Developing & Executing Good Clinical Practice (GCP) & Research Billing Audit Plans from Practical Risk Assessments

How to Get (More) Bang for Your Buck!

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Objectives

- Discuss strategies for developing risk-based audit plans using thoughtful and pragmatic risk assessments, sampling, testing techniques, and internal vs. external auditors
- Examine nuances of "process audits" vs. audits of individual studies including Phase 1 studies and investigator-initiated trials
- Share success stories and lessons learned conducting risk assessments, GCP and research billing audits

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What is a Risk Assessment?

Identifying & analyzing potential events that may negatively impact individuals, assets or an environment

A process of identifying things, situations, processes that may cause harm

What is it used for?

- Identifying Risk
- Mitigating Risk

https://www.bwjp.org/our-work/topics/risk-assessment.html

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Why Do a Risk Assessment?

Identifies gaps in knowledge and understanding

Detects, classifies, quantifies high-risk patterns

Utilizes a proactive, rather than reactive approach

Minimizes liability and risk

Self-assessment processes allows the process owners to be involved in identifying risks

Utilizes risk assessment to better mitigate issues

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What are the Research Risks?

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How Are Risk Assessments Done?

Identifying Risk – Be Objective

Learn to identify 'real' risk vs. speculation

- Surveys/Questionnaires
  - Stakeholder feedback
- Previous/Repeat Audit Findings
  - Same ole, same ole
- Interviews/ Facilitated Discussions –Exit Interviews
  - Compliance issues identified
- Hotline Incidents
  - Investigation outcome
- New Processes
  - Check to ensure it works
- Self-Assessment - Areas/Processes Never Previously Audited
  - Gap analysis
- Competing Priorities and Downstream Effects
  - Team/departments with multiple/other priorities causing risk or critical operations to be compromised
- Items of Interest – Regulatory Bodies
  - What are the FEDs looking at?
- Audit Referrals
  - For-cause
- Document Review
  - Processes/Policies/Procedures/Reports
- Parking Lot Issues
  - Risks identified out of scope

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Organizational Risk Assessment

Understand business, operations and mission/goals

Define the compliance/audit universe

Rank each risk area identified

Develop a plan to address risk areas:

-Monitoring
-Auditing
-Project Plan
-Other

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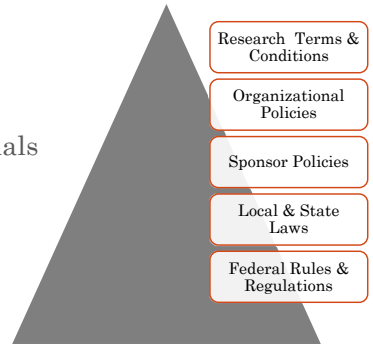
Organizational Risk Assessment

Step 1 – Understand Business Operations

- Mission/Strategy /Policy
- Ethical
- Information Technology
- Legal/Regulatory Compliance
- Public Relations & Perceptions
- Collaborative Relationships
- Academic
- Commercial
- Humans/Animals
- Personnel
- Financial
- Physical



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Organizational Risk Assessment

Step 2 – Define the Universe, then……

- IRB & Protocol Compliance
- Investigational Drugs
- Privacy & Security
- Animal Use
- Research Billing
- Grants Management

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Organizational Risk Assessment

Step 2 – Breakdown categories further as needed

Example: Investigational Drug

- IND Application
  - Required reporting/ monitoring
  - Exemption
- Safety Events
  - AE/SAE reporting
- Disposition & Dispensing
- Informed Consent

Example: Research Billing

- Double-billing Medicare
- Billing for services promised for free in the ICF
- Sponsor contract issues

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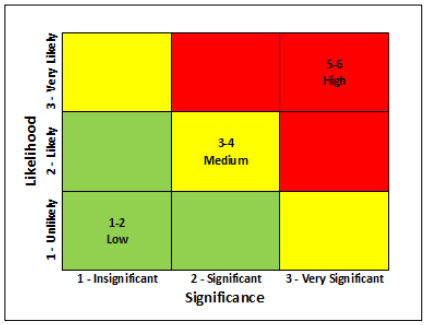
Organizational Risk Assessment

