

Internal and External Audit Readiness

Managing All the Moving Parts

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Conflict of Interest Disclosure

- Neither Jill Mortali or Erika Stevens has conflict of interest disclosures in relation to this presentation.



Learning Objectives

- Describe the enterprise audit readiness
- Analyze key processes for developing a standard approach to managing audits
- Evaluate case studies from large research organizations response to audits and audit response



Defining the enterprise research risk landscape



Spectrum of enterprise research risks

- Financial
- Billing
- Human subject protection
- Operational
- Regulatory
- Strategic
- Technology
- Human Resource
- Reputational



Regulatory considerations for enterprise risk assessments

- Affordable Care Act
- OMB – Minimum Grant Requirements for Financial Management Systems
- HIPAA
 - Privacy
 - Security
- Medicare/Medicaid Billing Rules (CMS)
- False Claims Act (CMS)
- Federal Grant Requirements (PHS)
- Human Research Requirements (OHRP & FDA)
- National Coverage Decisions (CMS)
- Investigational New Drug / Investigational Device Exemption (INDs/IDEs)
- Fraud, Waste, and Abuse
- Joint Commission Accreditation requirements

Objective: Develop a clinical research compliance universe that includes key focus areas, risk and a proposed approach to confirm key controls are implemented and operating effectively

| Focus Area | Sub Area | Regulatory Agency | Risk Description | Proposed Approach |
|-------------------------|-------------------------|---------------------------|--|---|
| Policies and Procedures | Policies and Procedures | CMS, FDA, OHRP, PHS, etc. | <p>The lack of clearly defined policies, standard operating procedures and clinical research controls increases the risk for:</p> <ul style="list-style-type: none"> • Improper billing • Loss of revenue • Loss of reputation • Non-compliance with regulations | <ul style="list-style-type: none"> • Develop clinical research policies and procedures which are standardized and consistently applied across the Enterprise. • Update and consolidate current policies on a regular basis. Work instructions should exist that describe the specific tasks needed to complete activities related to clinical research. |
| Billing Compliance | Coverage Analysis | CMS | <p>Without a documented coverage analysis, the institution is at risk of potentially billing Medicare for non-qualifying clinical trials and/or potentially inaccurate clinical research billing. In addition, this step is key to the successful execution of the remaining steps in the billing compliance continuum. The institution may also be losing revenue due to billing denials by third party for services billable to a sponsor.</p> | <p>The following controls should be incorporated into operational procedures:</p> <ul style="list-style-type: none"> • Consolidate coverage analysis, oversight and enforcement into a central office • A documented coverage analysis should be used for all the current clinical research studies (with billable procedures) |

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| Billing Compliance | Patient Tracking / Enrollment Registration | CMS | Without a centralized location for recording all enrolled clinical research participants, registration and scheduling of these participants is difficult and could lead to errors. | <ul style="list-style-type: none"> A central database for patient billing compliance should be used that identifies all clinical research participants, and which has mechanisms for recording whether an individual procedure charge is considered Standard of Care (SOC) or Research related (RS). |
| Billing Compliance | Coding and Billing | CMS | <p>Without appropriate routing of SOC vs. RS charges, the institution is at risk for:</p> <ul style="list-style-type: none"> Improper billing Loss of revenue due to denials Non-compliance with Medicare clinical research coding and billing regulations | <p>The following controls should be incorporated into operational procedures:</p> <ul style="list-style-type: none"> Standardized coverage analysis billing grids should be used Billing grids should be centrally available and shared with coding and billing teams within each ancillary department. |
| Billing Compliance | Reconciliation | CMS | <p>Without a periodic reconciliation process, there is a risk of:</p> <ul style="list-style-type: none"> Loss of revenue Not remediating improper billing in a timely manner | <ul style="list-style-type: none"> A centralized, single source of clinical research billing data should be used (SOC and RS charges). The centralized clinical trials office staff should generate monthly or quarterly reconciliation report utilizing this data. |

