



Rutgers iJOBS: *Successful Management of Life Science Projects*

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Agenda



- Introductions
- Project Lifecycle Integration – Processes and Knowledge Areas with Life Science Requirements
- Project Charter Case Study Exercise – Breakouts
- Wrap-Up



Project Management Institute (PMI)[®]

www.pmi.org

- World-wide advocate for PM profession and best practices
- Global Standards = Common framework
- 8 Credentials
 - Credential maintenance via Continuing Education

PMI New Jersey Chapter (PMINJ)

www.pminj.org

- 3rd largest chapter in the world
- Serves all NJ, > 5500 members

PMINJ Life Sciences LCI*

Mission Statement

To create a forum for project management (PM) professionals with an interest in the Life Sciences (LS) industry** to:

- **Network, collaborate, and share** experiences from managing and/or working on LS project teams
- **Discuss and learn** about topics and activities specific to LS projects, such as validated projects, quality assurance issues, and project execution within a highly regulated environment
- **Educate and share** knowledge about the LS industry with the larger project management community.
- **Act** as champions in support of required project activities related to compliance with FDA or other healthcare-related regulations
- **Mentor, develop, and foster** growth of the next generation of LS project managers
- **Leverage** best practices, tools & techniques from other industries, such as Agile

** *Pharmaceutical, medical device, biotechnology, and healthcare/medical organizations*



*“Life is one big project.
The trick is managing it.”
Dr. Harvey Maylor*

Reference: “Life is a Project: Project Management as an Enabling Life Skill. Neil Robinson, July 12, 2010. IPMA International Project Management Association. Accessible at: www.ipma.world.

Quote from: H. Maylor, Project Management, 4th Edition, 2010.

Definitions

Project*

- Temporary endeavor undertaken to create a unique product, service or result

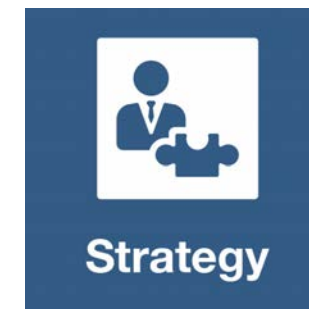
Project Management*

- Application of knowledge, skills, tools & techniques to project activities to meet project requirements

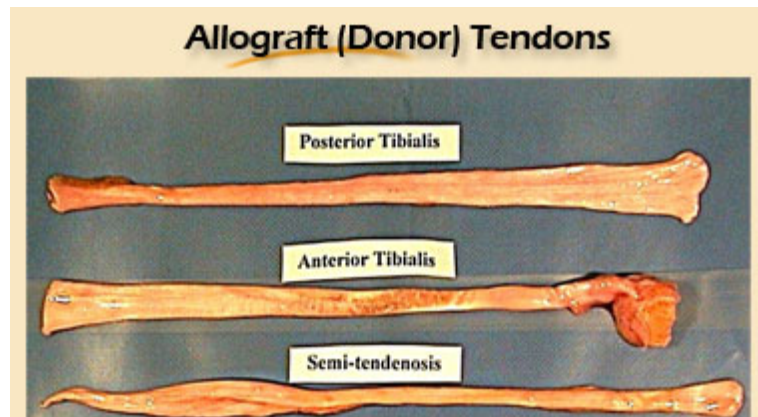
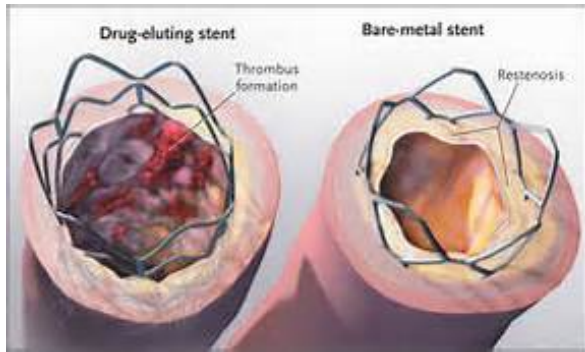
Why Project Management



Provides structure to deliver an outcome (benefit) meeting objectives & stakeholder expectations



Life Science Projects Create:



www.pminj.org



Regulated Industries



Health
Canada

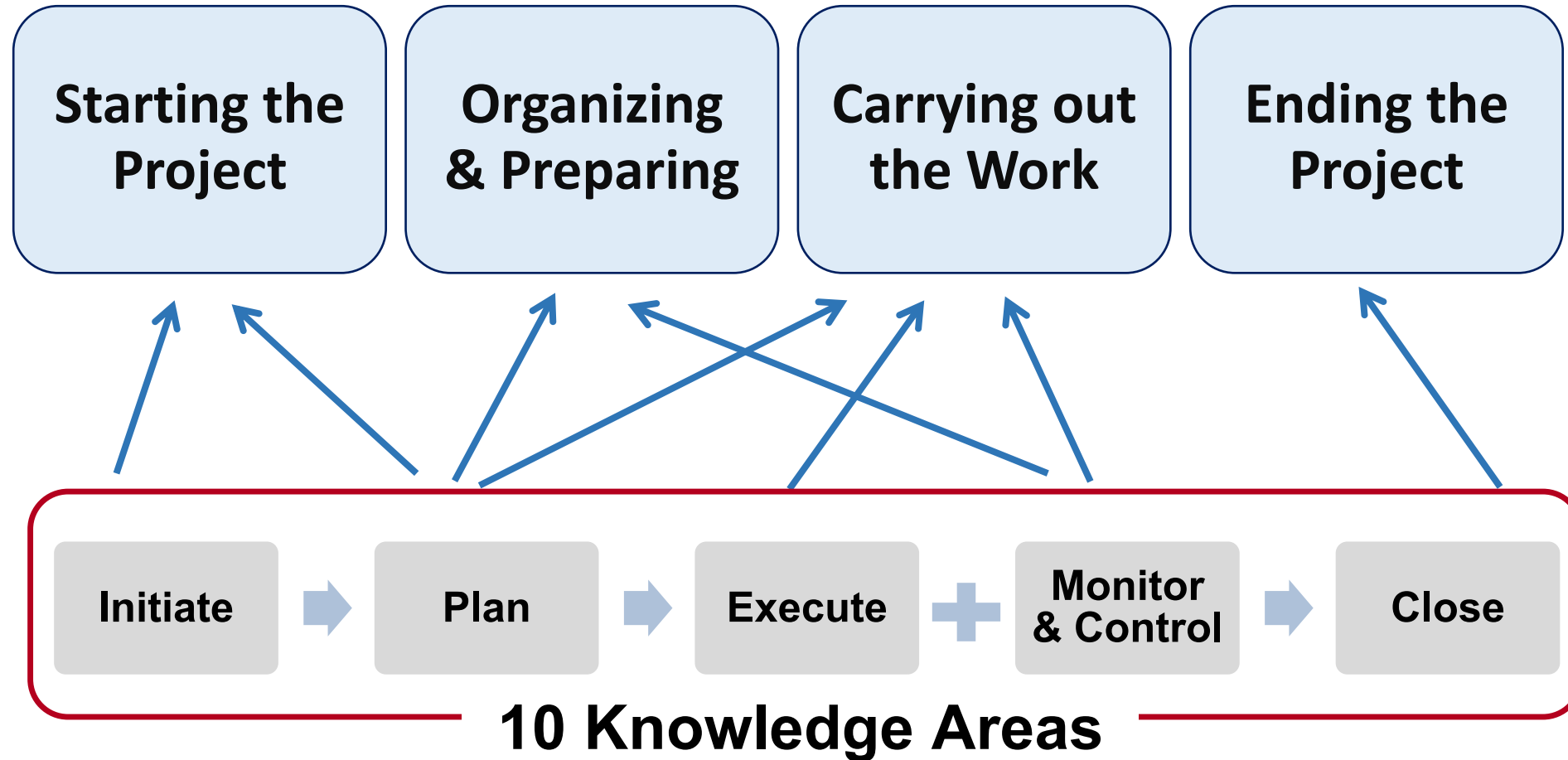
Santé
Canada



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

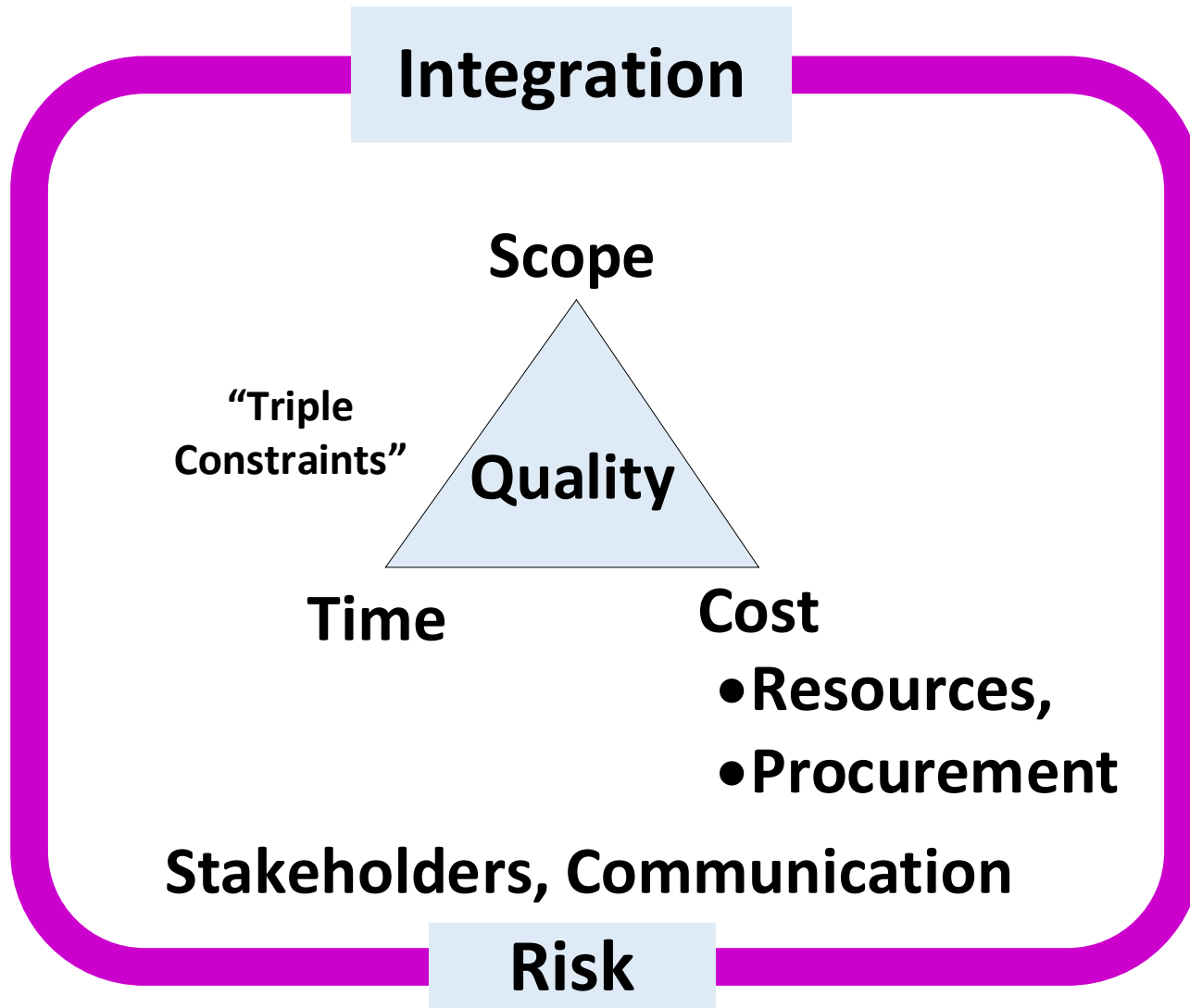
- Ensure safety & efficacy to benefit people (patient, user)
 - And safety for property / environment
- Quality Management System (QMS), localized Regulations and harmonized Standards & Guidances apply

Project Lifecycle & PM Processes Grounded in PM Knowledge Areas



Integration – Scope – Schedule – Cost – Resources – Risk – Quality – Stakeholders – Communications – Procurement

Knowledge Areas Interactions



Integration - Brings it all together!	
Scope	Requirements & work: project & outcome
Schedule	Time
Cost	Budget
Resources	People, equipment, materials, etc.
Quality	KSFs, meeting stakeholder expectations
Risk	Impacts – negative & positive – to project, and outcome’s safety & risks
Communications	Information
Stakeholders	Engage for decisions & roles
Procurement	Purchasing needs, including supplier quality

Pop Quiz!

- Integration of project lifecycle, PM processes and knowledge areas is important because:
 - A: It provides breadth of project activities to manage and stakeholders to engage
 - B: My instructor said so
 - C: It provides structure for project progress
 - D: A & C