Understand the Business & Operations → Define Universe → **Assess and Prioritize Risk** → Create Plans: Auditing, Monitoring, Special Projects

Step 3 – Assess & Prioritize Risk

Assign a baseline risk rating to each potential area

- **Likelihood** – Probability of a risk occurring
- **Significance** – Potential significance of a risk
- **Detectability / Control** – Presence of control activities to reduce risk occurrence/impact



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Risk Assessment Scoring Matrix

Topic	Likelihood	Reputation	Financial	Regulatory	Operational	Detectability	Controls	Risk Prioritization Score (RPS)	Comments
Human Subjects	2	3	4	2	2	3	3	19	
Clinical Trial Billing	3	5	5	4	4	3	3	27	
Animal Use	3	3	2	2	2	1	1	14	
Privacy and Security	5	4	5	4	4	4	3	29	
Investigator-Initiated Trial Auditing & Monitoring	1	2	2	3	4	4	4	20	
Investigational Drug	3	3	2	2	2	3	2	17	

Risk Assessment Scoring Matrix

		Business Impact						
Score		Likelihood	Reputation	Financial	Regulatory	Operational	Detectability	Controls
1	Negligible	Events occur less than 1% of the time.	Slight media attention. Little stakeholder impact.	Negligible costs.	Technical violation of law possible. No risk of exclusion, CIA or loss of accreditation/licensure.	Minimal if any operational impact. Safeguards in place with regular management oversight.	Routinely audited and/or tested. Process failures most likely will be detected.	Performance metrics are established, routinely reviewed and show little variation. Current policies and procedures exist. Employee training and competency established. Established contingency and risk management plans.
2	Low	Events occur occassionally, 2-10% of the time.	Local media attention. Minor stakeholder impact.	Slight risk of expense or loss of gross revenue.	Technical violation of the law and Civil fines and/or penalties possible. Little risk of exclusion, CIA, loss of accreditation/ licensure.	Some safeguards in place. Some automated processes with moderate management oversight.	Routinely audited and/or tested. Slight risk that process failures will not be detected.	Performance metrics are established, routinely reviewed and show some variation. Current policies and procedures exist, but may need updating. Employee training and competency established. Many built-in safeguards in place.
3	Moderate	Events occur regularly, 11-50% of the time.	Regional media coverage. Moderate stakeholder & long-term brand impact.	Some risk of expense or loss of gross revenue	Civil fines possible. Moderate risk of exclusion, CIA or loss of accreditation/ licensure.	Some safeguards in place with limited management oversight.	Periodically audited and/or tested. Process failure most likely not be detected within a reasonable amount of time.	Limited performance metrics established. Limited policies and procedures exist. Employee training and competency established but not followed.
4	Significant	Events occur most of the time, 51-75% of the time.	National media coverage. Substantial stakeholder & long-term brand impact.	Moderate risk of expense or loss of gross revenue.	Civil fines and/or penalties probable. Moderate risk of exclusion. CIA possible.	Limited safeguards in place with sporadic management oversight. Slightly complex or partially manual process.	Process rarely audited. Process failure will most likely not be detected.	Very few performance metrics. Very few automated processes with limited management oversight. Little to no policy or procedure guidance. Few built-in safeguards, cross-checks, or other mechanisms in place to identify failure prior to occurrence.
5	Critical	Events happen almost or all of the time, >75% of the time.	International media coverage. Significant and/or extensive and prolonged negative press coverage. Irreparable stakeholder impact. Brand significantly affects organizational abilities.	Significant risk of expense or loss of gross revenue.	Criminal conviction and/or exclusion of hospital or system probable. Fines, penalties and or legal exposure. Exclusion and/or CIA most likely.	Little to no automated processes with little or no human interventios, oversight or control. Complex and/or totally manual process. Relies on extensive specialized skills.	Process never audited or tested. Significantly or extremely hard to detect prior to failure.	Very few or no performance metrics. Little to no policy or procedure guidance. No safeguards, cross-checks, or other mechanisms to identify errors/failures prior to submission/completion.