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| HIPAA Compliance | HIPAA Compliance | HHS, OCR | A lack of monitoring procedures to manage HIPAA compliance for personnel and activities related to research may result in HIPAA violations and penalties. | <ul style="list-style-type: none"> Enterprise oversight should exist to verify that the use and disclosure of PHI for research purposes are compliant with HIPAA privacy rules for research HIPAA security controls should exist |
| Financial Management | Budgeting | OMB | The lack of a formal clinical research financial budget process places the institution at risk of not capturing and recouping all research costs. | <p>The following controls should be incorporated into operational procedures:</p> <ul style="list-style-type: none"> A formal budgeting process which links central clinical research business staff and research team members. Appropriate hierarchical budgetary approvals should be documented and enforced |
| Financial Management | Sponsor Invoicing | | An inconsistent invoicing and tracking process may result in unbilled invoices and loss of potential revenue. | <ul style="list-style-type: none"> A centralized AR invoice tracking system should be used for sponsor invoices. Alternatively, an enterprise-wide clinical research management system (CTMS) could be used. |

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|----------------------|-------------|-------------------|--|--|
| Financial Management | Reporting | OMB | The lack of a formal accounting management process for clinical research may place the Enterprise at risk for loss of revenue through missed research-related expenses or late sponsor invoicing | <ul style="list-style-type: none"> A formal periodic (e.g., monthly or quarterly) financial reconciliation process should be in place. Periodic (e.g. monthly and quarterly) reports on clinical research financial activities should be provided to Investigators and their staff. Financial reconciliations should be performed within 90 days of the close of the study. |
| Regulatory | IRB Reviews | FDA, OHRP | Delays in IRB study approval may create losses in resource time investment and potential revenue from studies. In addition, it could negatively impact the reputation of the institution with research sponsors. | <ul style="list-style-type: none"> Enterprise senior leaders should perform an assessment of the IRB review processes to identify potential areas of improvement in timeliness of reviews. |
| Regulatory | IRB Reviews | FDA, OHRP | IRB reviews which do not meet federal regulatory requirements can put the Enterprise at risk for federal disciplinary actions (e.g. 483s, Warning Letters, research program shut-down) | <ul style="list-style-type: none"> Enterprise senior leaders should perform periodic assessments of the IRB policies, procedures, and processes to identify potential regulatory compliance concerns. |

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|-------------------------------|----------|-------------------|---|--|
| Regulatory | GCP | FDA, OHRP | Lack of a formal clinical research auditing function can result in serious and/or continuing noncompliance with federal regulation and/or study participant harm. This can lead to shut-down of research study (or entire research program) with resulting loss of revenue and Enterprise reputation. | <ul style="list-style-type: none"> Institute a system proactive regulatory reviews of randomly selected studies to include regulatory documents, eligibility criteria, protocol adherence |
| Study Participant Recruitment | | | <ul style="list-style-type: none"> Risk of insufficient return on study start-up investment if participant enrollment does not meet budgeted target. Risk of negative reputation for investigator and institution. | <ul style="list-style-type: none"> Utilize feasibility assessment tool to support decision to move forward with new study. This assessment should include determination of there being a sufficient potential study participant pool to meet enrollment goals. |
| Technology | | FDA, OHRP | Risk of missed data (improper billing) or need to enter same data multiple times (added cost) If relying on multiple IT systems which are not interconnected. | <ul style="list-style-type: none"> Integrated comprehensive IT solution is ideal (CTMS, patient registration, billing, financial management/accounting, grants management, etc.). Minimally, need close collaboration and cooperation between all responsible areas (central clinical research office, research teams, revenue cycle, patient registration, compliance, IT, etc.) |

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| Grant expenditure compliance | Allowable expenses | PHS | A lack of Enterprise oversight to verify valid expenses may limit management's ability to prevent and detect misappropriation of research funds. Unallowable expenditures applied to federal funded grants may result in non-compliance with applicable regulatory requirements (e.g., NIH grant policy statements) | <ul style="list-style-type: none"> A system should be implemented to routinely verify that expenses are appropriately allocated and that controls are incorporated into operational procedures.. |
| Time and effort oversight | Time and effort oversight | PHS | A lack of monitoring procedures to verify the accuracy and appropriateness of time and effort reporting may limit management's ability to track and allocate personnel expenditures. | <ul style="list-style-type: none"> Timesheets and consultant expenses should be consistently reviewed and approved by individuals who directly oversee the study. Disbursements to student employees should be consistently supported by pay rates or hours worked. A compliant Time and Effort Policy should be in place Weekly time sheets should be signed by a responsible supervisor |