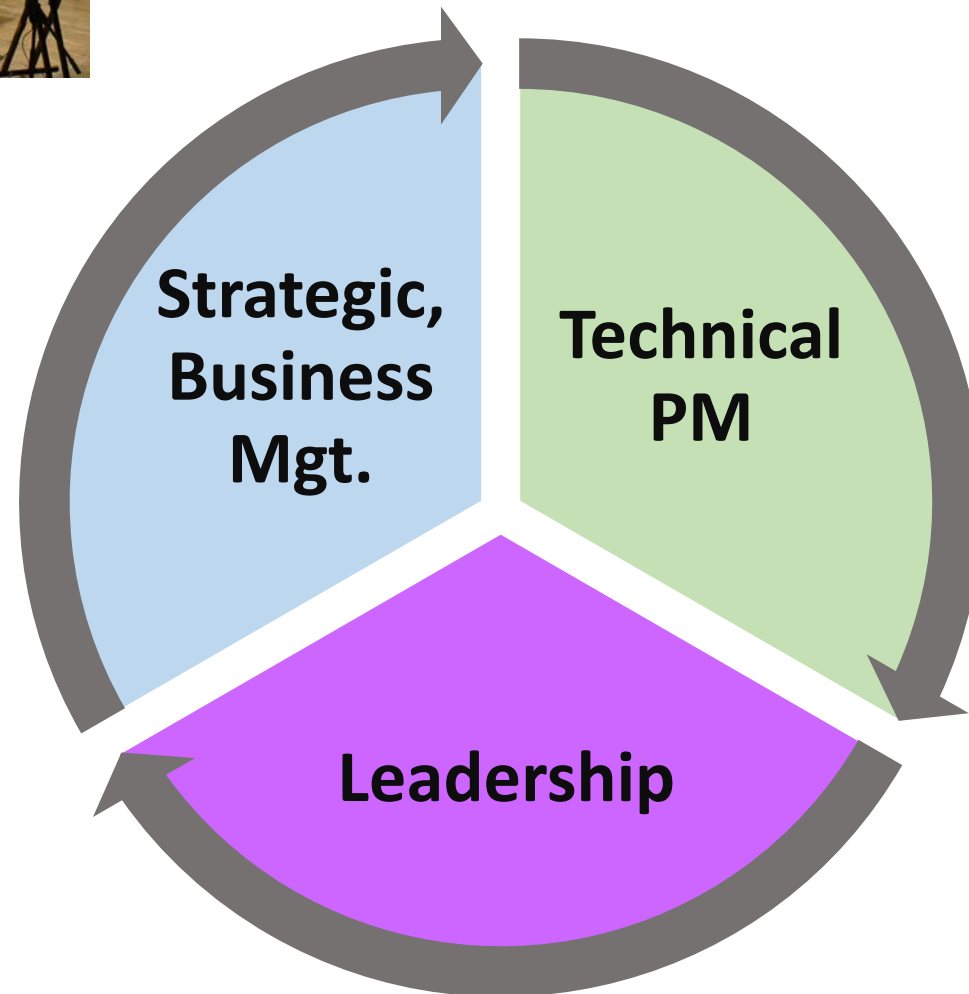
PM's Roles throughout Project Lifecycle



General	Initiate	Execute (Getting Work Done)	Monitor & Control (Project Performance)	Close
Integrates & manages project activities & knowledge areas	Leads team & works with stakeholders to justify project	Manages team and work to meet key objectives and deliverables	Measures performance vs. key objectives	Ensures all deliverables are complete and meet requirements
Communicates; conducts reviews & reports status	Plan (Project's Work)	Track progress & removes obstacles	Monitors risk; works with team to implement mitigations, contingencies	Conducts closing review; ensures stakeholders alignment
Engages stakeholders	Leads team & works with stakeholders to plan project		Controls work and manages changes	
Work with team to updates plans, inputs and outputs			Ensures outputs meets inputs	
Conducts "lessons learned"				



PMI – Key PM Competencies



*Life Science Industry
Expectations:
PM will also have subject
matter expertise and be
knowledgeable in applicable
Regulations & Standards*

Initiating the Project

- Project “Vision”
- Authorizes project, PM, team, objectives
 - Initial plans & justifications



Best Practices

- Kick-off meeting
 - Align on roles before!
- Project Charter (approvals)

PM Project Charter Template (from projectmanagement.com)

Project Name:	<Project Name>
Project Manager:	<Project Manager>
Project Sponsor:	<Name>
Date:	<MM/DD/YYYY>

Project Description: [Use this space to describe the project at a high level.]
Project Background: [Use this space to describe the situation that led to the need for this project. Look at business needs, user needs, and try to quantify challenges.]
Project Objective: [Use this space to describe the specific results you expect to achieve for the business, your sponsor, and known stakeholder groups. The more measurable the better.]
Critical Success Factors: [Use this space to describe the what has to happen in order for the project to be successful.]
Required Resources: [Use this space to describe the required staffing for this project. If some resources are key, highlight them here as well.]
Constraints: [Use this space to describe your assumptions and constraints that you must work within.]
Project Authority: [Use this space to describe roles and responsibilities of each project participant and group.]

Project Charter Approval

Project Sponsor Name: _____

Action: Accept Reject

Project Sponsor Comments: _____

Project Sponsor Signature: _____ Date: _____

Agreement to Secure Required Resources

Approver Names: _____

Roles: _____

Approvers Comments: _____

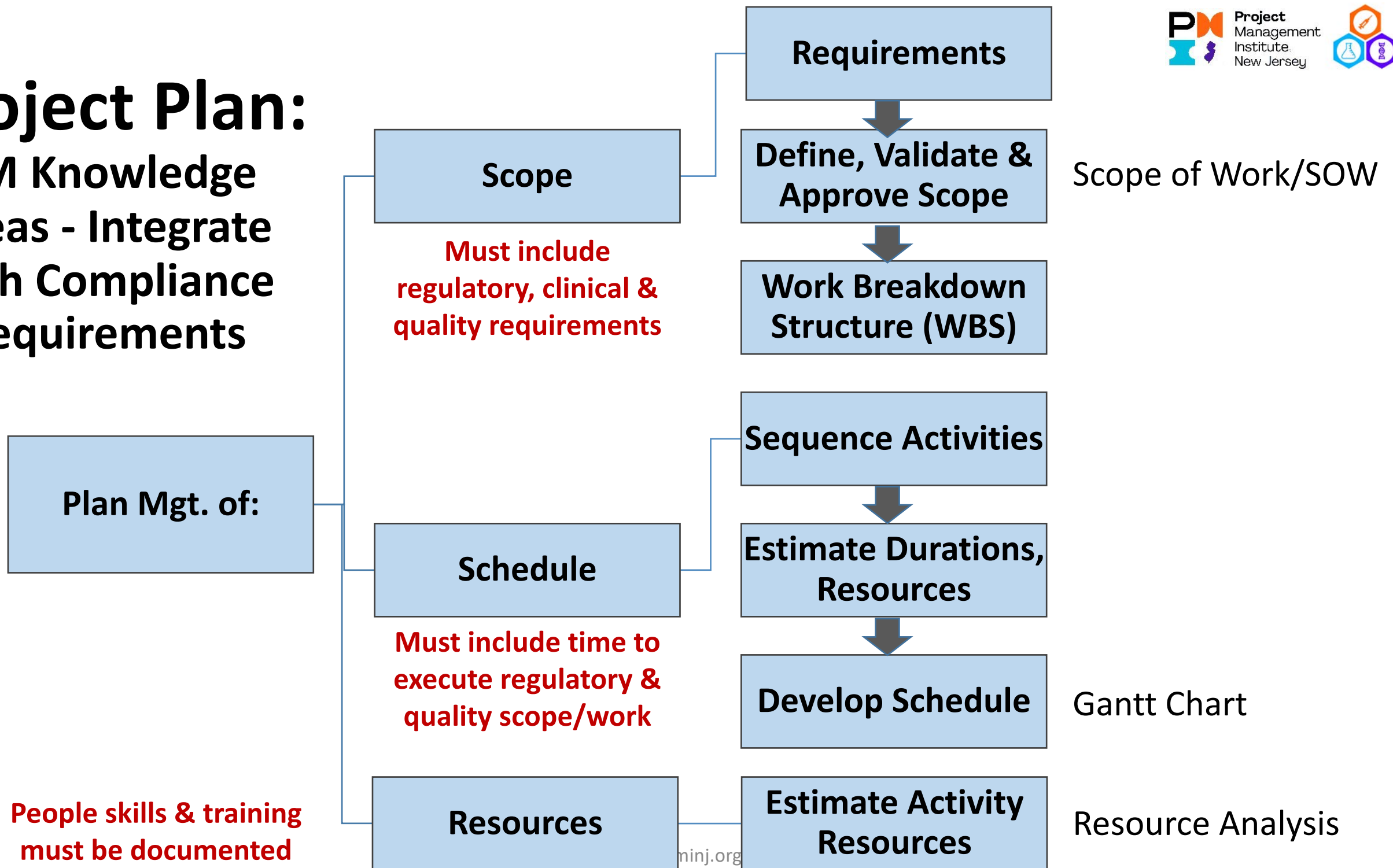
Approver Signature: _____ Date: _____

Breadth of Planning & Integration for Life Science Projects



Project Plan:

