


Building a Quality Assurance Program to Manage the Risk Associated with Investigator-Initiated Studies

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I have no conflicts to disclose

Objectives

A look at our **presentation** agenda

Background



Risk Assessment



Program Organization

Prioritize Initiatives



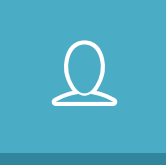
Establish Goals / Objectives



Develop Performance Metrics



Build Relationships



Determine the Scope of Review



Monitoring
Quality Assessments

Prioritize Study Review



Pilot Review Process



Evaluate Review Process



Reform Review Process



Key Points



Conclusion / Reflection



Background

Investigator-Initiated Trials (IITs)

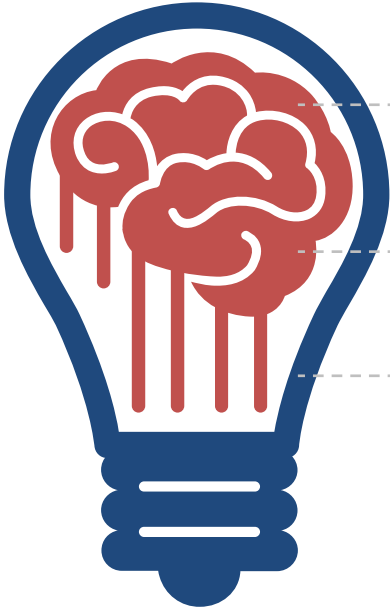
Why Develop a QA Program for IITs?

What are the benefits?

What are the challenges?

Is it worth the investment?

Risk Assessment



Investigational New Drugs (INDs)
Investigational Device Exemptions (IDEs)



IND / IDE Exempt Research
Multi-center
Single-center



Non-interventional Research
Correlative Studies
Chart Reviews
Databases – Repositories

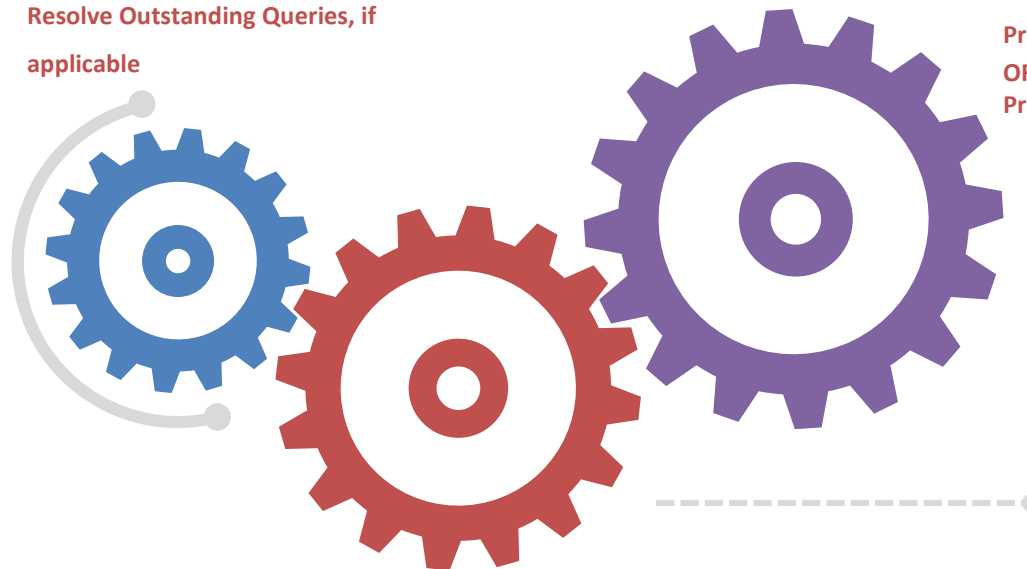
Program Organization

Evaluate Current QA Activities

Resolve Outstanding Queries, if applicable

Devise a Strategic Communication Plan

Program Creation
OR
Program Restructure



Assess Current QA Policies / Procedures / Templates

Update Governing Documents and Templates, if needed

Program Goals / Objectives

Support PI Sponsored Research



Mitigate Risk



Reduce Deviations



Improve Trial Management



Facilitate Innovation



Expand IIT Program



Develop Metrics

- Number of reviews
- Monitoring plan frequency compliance
- Number of observations