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|------------------------|----------|-------------------|--|--|
| Training and education | | All | Lack of a strong, comprehensive research training program could result in noncompliance with regulations, policies and procedures, and negatively impact personnel's ability to grasp the importance of research compliance to the Enterprise. | <ul style="list-style-type: none"> A training program should be implemented for clinical researchers, research team members, and applicable administrative personnel Training program should encompass all areas of research compliance risk: human subject protection, financial, billing, study performance, scientific misconduct, etc. Training program should be standardized across all of the Enterprise's research groups to ensure consistency. |
| Internal Communication | | All | Disjointed or nonexistent paths of formal and informal communication between clinical research stakeholders can prevent the Enterprise from effectively implementing its overall research compliance plan. | <p>Use a multi-faceted communication plan including strategies such as:</p> <ul style="list-style-type: none"> Regularly scheduled research team meetings with required attendance by all team members, including those representing central research offices. Periodic, formal in-person reporting of research leaders to Enterprise senior leadership Programs of clinical research conferences (e.g. Grand Rounds) to allow for informal collaborative opportunities |

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Defining the regulatory landscape & impact

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Although the regulatory landscape for research remains relatively constant, determining the institutional risk impact is challenging.

| IMPACT | SCORE | RATING | FINANCIAL | OPERATIONS | GOVERNANCE | EXTERNAL | PEOPLE |
|--------|-------|--------------|------------------------------------|--|--|--|--|
| | 5 | Catastrophic | Greater than 20% increase in costs | Talent loss that is not easily replaced (scale of loss, degree of talent) so severe to shut down operations | Criminal sanctions, penalties/sanctions /performance guarantees with loss of >\$1M Loss of government contract, licensure, or accreditation | Serious damage by media exposure (breadth and length of negative coverage) - irreparable loss of member confidence Broad implications for patient, employee health and safety | Requires senior management and/or BOD oversight There is a leadership vacuum so severe would require fundamental, large scale changes |
| | 4 | Significant | Greater than 10% increase in costs | Loss of confidence in the function/area to deliver its business objectives | Sanctions \$500K up to \$1M | Broad and extended negative media coverage Implications for patient, employee health and safety | Requires high level of senior management attention May involve changes to management team |
| | 3 | Moderate | Greater than 5% increase in costs | Future composition of the service, activity, production, function in question Known risks identified in monitoring, audit, testing, assessments or investigations | Sanctions \$100K to \$500k Moderate impact to government contract or accreditation | Negative press/social media mentions limited in duration/audience Potential implications for patient, employee health and safety | Requires management team focus with some senior management oversight |
| | 2 | Limited | Greater than 2% increase in costs | Routine operations would be able to cope with these issues Indication of risk identified in monitoring, audit, testing, assessments or investigations | Regulatory warning or nominal sanctions Government contract or accreditation requires corrective action plans | Negative press/social media mentions confined to one story or local coverage only No indication of risk to patient, employee health and safety | Limited management team time is required, generally only periodic briefings to oversee resolution |
| | 1 | Minimal | Less than 2% increase in costs | Routine operations would be able to cope with these issues. No indication of risk identified in monitoring, audit, testing, assessments, or investigations | No regulatory sanctions or fines Business objectives being met | No negative press/social media mentions No indication of risk to patient, employee health and safety | Minimal, if any, management team time is required |

* A risk may be assigned a rating of 1-5 by meeting one or more of the criteria associated to that rating; it is not necessary to meet all associated criteria for a given rating.



