

110: Monitoring vs Assurance Managing Risk in a Decentralized Environment

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Session Objectives

- ❑ Understand the difference between monitoring and audit assurance
- ❑ Review key elements of an effective compliance program based on U.S. Department of Justice guidance
- ❑ Understand the three lines of defense model and how it can be used in effective risk management
- ❑ Understand how both monitoring and assurance activities are important in mitigating risks with practical examples

Monitoring vs Assurance

What's the Difference?

Monitoring

- “Near” Real Time
- Ongoing
- Targeted Business Activities (Risk Based)
- Proactively Identify Issues and Trends
- Inform Corrective Action Plans
- Identify Need for Focused Audits

Audit Assurance

- Retrospective
- Internal Controls Focused
- Detect Irregularities
- Limited time, frequency and scope
- Evaluate the effectiveness of Monitoring Programs
- Recommends improvements in controls



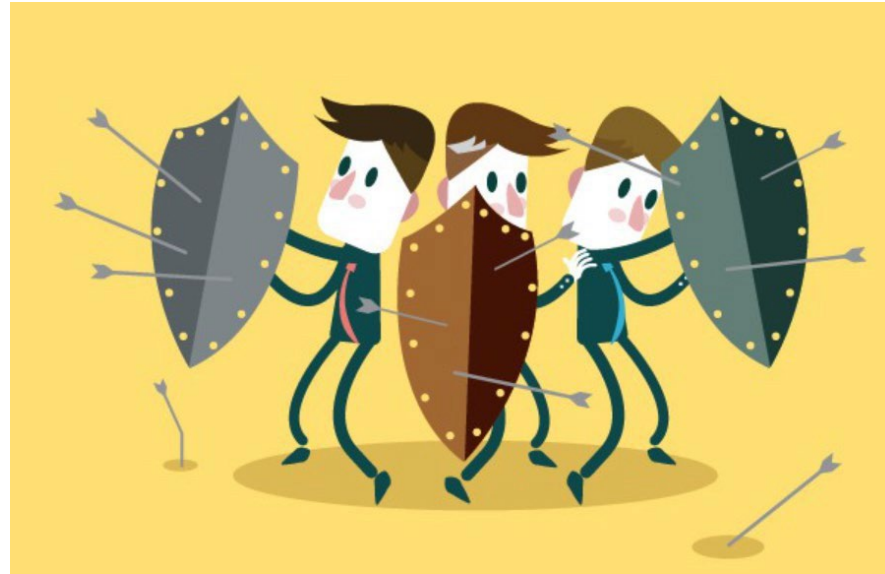
Auditing Function



Monitoring Function

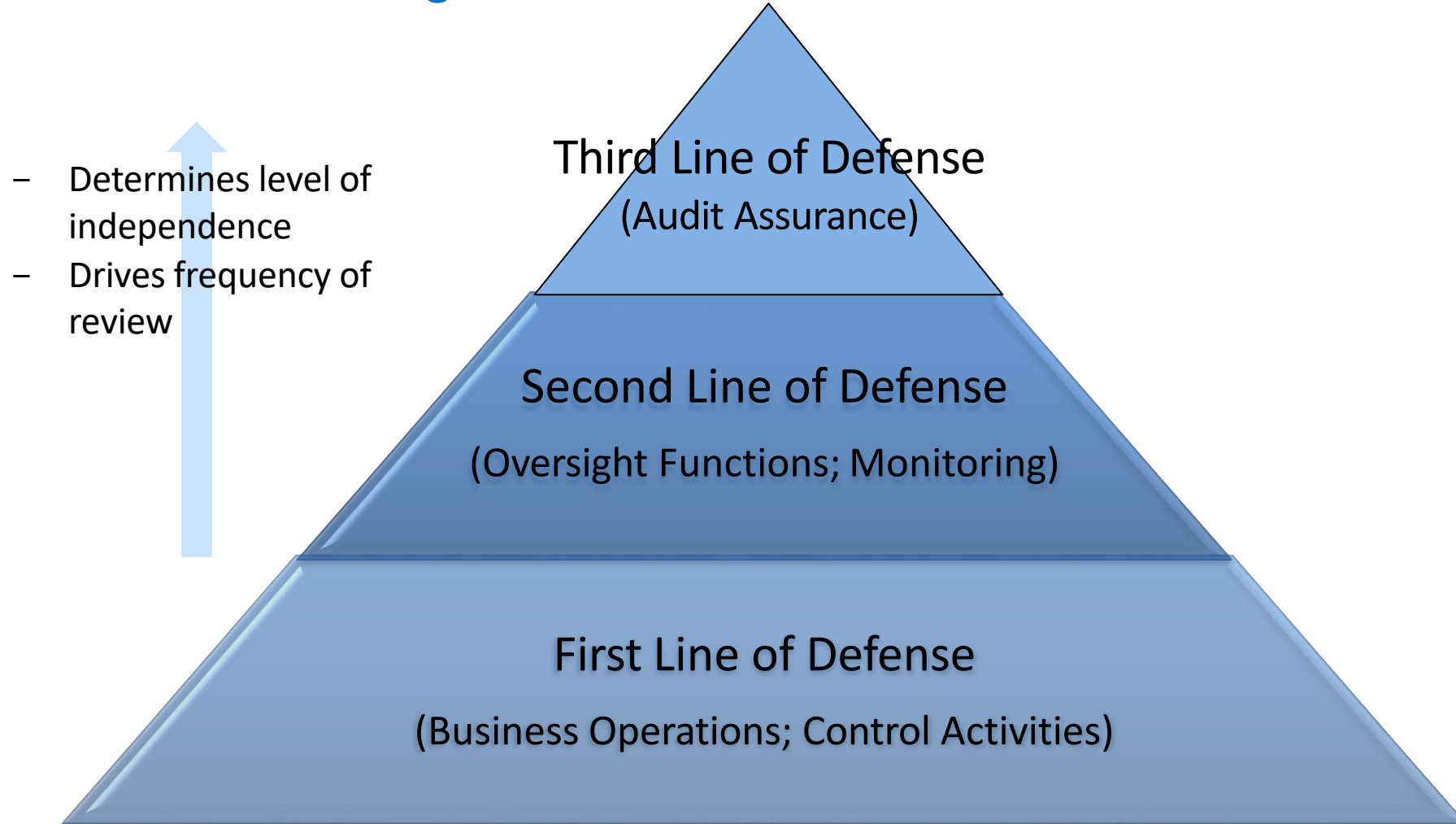
- Both are needed to inform risk assessments
