for products promoted through a field force
- Monitor execution against product risk mitigation plans

- RAMP Activities are part of Pfizer's new Corporate Integrity Agreement
  - Pfizer must continue its RAMP process for the term of the CIA.
  - RAMP will be reviewed by an external party
  - External review will be limited to the RAMP "Promotion" category

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## Assess Risks

*For all relevant categories of potential risk (e.g., safety, promotion, etc.)*

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## Develop Mitigation Plans

*Based on risk assessment and through collaboration with relevant stakeholders*

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## Ongoing Risk Mitigation

*Execution against mitigation plans as well as other necessary risk mitigation (review committee, etc.)*

- **Engagement of leadership and subject matter experts when developing risk assessment questions and scoring**
- **Driving usability and simplicity in software design**
- **Embedding RAMP into the workflow of users rather than making it a standalone activity**

- **Risk Assessment and Mitigation Planning (RAMP)**
- **Promotional Quality Assurance (PQA)**



## Objectives

- Gain new levels of visibility into key promotional interactions
- Apply a risk-based approach to monitoring US promotional activities
- Report and escalate findings to relevant stakeholders
- Refer potential compliance issues to Corporate Compliance as appropriate

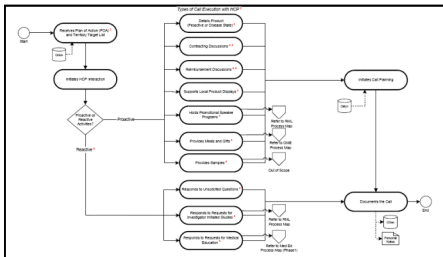


## Approach

- Develop a first-in-class promotional quality assurance model
- Collect and analyze data on promotional interactions
- Use gathered insights to identify trends, remediate potential issues, and enhance compliance controls

**PQA Supports Certain CIA Record Review Activities**

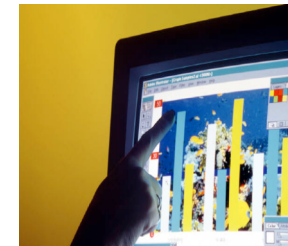
## Map Field Force Promotional Activities



## Identify Available Data Elements



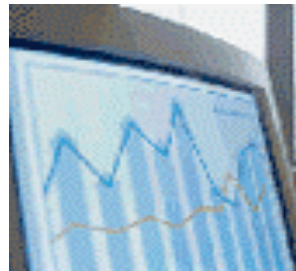
## Define Risk Indicators



## Mine Data



## Analyze and Trend



## Reporting and Remediation



**PQA's Activities are Informed by RAMP**

- **PQA reviews multiple data sources including:**
  - Email
  - Sampling records
  - Verbatim records
  - Medical information requests
- **Future review activities may include:**
  - Additional detailing records
  - Prescriber and diagnosis data

- **Strong relationships with Compliance, Legal, and Business Colleagues**
- **Development of product-specific expertise**
- **Effective leveraging of existing technologies and data sources**

**Questions?**