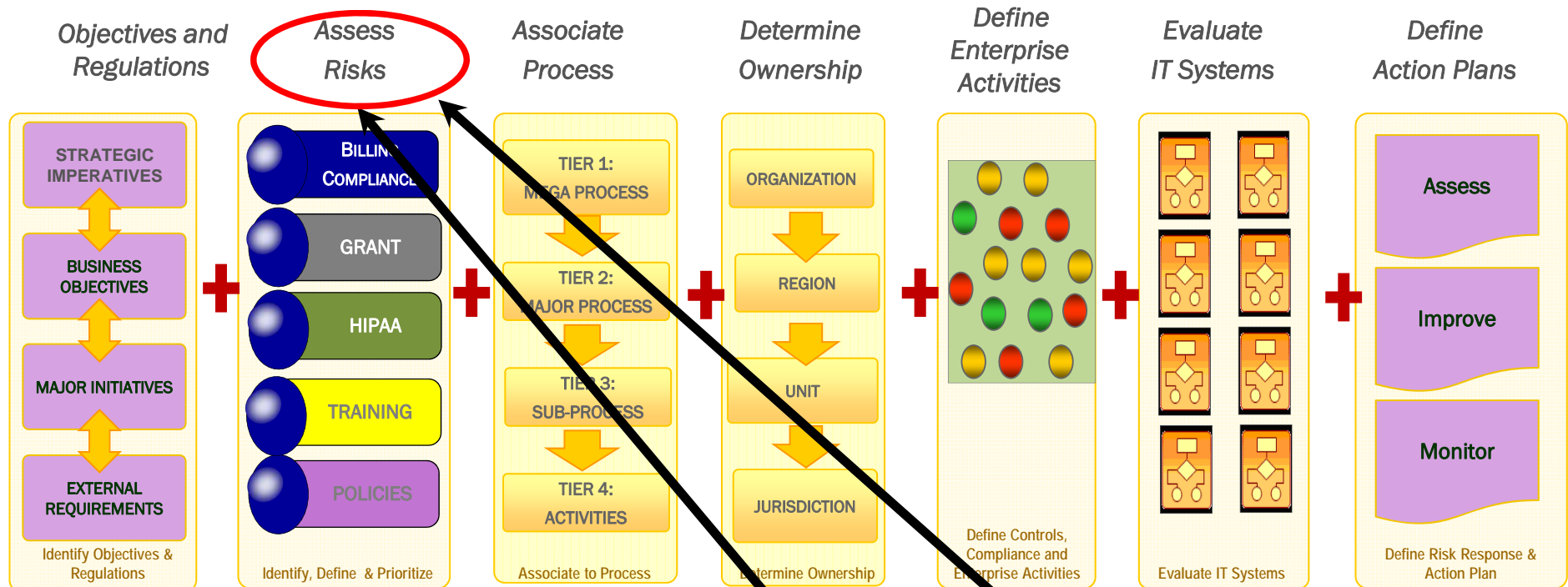
Research enterprise assessment

Seven part enterprise risk assessment approach

An approach such as that demonstrated here may be utilized to assist an organization's clinical research team to better enable efficient and effective risk, compliance, and controls management.