- Difficult to have an effective compliance program without both

Risk Management Three Lines of Defense



- ❑ Shared responsibility; Working together at different stages to provide increased protection against an array of risks
- ❑ Encourages a stronger risk management culture while eliminating inefficiencies, gaps and overlap

Risk Management Three Lines of Defense



Elements of an Effective Compliance Program



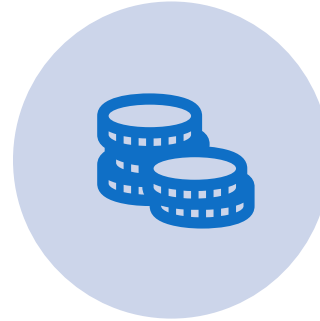
Elements of an Effective Compliance Program & Risk Management



Getting to Know Duke's Research Portfolio



APPROXIMATELY \$1.5B
IN RESEARCH FUNDING



APPROXIMATELY 80%
FEDERALLY FUNDED



CLINICAL AND BASIC
SCIENCE RESEARCH

Duke Research Audit Assurance Approach

SPARC

- ❑ Assurance engagements support the two research institutional compliance risks
 - ❑ *Sponsored Program Administration, Oversight and Reporting*
 - ❑ *Promote and Maintain Research Excellence, Responsibility and Integrity*
- ❑ Evaluate **internal controls** to identify strengths and gaps
- ❑ Evaluate **process design effectiveness and efficiency** against operational objectives and risk tolerance