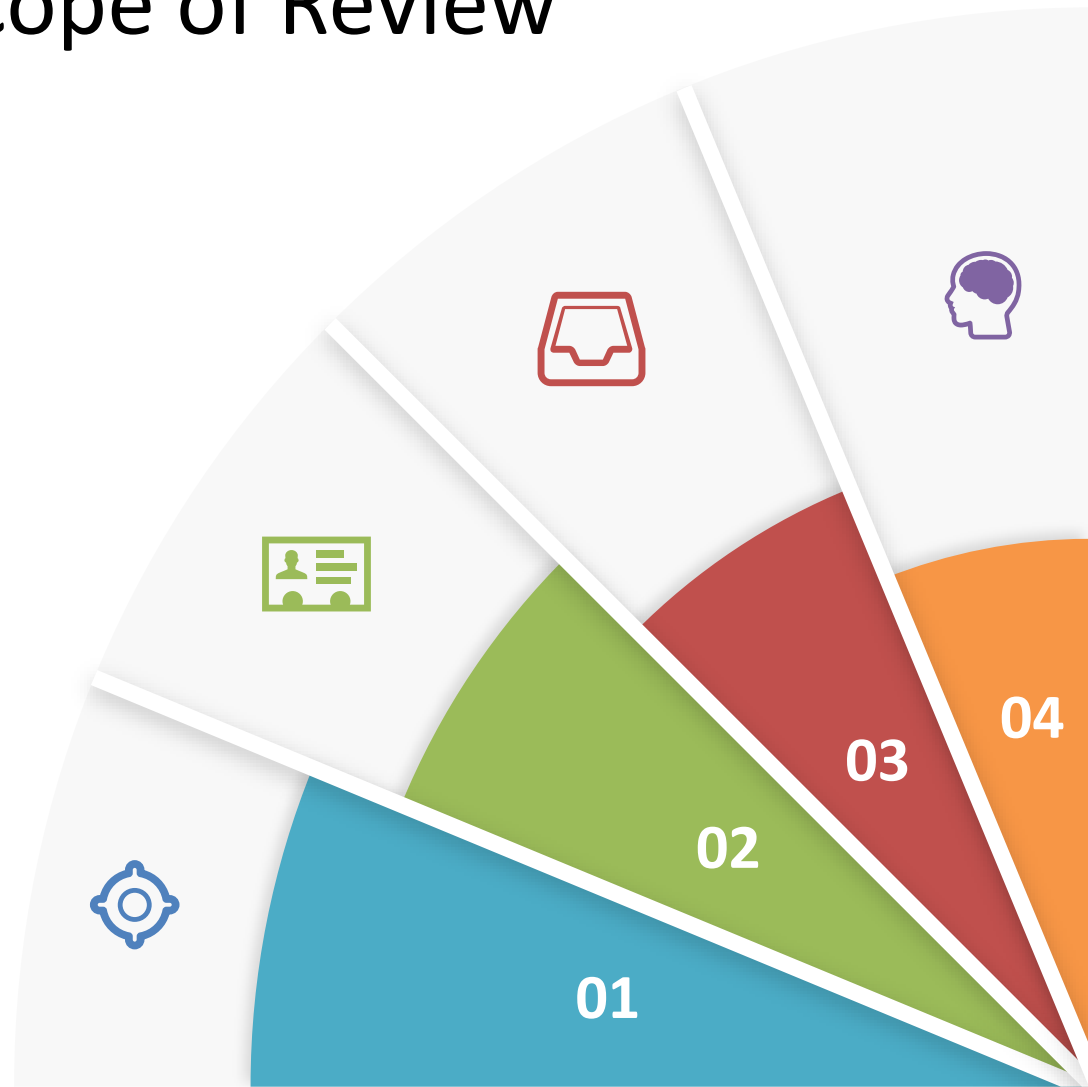


Build Relationships

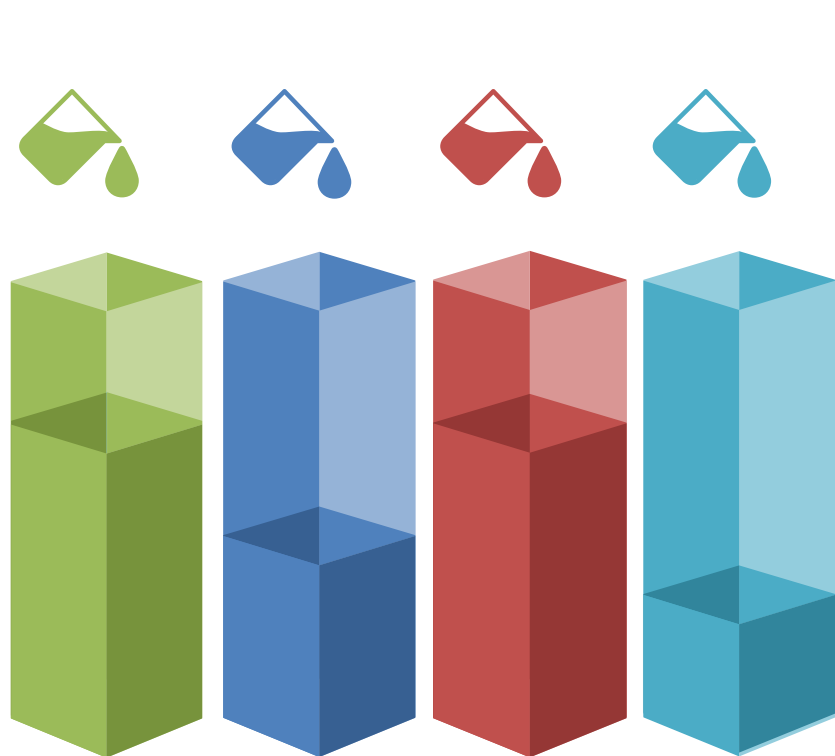






Determine Scope of Review

- Monitoring
- Quality Assessments
- Audits
- Other

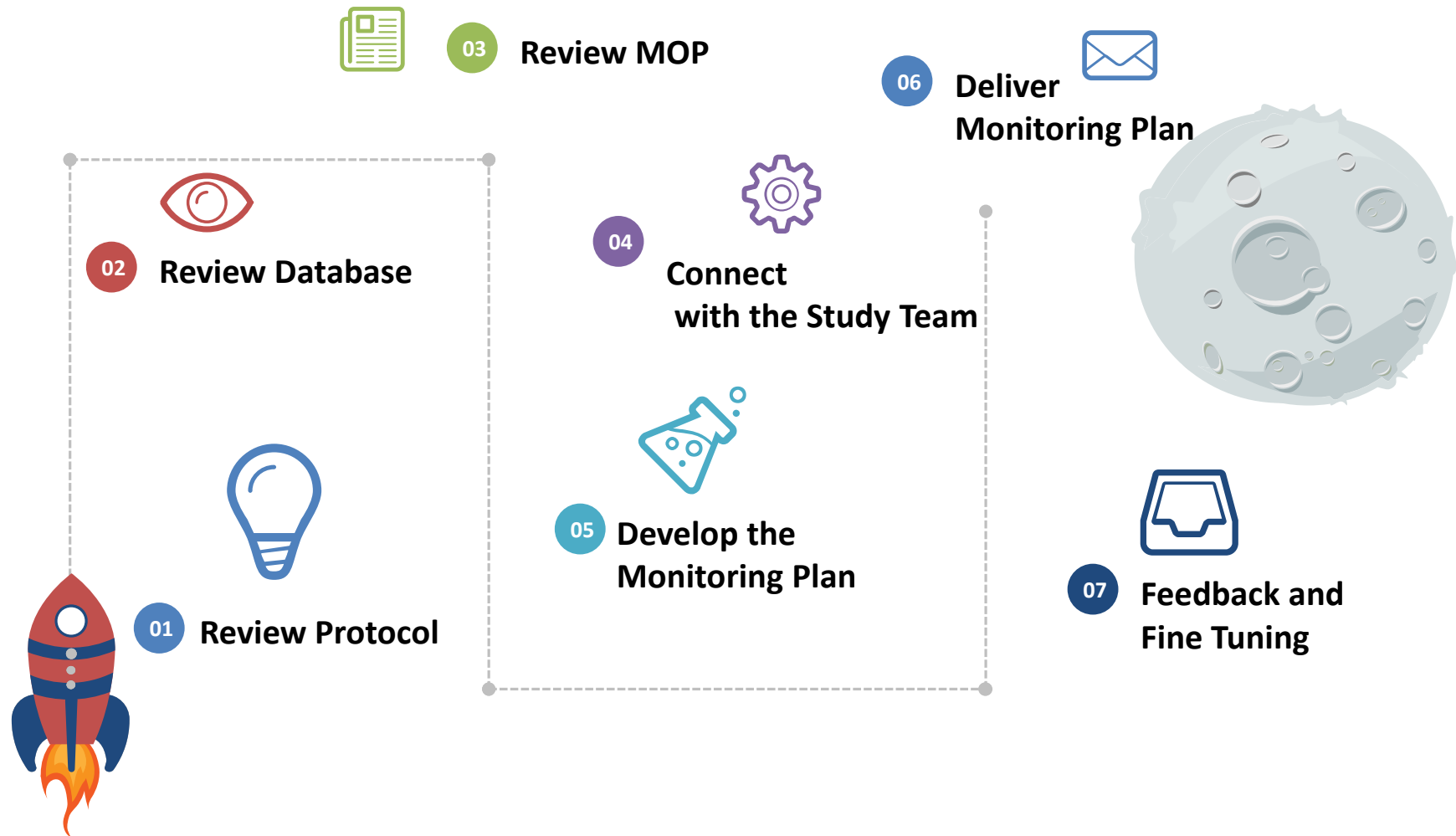