Understanding Sources of Risks

Developing Risk Assessment Approach



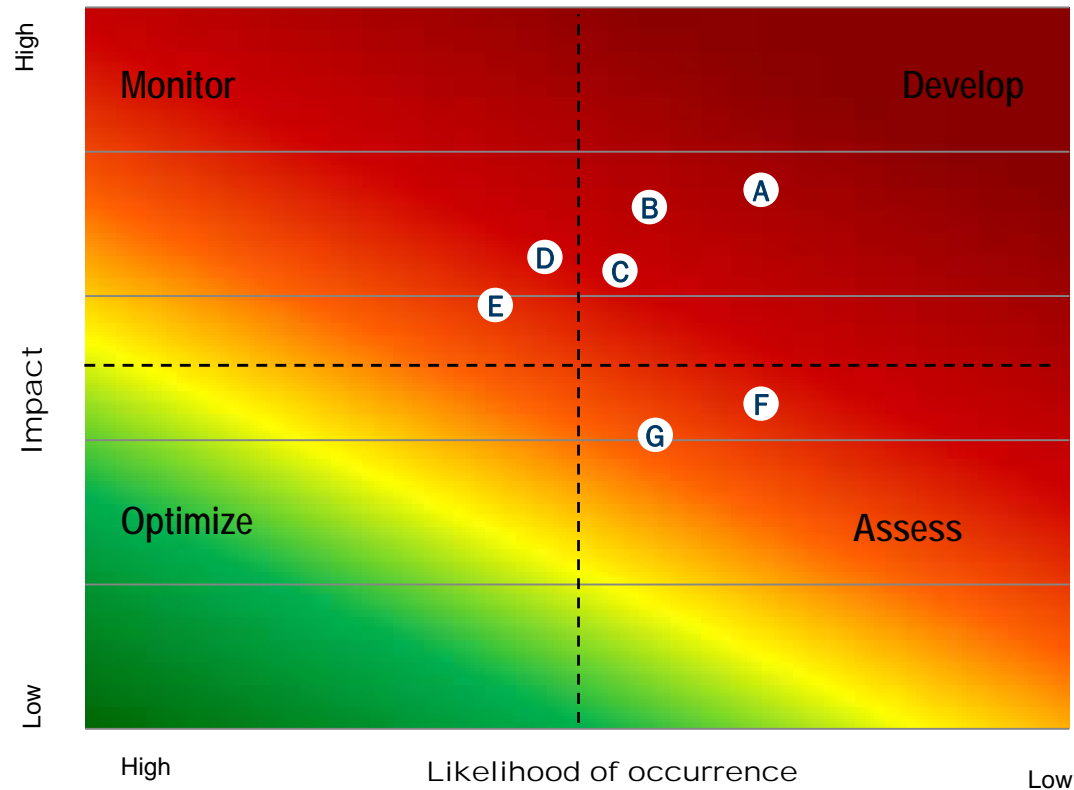
To Assess Risk consistently, we require common:

- Linkage to Objectives, Common Categories
- Linkage to Process Map
- Common impact/likelihood scale
- Common Source of Risk Categories

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Risk mitigation tool: Heat map

Enterprise risk assessment heat map tool: *Provides guidance for risk mitigation*

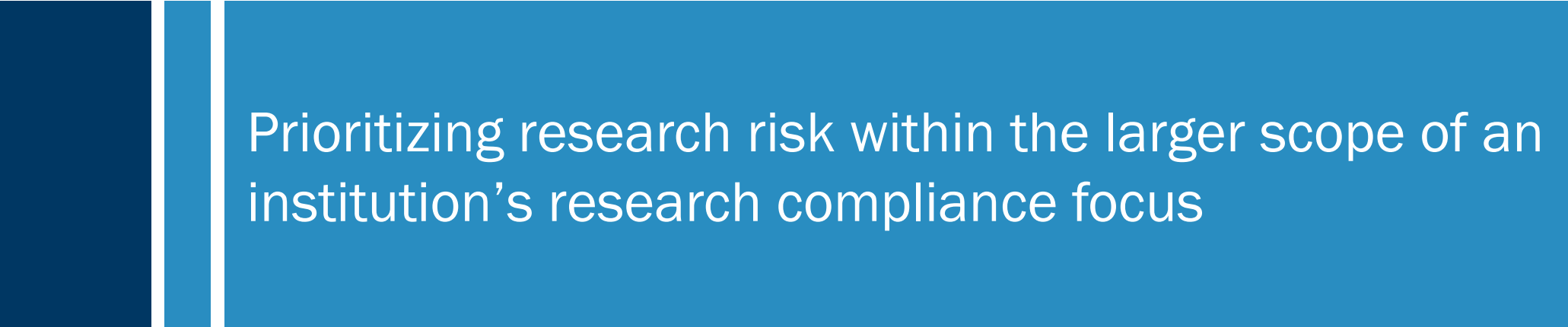


The quadrants on this chart are intended to provide directional guidance for determining potential risk Enterprise strategies.

Impact: Potential **impact (financial / operational)** each risk could have on the Client if left unmanaged.