PM Knowledge Areas - Integrate with Compliance Requirements

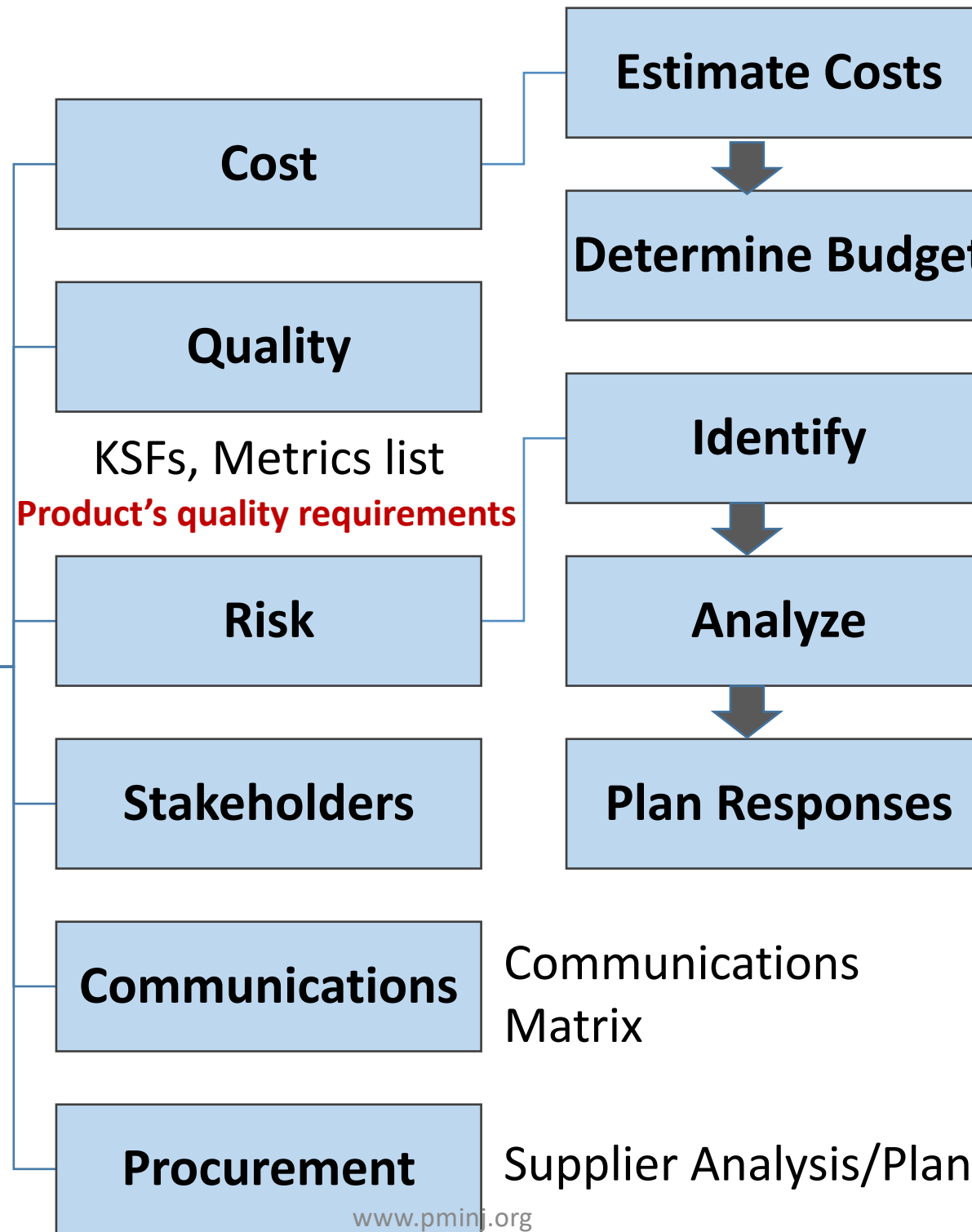


Project Plan: PM Knowledge Areas - Integrate with Compliance Requirements

Plan Mgt. of:

Stakeholder Analysis
(RACI Matrix)

Stakeholders include: users, patients, regulatory bodies, suppliers, strategic partners, more!



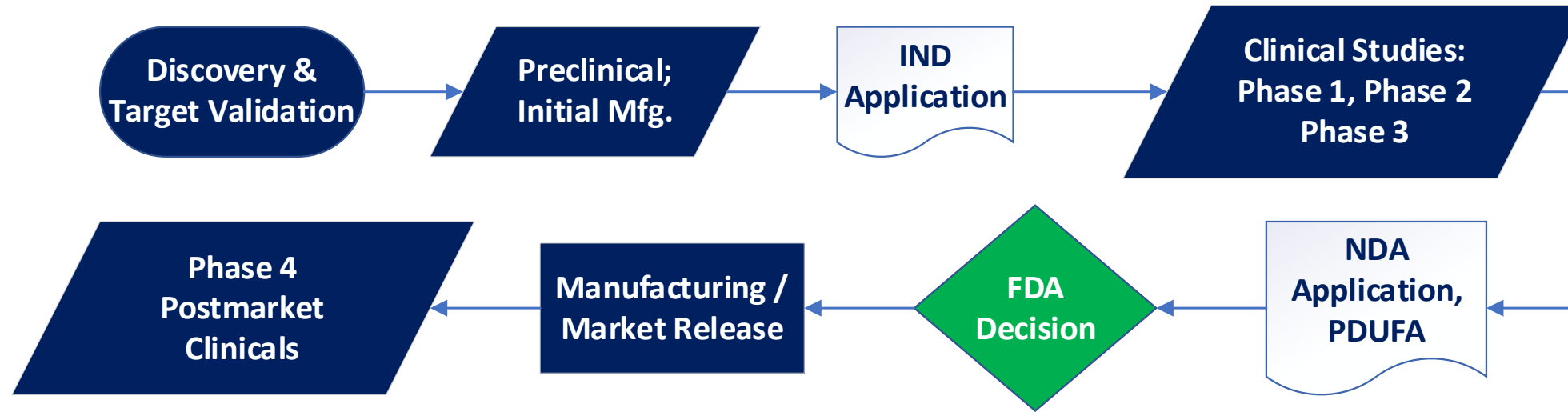
Financial Analysis

Risk Analysis

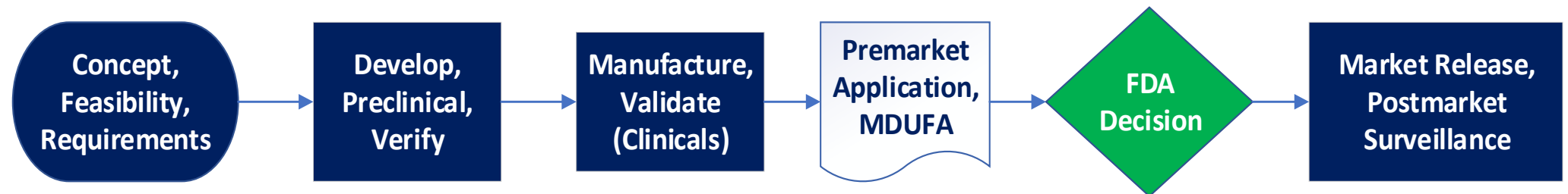
Must manage product risks per applicable Regulations & Standards