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Baseline Risk Assessment: Create Plans

Understand the Business & Operations → Define Universe → Assess and Prioritize Risk → Create Plans: Auditing, Monitoring, Special Projects

- Perform specific audits
  - Compliance area audits
  - Process audits
  - Study-specific audits
  - Probe audits
- Perform monitoring
  - Audit follow-up
  - Routine monitoring
- Complete special projects
- Perform deep dive assessments
- Other

Area	Likelihood	Significance	Baseline Risk Score	Controls	Overall Score	Relevant Requirements	Potential Risks	Action Plan
HSP - Informed Consent Process *Are IRB approved consent forms used?*	2 Likely	2 Significant	4 Medium	- 1 Yes	3 Medium	45 CFR 46 GCP 21 CFR 50 & 56	Research activities on a research subject without consent	Probe Audit
IND / IND Exempt Research *Are IND requirements assessed for Investigator Initiated Studies?*	3 Very Likely	2 Significant	5 High	0 No	5 High	21 CFR 312	Research conducted without appropriate FDA oversight Subject harm	Project
Protocol Eligibility Compliance *Are eligible subjects enrolled into research studies?*	2 Likely	3 Very Significant	5 High	- 1 Yes	4 Medium	21 CFR 312 GCP 21 CRF 50 & 56	Research conducted on ineligible subject; potential subject harm	None – Recent satisfactory audit of eligibility unit
Billing Compliance – Subject Identification *Are subjects identified for billing purposes?*	3 Very Likely	3 Significant	6 High	0 None	6 High	NCD 310.1 CMS	False Claims to Medicare Billing Patients Inappropriately	Implement Subject Identification / Bill Hold Project
Billing Compliance – Medicare Advantage (MA) *Are MA claims routed to Medicare for drug trials?*	2 Likely	2 Significant	4 Medium	Unknown	4 Medium	NCD 310.1 CMS	Inappropriately Billing Patients / MA Plans	Probe Audit & Process Review

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Baseline Risk Assessment

Understand the Business & Operations → Define Universe → Assess and Prioritize Risk → Create Plans: Auditing, Monitoring, Special Projects

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Project Level Risk Assessment

Objective

- To assess viability/feasibility of a proposal/project
- Identify potential risks that could impact the project
- To identify areas for auditing & monitoring
- To determine level of oversight or authorization required

Process

- Perform risk assessment on a study or process
- Assign risk score
- Create & implement plan to address risk:
  - Auditing plan
  - Monitoring plan
  - Training plan
  - Additional resources
  - Other

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Example: Risk Categories for Investigator-Initiated Studies

Risk Category – Study #	Objective
Safety	Determine known risks to subject safety
Study Phase	Risks inherent to study phase
Complexity	Determine how study complexity impacts risk
Subject Population	Determine whether subject population increases risk for the study
Technology	Consider level of technology competence required for a successful study
Data Collection	Assess integrity of the data based on data collection methods
Endpoints	Determine if the method for capturing endpoints will affect the data integrity
Individual Investigator Experience	Determine possible risks related to Investigator experience
Investigational Product (IP)	Determine any risks associated with IP administration
IP Logistics / Supply Chain	Determine risk involving logistics & supply chain
Operational Complexity	Determine to what extent the degree and nature of outsourcing increases the risk of the study

Project Level Risk Assessment

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Example: Risk Categories for Research Billing