Likelihood Of Occurrence: Potential **likelihood** of unfavorable instances of occurrence; considering contributing factors (e.g., Enterprise control, people, process, technology or external factors).

| | Risk Ref. | Risk Title |
|----------------|-----------|------------------------------|
| Develop | A | Billing Compliance |
| | B | Grant Expenditure Compliance |
| | C | HIPAA Compliance |
| Monitor | D | Financial Management |
| | E | Time and Effort Oversight |
| Assess | F | Training and Education |
| | G | Policies and Procedures |

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Prioritizing research risk within the larger scope of an institution's research compliance focus

Prioritizing risk to coincide with the compliance focus

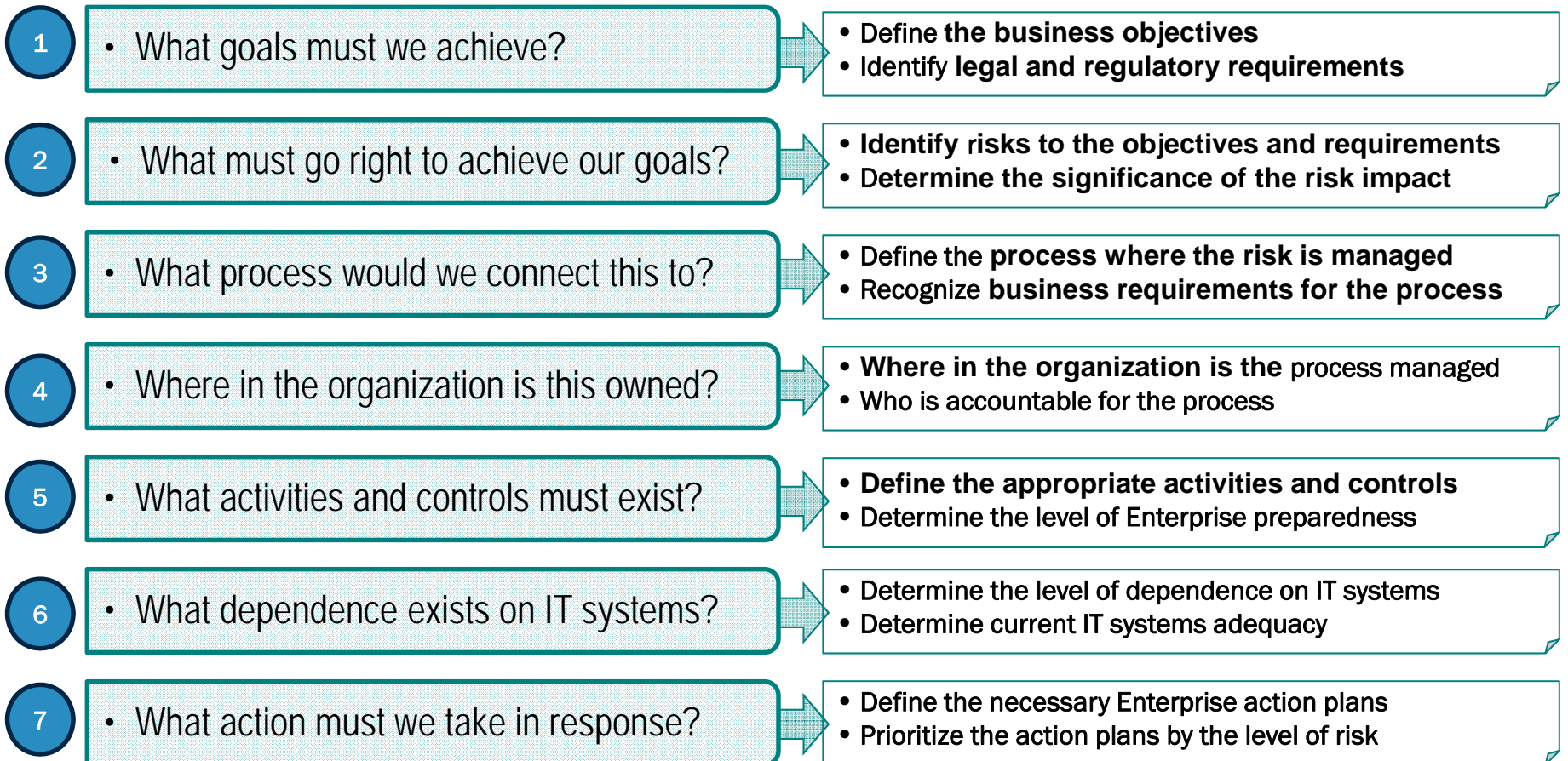
Enterprise Risk Based Planning and Scoping Determines Ongoing Risk and Compliance Enterprise Activities