Must include supplier quality requirements including audits

Pharma Drug Development Process

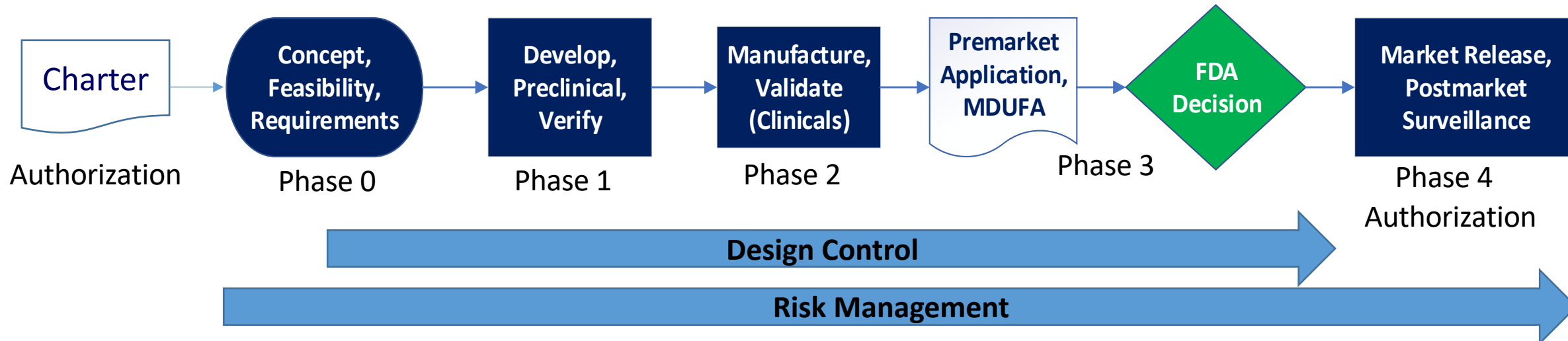


Medical Device Development Process



High level processes for project planning & phases

Ex: Integrating PM Processes with Medical Device Development Process



Updated Project Planning + Execution, Monitoring and Controlling



10 Knowledge Areas

Integration – Scope – Schedule – Cost – Resources – Risk –
 Quality – Stakeholders – Communications – Procurement

Managing the Project



Project Sponsor =
Leadership Project
Champion





Breakout Session

- Groups of 5 or 6 into breakout “rooms”
- Your project: Develop an *in vitro* diagnostic (IVD) device for screening or diagnosis of a disease, condition of your choice
- Use template provided to draft your project charter
- Return to present & discuss with the entire group

Scope and Changes

- Define in-scope and out-of-scope, key success factors & deliverables
- Requirements must be written well
- Integrated Change Management:
 - Obtain justifications
 - Analyze risks
 - Adhere to change control process, avoid “scope creep”!

Change Request

Legitimate business reasons for re-establishing a baseline for a project:

1. Project scope changes
2. Assumptions/Constraints used as a basis for planning have proved false
3. Business priority shifts, and resources / budgets are re-appropriated for a different project

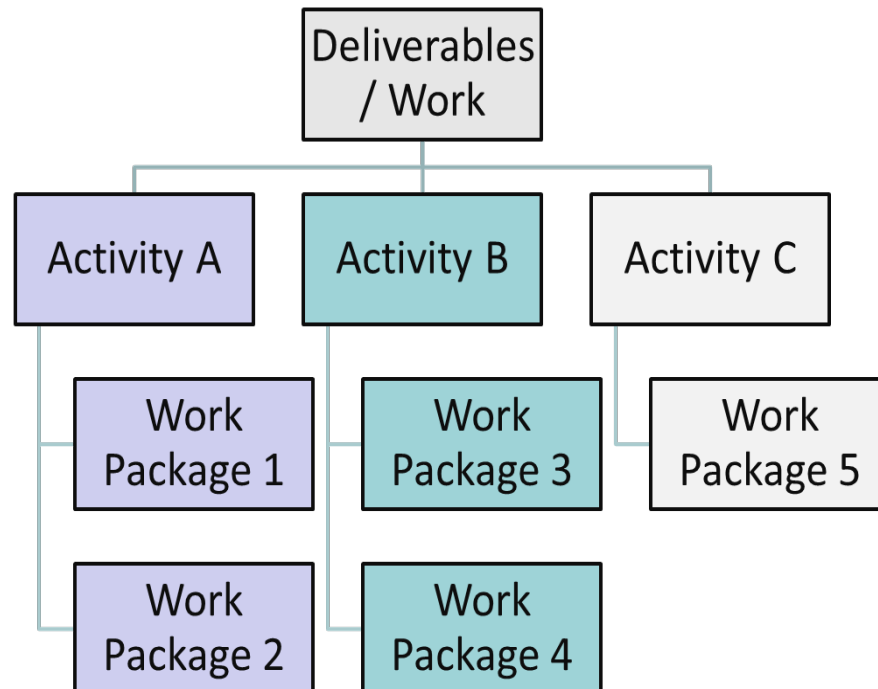
Guidelines in blue should be deleted prior to submission and are meant to aid in preparation of the change request.

Project Name	<i>Common name of the project</i>	Protocol #	
		Date	<i>Doc creation date</i>
Change from:		Change to:	
Change rationale	<i>Reference the criteria for baseline change (#1, 2, or 3 noted above) and include the reason the change is valid (and provide justifying data/analysis if relevant) and should be made.</i>		
Impact	<i>Concisely document the impact of the change. For example, do all downstream milestones change? Is more funding required? Is funding deferred to the next fiscal year? How is project quality to be maintained? Risks to organizational goals & mitigations. etc.</i>		
Requestor signature/date			
Approver signature/date			

Schedule

- Create WBS* with your team to determine tasks and time
- Review, update & report throughout lifecycle

*WBS: Work Breakdown Structure



Define / Sequence

- Determine logical task order
- Coordinate inter-dependencies

Resources & Costs

- People / skill sets, services
- Materials, equipment, tangibles

Duration

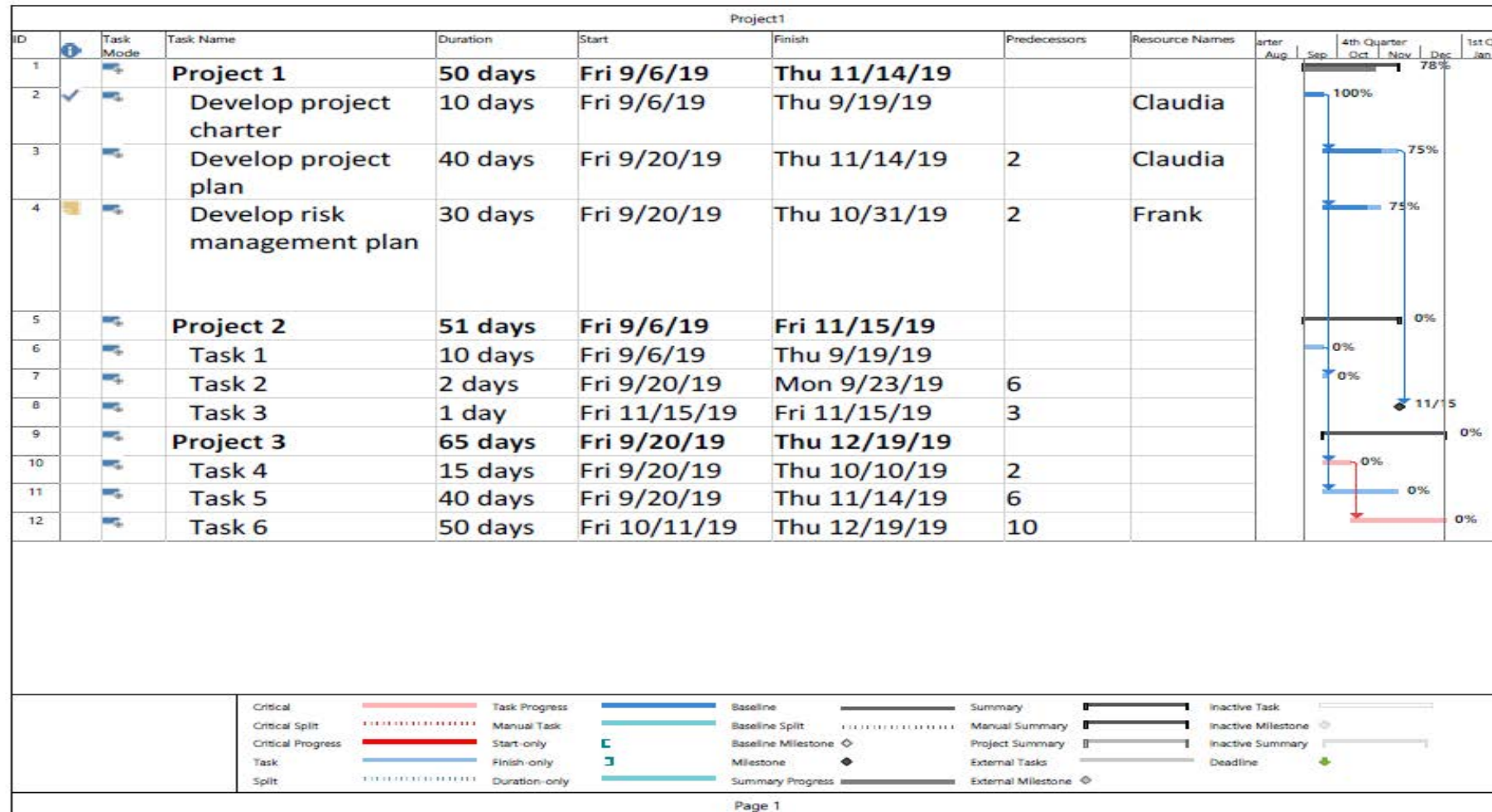
- What can go wrong (risks), e.g., unavailable or delayed predecessors