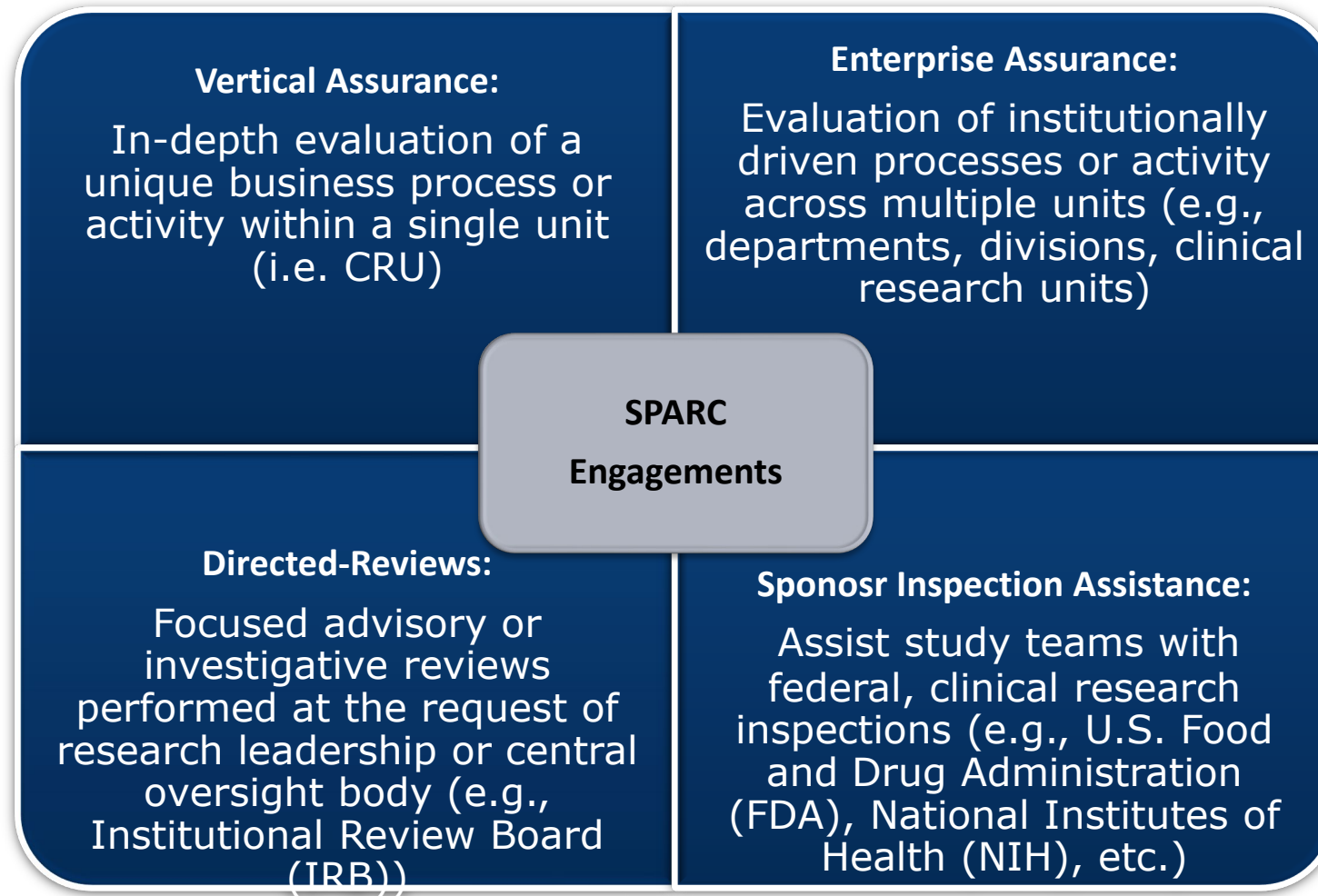


ASSURANCE



ADVISORY

OTHER COMPLIANCE
SUPPORT



Clinical Research At Duke



Clinical Research Unit
(CRU)

Established in 2012



CRU Structure

Medical Director
Research Practice Manager
Financial Practice Manager
Data Practice Manager
(upcoming)



Active Studies FY22

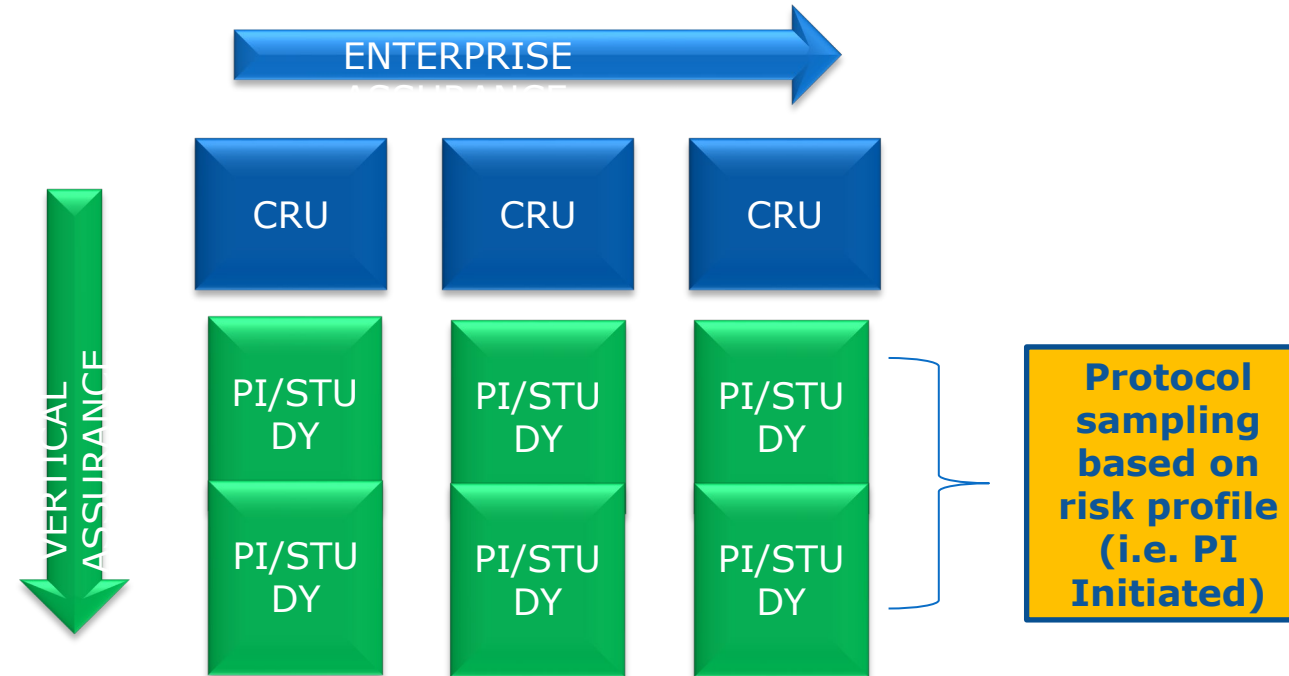
2,280 active clinical research
studies
Approximately 24K study
participants