Risk Category – Study #	Objective
Coding	Determine if correct codes are affixed to claim
ClinicalTrials.gov	Validate if study is registered on ClinicalTrials.gov
Contract	Validate that there an appropriate contract in place to allow collaboration, sharing of data, PHI
Budget	Determine if budget covers enough for the study to be feasible
Outside Providers	Determine the process of informing outside providers of a research subject
Billing Correct Payer	Validate that correct payer is billed, e.g. Medicare vs. Medicare Advantage
Routine Costs	Determine if there will be any routine costs associated with the trial
Informed Consent	Validate that the Informed consent appropriately outline the items paid by the research study and those items in which the subject will be responsible
Medically Necessary	Determine if the calendar outlines procedures that are medically necessary
Document Concordance	Validate that all the documents of the study align

Project Level Risk Assessment

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Project-Level Risk Assessment Matrix:

Example

Area	Likelihood	Significance	Baseline Risk Score	Controls	Overall Score	Relevant Requirements	Potential Risks	Action Plan
Safety: IP Logistics & Supply Chain *Are there temperature, light or humidity restrictions with the IP?*	3 Very Likely	2 Significant	5 High	- 1 Yes	4	GCP Other	Protocol violations IP ineffective Subject harm	Monitoring Plan / Process Review
Protocol Compliance – Subject Eligibility *Is the inclusion/exclusion criteria complex?*	2 Likely	3 Very Significant	5 High	- 1 Yes	4	21CFR312 GCP	Enrolling ineligible subject Subject harm	Audit subject eligibility after each enrollment before randomization
Billing Compliance – *Is each item/service billed to correct payer?*	2 Likely	3 Very Significant	5 High	-1 Yes	4	NCD 310.1	Inappropriately Billing MA Plans	Probe Audit

- Many more areas to consider
- Sum "Overall Score" for each project
- Implement action plan(s) to address risks as needed

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Process Audits vs. Individual Study Audits

Process Audit – an examination of how processes work within an organization

Individual Study Audit – an examination of an individual study (product) to evaluate whether it conforms to requirements

Process Audit	Individual Study Audit
Determine root cause	Determine compliance to requirements
Identifies weaknesses	Identifies trends
Opportunities for improvement	May not identify processes that affect other studies/products
Verifies controls	

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Measurement	Internal Auditor	External Auditor
Processes	Better knowledge of processes/people	Requires time to review processes
Cost	Cost effective	More expensive
Objectivity	May be difficult to be objective	May provide better objectivity
Leadership buy-in	May be lacking	Sometimes enhanced
Scope	Conducts ongoing audits	Can be used for special projects or deep dive assessments
Experience	May lack experience needed to conduct specific audit	May have experience to conduct specific audits

Internal vs. External Auditors

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Audit Sampling & Testing Techniques

Audit Sampling <100% of universe selected for audit

- Used in field audits
- Reduced resources and disruptions to operations
- Gathers enough evidence to conclude an opinion

Statistical sampling –

- Can be used in regulatory audits or external reviews

Non-statistical sampling – sample chosen based on specific criteria

- Can be used when auditor has lots of experience

https://linfordco.com/blog/audit-sampling/

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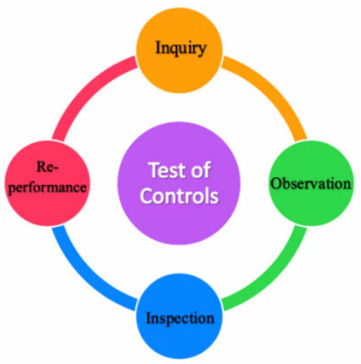
Audit Sampling & Testing Techniques



Testing Techniques – Controls Testing

- Inquiry/Interviews
- Observation
- Re-performance of control

https://accountinguide.com/test-of-controls/

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Identify	Score	Audit
Identify risk through a risk assessment • Surveys/Interviews • New Processes • Hotline incidents • Gap Assessments	Determine a risk score • Know the business operations • Break down the risk categories • Prioritize	Determine how you will eliminate/monitor the risk • Develop an internal work plan vs. engage an external firm • Monitor and assess? • Determine sampling method and testing techniques

Develop an Audit Plan- Summary

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Thank You!

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