Estimate

- Historical information
- Expertise (internal / external)
- **Granularity is key!**



Gantt Chart MS Project





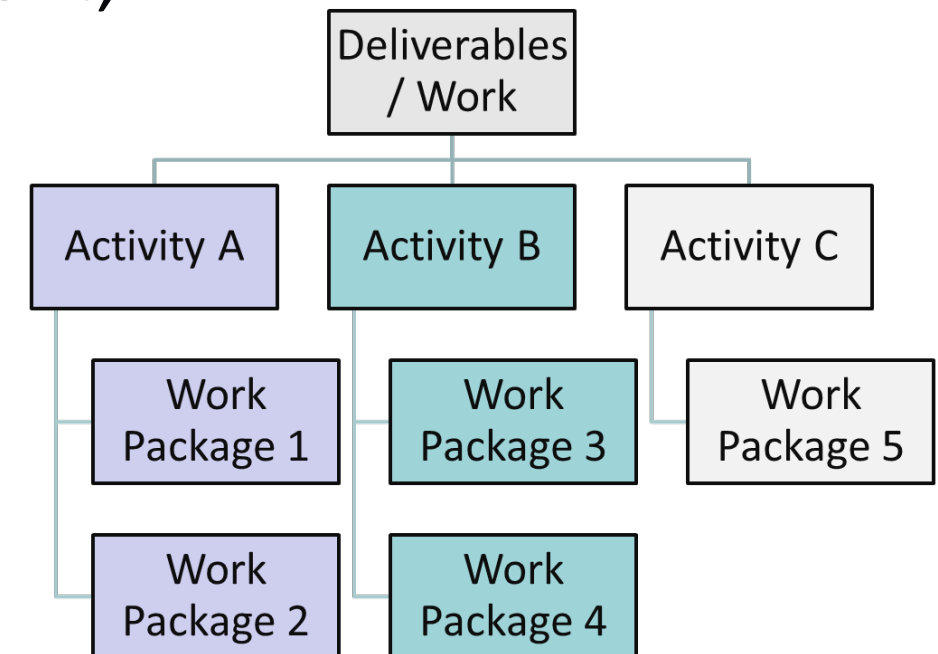
Costs

- Resources: People, Materials, Equipment, other Tangibles, Services
 - Estimate from: previous projects, internal estimates, supplier quotes
- Needs regular reviews, updates, reporting
- Prepare “cases” with risks & rationales
 - Don’t pad!
- Challenge assumptions



Human Resources: The Team

- Evolves throughout project lifecycle
 - Needs buy-in from functional management, Sponsor and Leadership
- What people / skills are needed?
 - When, how long? In-house?
 - What is competing for their time?
- Review, update and report on costs & strategies throughout lifecycle



Procurement

- Part of budget / costs determination
 - Determine needs (including resources) and purchasing approaches
- Ensure scope, deliverables, responsibilities, exit terms are clearly defined and approved
- Understand supplier processes
- Plan for risks & quality per regulatory requirements
- Review, update & report on throughout lifecycle
- Consider strategies throughout project



Project Quality Management: Meeting Requirements and Stakeholder Expectations

Organization
Quality Mgt. System
& Quality Policy

Stakeholder
Expectations,
Requirements

Project Quality
Attributes:

How?

- Re-verify & manage stakeholder expectations throughout lifecycle
- Ensure KSFs & metrics are defined and reviewed regularly to assess project performance
- Ensure quality efforts, including lessons learned, have adequate time in the schedule

- Systematic approach
- Transparency about issues
- Authenticity in relationship
- Regular & effective communications
- Continuous improvement mindset
(These are also PM attributes!)