Prioritize Reviews

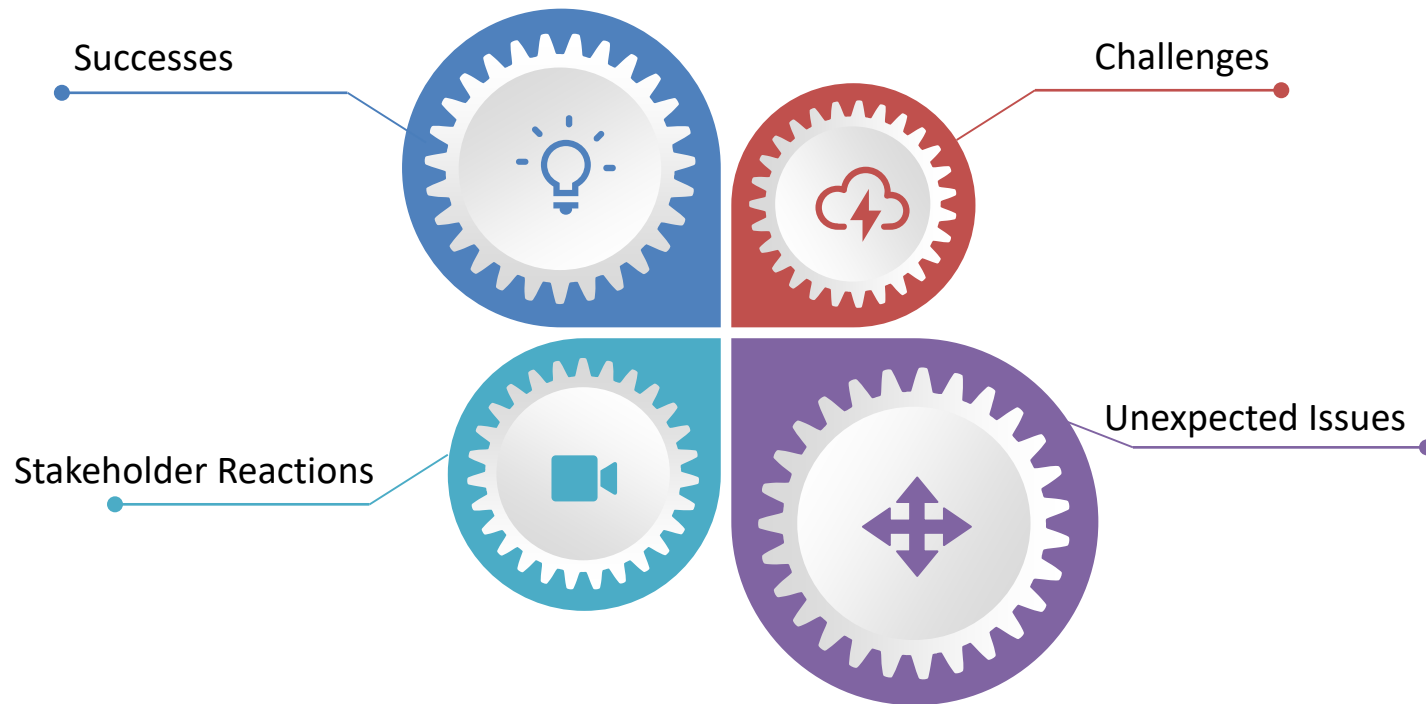


-  **IND / IDEs**
-  **Exempt (IND / IDEs)
- Multicenter**
-  **Exempt (IND / IDEs)
- New Investigator**
-  **IITs sponsored by
Outside Academic Medical Centers**