Understanding Sources of Risks

- 1 Objectives and Regulations 2 Assess Risks 3 Associate Process

Developing Risk Enterprise Approach

- 4 Determine Ownership 5 Define Enterprise Activities 6 Evaluate IT Systems 7 Define Action Plans



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Developing systematic approach

Developing systematic approach

Action Plans for Research Risks

| Key Business Risks | | | Assessment | | | | | Advisory | | | Assurance | | | |
|--|------------------------|---------------|-----------------|---------------------|---------------|-------------------|--|---------------------------|--------------|----------|--------------|--------------|---------------------|-------------|
| Risk Classification | Risk Sub Category | Risk Category | Inherent Impact | Inherent Likelihood | Risk Exposure | Mgmt Preparedness | Existing Management & Control Activities | Enhancement Opportunities | Action Owner | Due Date | RMU Coverage | RMU Activity | Operations Activity | Key Metrics |
| Business Conduct Inability to demonstrate KP conduct with agents and brokers may result in regulatory sanctions and/or fines. | Code of Conduct | Governance | 4.0 | 3.3 | 13.2 | 3.3 | | | | | | | | |
| IT Reliability and Recovery IT systems may not be ready to accept enrollment files due to lack of capacity, performance issues, or inability to meet privacy and security requirements resulting in non-compliance, delayed file processing, inaccurate enrollment, inaccurate claims processing, inaccurate billing, and member and provider dissatisfaction. | Information Technology | Operations | 3.7 | 3.3 | 12.2 | 2.8 | | | | | | | | |
| Eligibility and Enrollment An HIX enrollment file that fails to be received by a QHP in accordance with federal and/or state regulations and guidance may result in non-compliance, risk of loss of QHP status, potential sanctions or fines, and a disruptive member experience. | Health Plan | Operations | 3.8 | 4.0 | 15.2 | 2.7 | | | | | | | | |
| Risk Description | Risk Subcategory | Risk Category | X.X | X.X | X.X | X.X | | | | | | | | |

ILLUSTRATIVE
Representative Sample



Case Study

*This represents an amalgamation of actual issues from multiple organizations. Any potentially identifying facts are changed “to protect the innocent”.



Your role?

- You were hired three months ago to fill a newly-created Research Officer position reporting to the Hospital President.
- Your role is both one of Research Compliance Officer and Research Operations leader. You are named as Institutional Officer on the Hospital's FWA.
- Your staff includes 3 IRB Coordinators, 1 IRB Auditor, 1 Research Finance Manager, and 1 Research Trainer. The latter primarily helps residents develop their research projects.



Case study-Background

- Large teaching hospital with strong reputation for quality care.
- Hospital is in a competitive market, and currently holds strong market share position overall and in several therapeutic areas, including oncology, cardiology, neurology, women's health, and pediatrics
- Hospital has three internal IRBs, and currently has about 1000 active studies. Most active research areas are oncology, cardiology, and pediatrics. About 1/3rd of the studies are industry-funded clinical trials or device studies. Federal research funding is minimal.
- Research administration has historically been highly decentralized.



Case Study – Potential Issues

- Whistleblower – allegation that third party insurers and study sponsors were billed for same procedures.
- IRB minutes show multiple protocol deviations from one investigator on multiple studies.
- Residents use one or more external biostatisticians to do their study analysis. Several of these residents have casually mentioned sending PHI through e-mail to one of the biostatisticians. There does not appear to be a contract of any kind in place for using this person's services.



Case Study – Potential Issues (Cont'd)

- Hospital does not have a CTMS in place. Invoicing of sponsors appears to be ad hoc, with study coordinators being primarily responsible for ensuring this gets done. Coordinators generally do not use the Hospital's AR system, instead relying on self-created processes of spreadsheets and simple Word-based invoices.
- You recently completed a round of introduction meetings with several of the Hospital's largest industry research sponsors (pharmaceutical and device companies). Most were highly complementary of the Hospital's research program, but there were concerns voiced regarding turnaround times for contracts and IRB approvals.

What would you do?

Where do you start?

Questions?



Thank you!



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