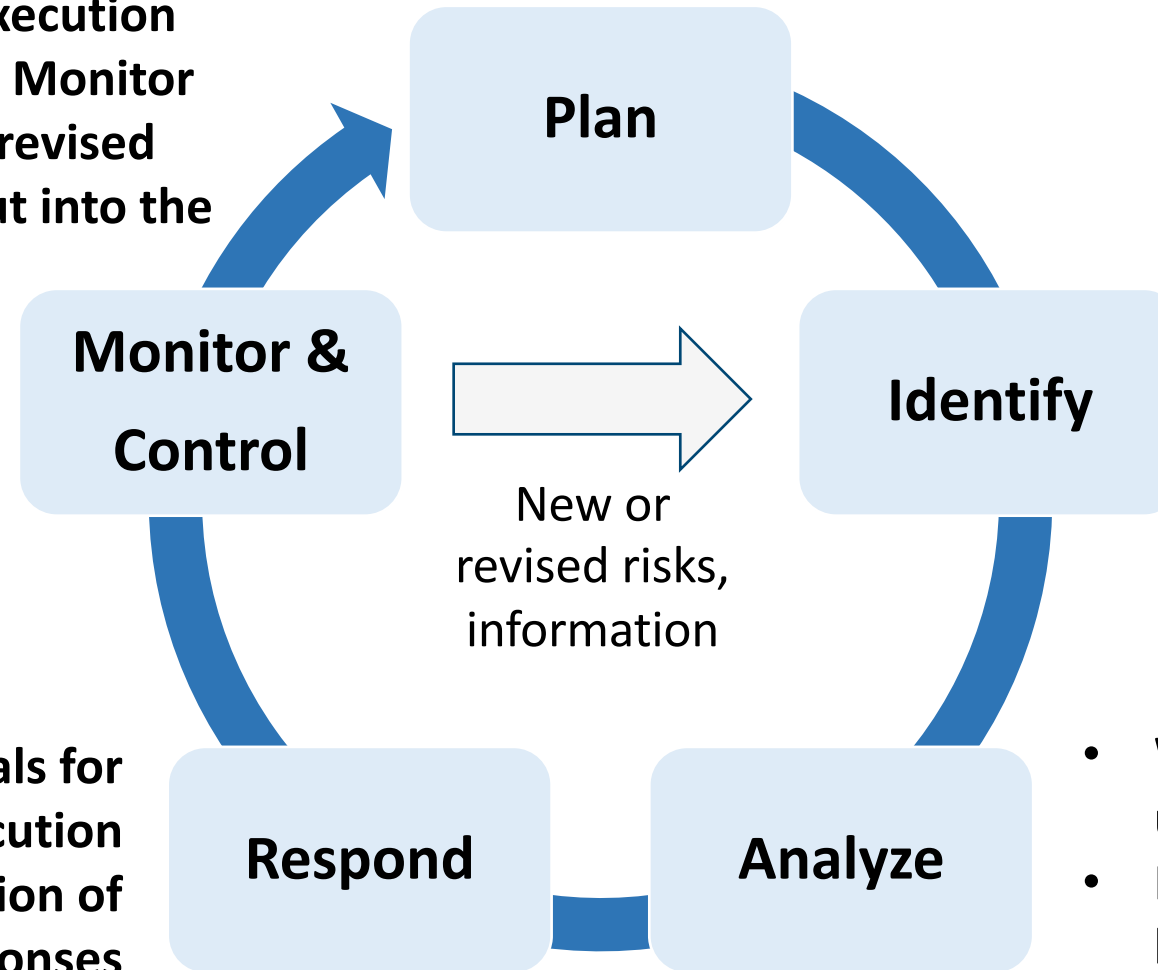
Project Risk Management

Negative and Positive Impacts

Key: Use as an iterative lifecycle process!

- When: Execution
- Includes: Monitor for new/ revised risks – put into the process

- When: Project planning
- Includes: Escalation pathway & Change control process



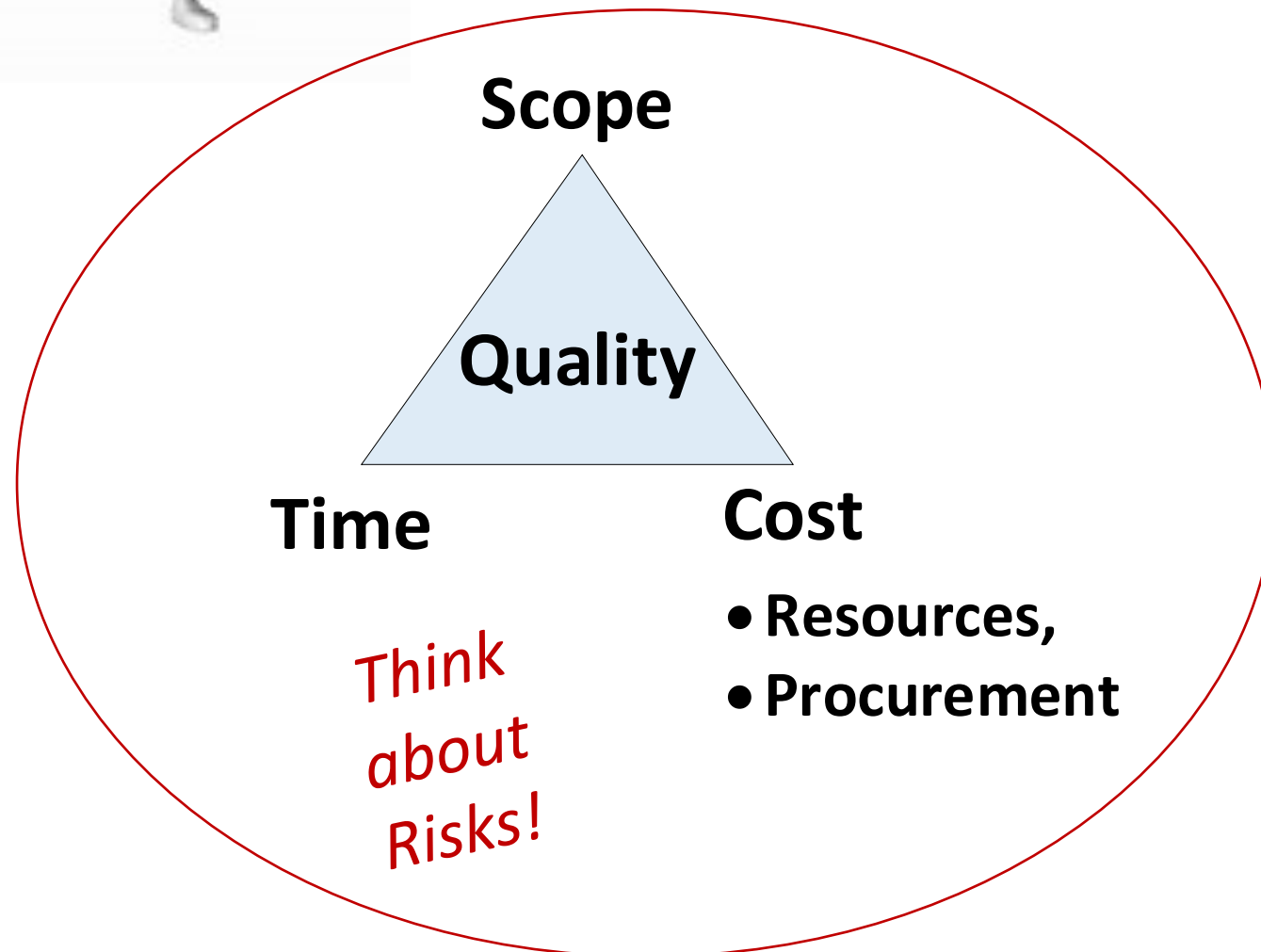
- When: Project planning, update in Execution
- Includes: Risk sources & triggers

- When: Project planning – gain approvals for response plans; Update plans in Execution
 - Includes: Effectiveness verification of executed responses

- When: Project planning, update in Execution
- Includes: Estimate impact level & likelihood to occur, then prioritize



Balancing the Triple Constraints and Fulfilling Quality



Less Time

- Reduce Scope
- Add Resources

Bigger Scope

- Add Time
- Add Resources (and Cost)