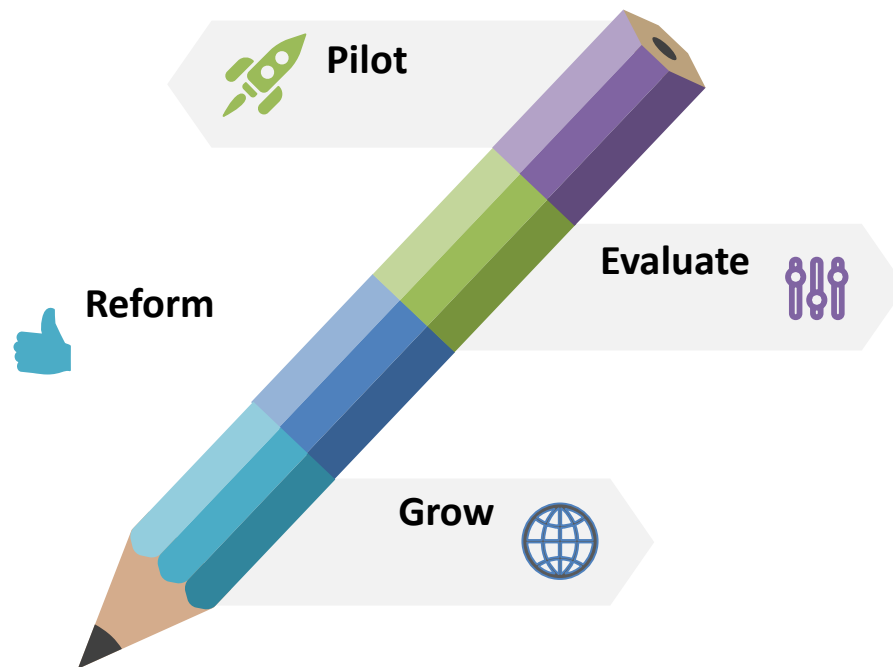
Pilot Review Process – Monitoring



Evaluate Review Process



Reform Review Process



Meet the Needs of the Health System

Change is **POWERFUL**

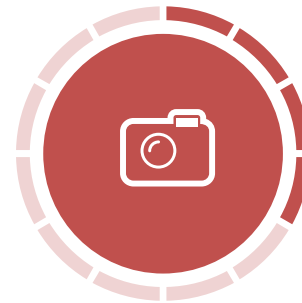
Key Points



Risk Assessment



**Program
Organization**
Goals / Metrics



**Standardized
Review Process**



Adaptability

Conclusion / Reflection

“It Takes a Village”



Thank you!



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