The Evolution of Audit Assurance

| | Prior to 2018 (CTQA) | New Approach (SPARC) |
|----------|----------------------------|-----------------------------------------------------------|
| Client | Principal Investigator | CRU leadership |
| Focus | Compliant/Non-compliant | Risk profile |
| Coverage | Individual protocols | Health and quality of CRU research processes |
| Report | Technical | Executive (business context) |
| Standard | 100% regulatory compliance | Assessing Risk & Internal Controls (Impact vs Likelihood) |

Reason for Change: Provide view into the overall health of the research enterprise for Duke Leadership and Board of Trustees Audit and Compliance Committee

New Audit Assurance Review Structure



SPARC APPROACH



Clinical Quality Management Program

- ❑ Risk based monitoring program
- ❑ Established in 2018
- ❑ Goals:
 - ❑ Formalize CRU responsibilities for monitoring prospective, consenting and no-monitored studies
 - ❑ Provide institutional standards for Clinical Research Units (CRU) to conduct ongoing internal monitoring
 - ❑ Identify issues and trends to support improved research quality
 - ❑ Provide transparent reporting to research leadership
- ❑ CRU-designated quality management (QM) reviewers
- ❑ Areas monitored: informed consent, participant eligibility, and safety reporting
- ❑ Inform audit activity based on trends identified

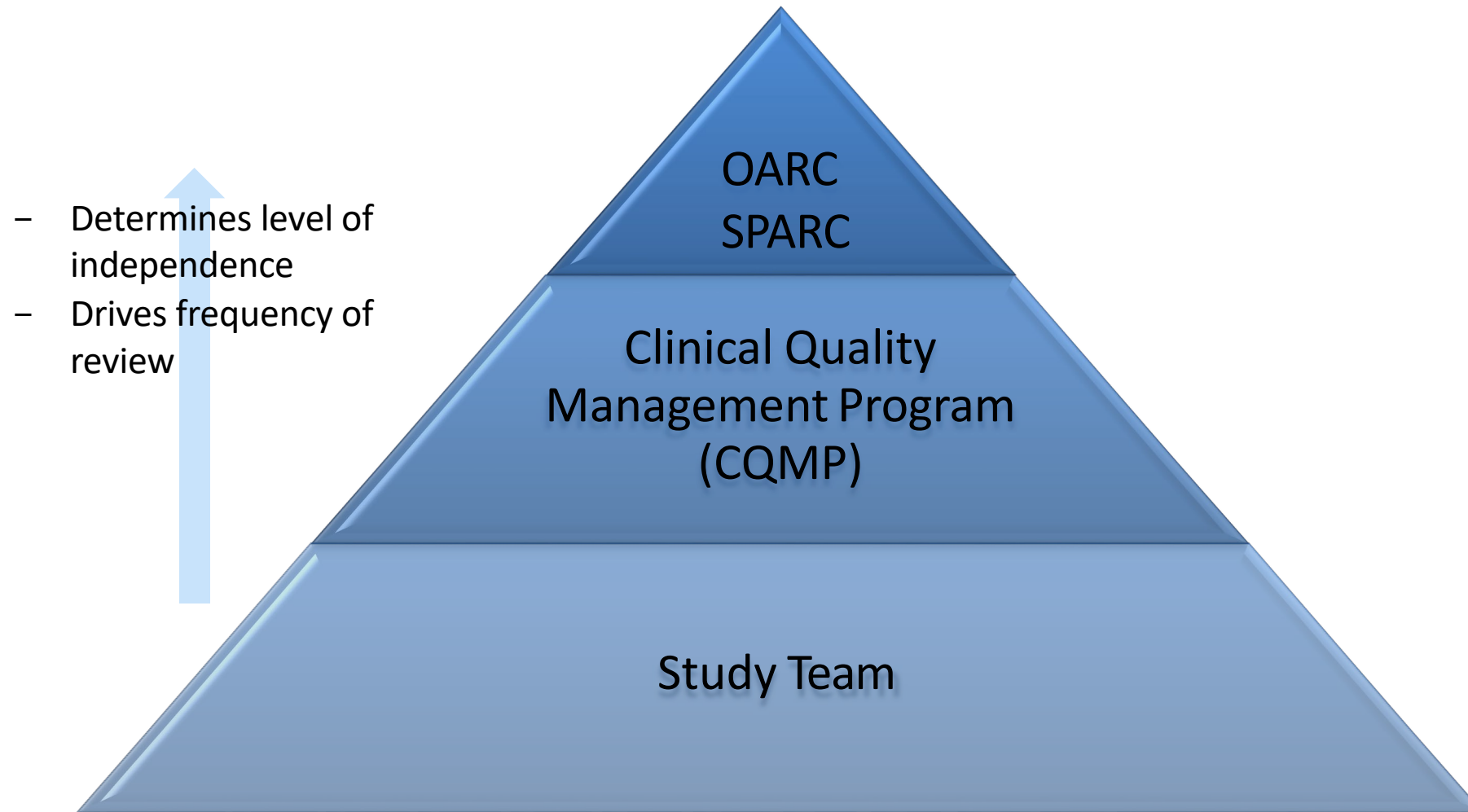
Clinical Quality Management Program

Protocol Review Frequency

| Complexity Level | Regulatory Reviews | Participant Chart Reviews – by Cumulative Enrollment | | |
|------------------|-------------------------------|------------------------------------------------------|-------------------------------|---------------------------|
| | | 1-39 | 40-99 | >=100 |
| High | Quarterly every 3 months | Quarterly 3 records | Quarterly 10% of records | Quarterly 10 records |
| Medium | Bi-annually every 6 months | Quarterly 3 records | Quarterly 10% of records | Quarterly 10 records |
| Low | Annually once per year | Bi-annually 3 records | Bi-annually 10% of records | Bi-annually 10 records |

- **High:** Prospective Phase I–III interventional procedure, device, and/or drug studies (novel product or indication). All studies under an IND or IDE with the FDA
- **Medium:** Studies using FDA-approved drugs, devices, or biologics for their approved indication. Other studies that do not meet high complexity but are more than minimal risk (e.g., behavioral intervention, complex observational, tissue collection).
- **Low:** Studies using procedures generally considered to be minimal or low-risk (e.g., blood sample collection, imaging not using sedation, questionnaires, and behavioral surveys)

Risk Management Three Lines of Defense



Sample Audit Assurance Engagement Process Design

| CQMP Design Review | |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Scope | Assess the design and/or effectiveness of the program: <ul style="list-style-type: none">– Policies and procedures– Training and communication of expectations– Central office and Clinical Research Unit (CRU) roles and responsibilities– Oversight and monitoring activities including CRU and central office reports and follow-up actions |
| Sample | 25 protocols across 9 CRUs; multiple PI's |
| Key Stakeholders | CQMP Management; Senior Leadership SOM; VPRI |

Sample Audit Assurance Engagement CRU CQMP Implementation

| CQMP CRU Implementation Review | |
|---------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Scope | <p>Review and assess CQMP implementation across a sample of CRUs in the following areas:</p> <ul style="list-style-type: none">– Effectiveness of QM Reviews– Adherence to Required Review Timelines– CRU Roles and Responsibilities– Training and Communication |
| Sample | 10-15 protocols within a single CRU; multiple PI's |
| Key Stakeholders | CRU Leadership |

Assurance Review Outputs



Highlight best practices



Root cause analysis



Identification of noncompliance



Recommendations for operational improvements

Annual Audit Assurance Planning



Collaborative process with input from various stakeholders



Recognition of industry trends and organizational changes



Agile and adaptive process that changes with emerging needs



QUESTIONS



COMMENTS