Less Budget

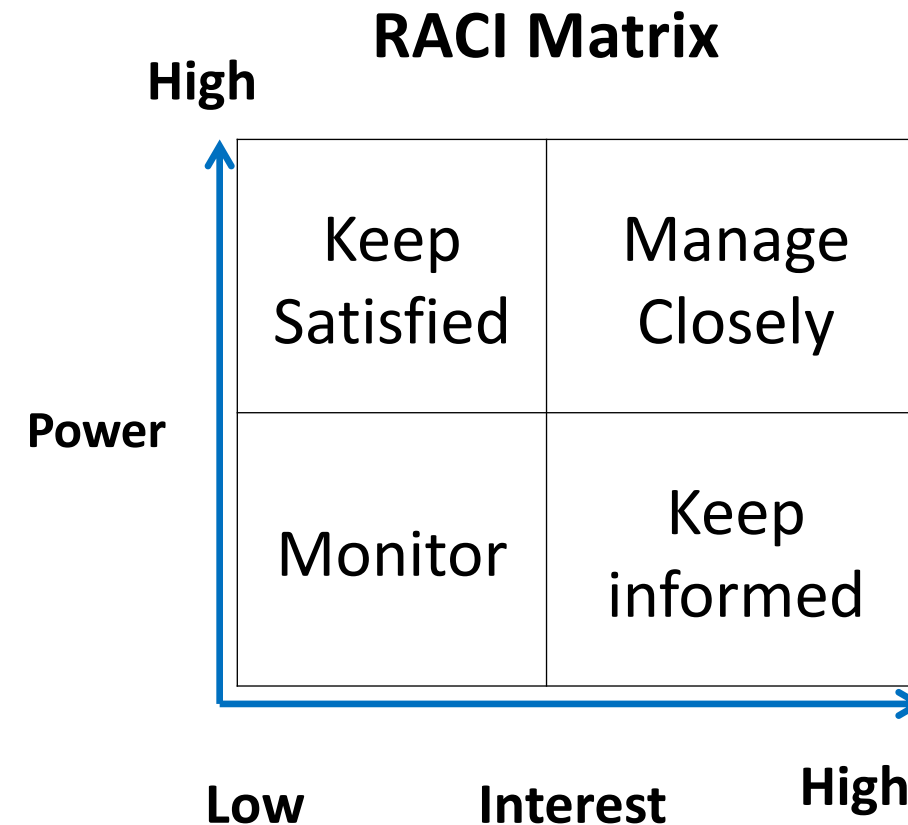
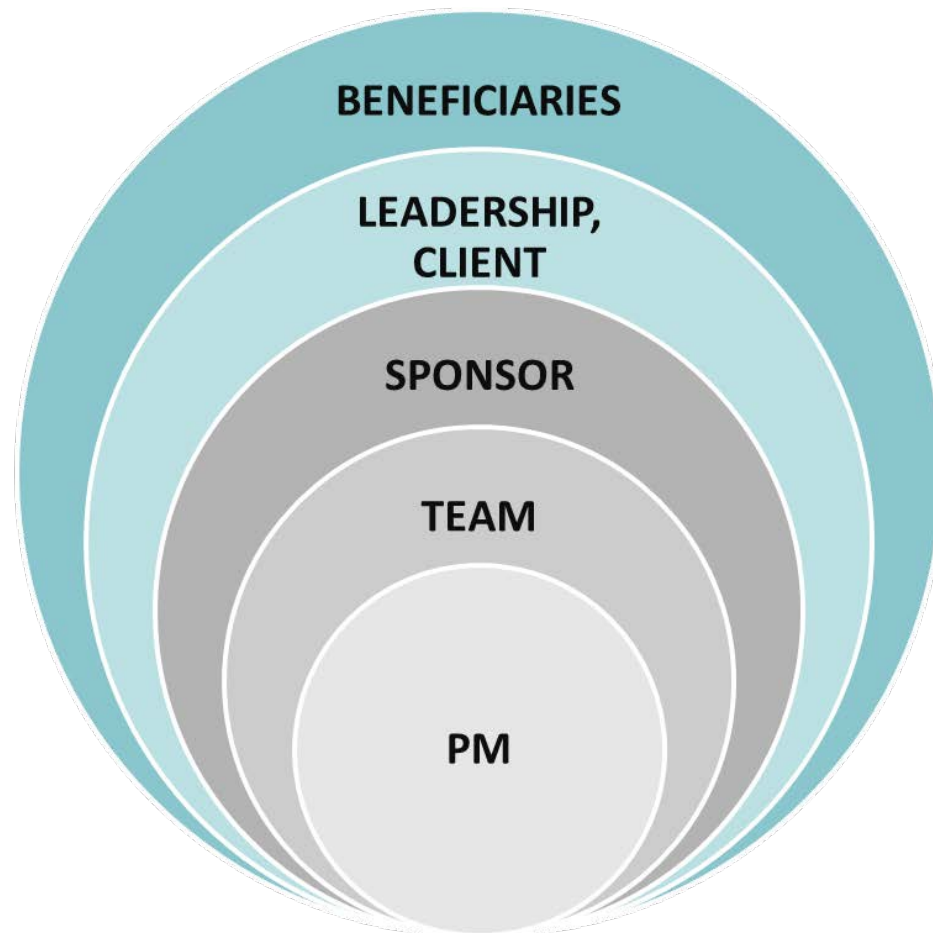
- Reduce Scope
- Reduce Resources (Adds Time)

Why do Projects Fail?

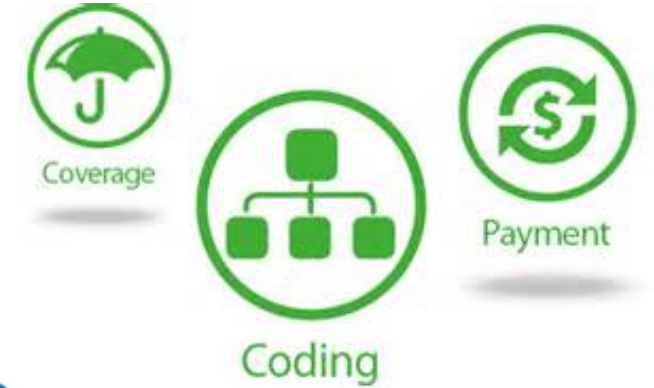


- PM lifecycle processes & tools not used, or not used effectively
 - Objectives / knowledge areas management
 - Ex: Lack of change management
- Misalignment of strategic goals
- Lack of common understanding

Stakeholder Identification & Analysis



Stakeholders beyond the Organization for Life Science Products



Engaging & Communicating with Stakeholders

- Communications: Who, when, how, frequency, for what purposes, using what tools?
- Ensure they know what is needed from them and when
- Evaluate & plan, including risks
- Build & maintain relationships
- Lifecycle 360 engagement – don't underestimate effort
- *Remember we're all human!*

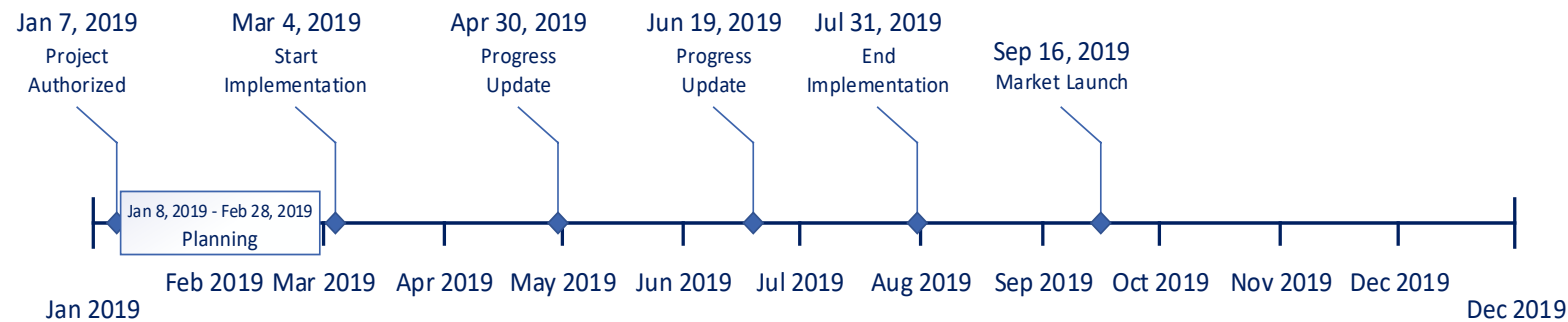
Communications Matrix Example


Meeting	Type	Frequency	Topics	Attendees	Lead
Project Kick-off					
Team Meetings					
Phase Gate Reviews					
Project Close-out					



Governance & Status Reviews

- *Engage your team for preparations!*
- Report progress & risks vs. objectives, metrics
- Enlist your manager and/or Project Sponsor for guidance/coaching in difficult situations
- Use visual, easy to understand tools & methods



Project Lead	% Complete	Next Steps	Risk Level	Risks	Potential Mitigations
					



Pop Quiz!

- Leading a project, managing your team and engaging stakeholders:
 - A: Requires hard & soft skills
 - B: Requires regular communications and different communication methods
 - C: Requires building relationships across all levels of an organization or across organizations
 - D: Can be like herding cats!
 - E: All of the above

Summary

- Project Management is art & science - requires soft & hard skills
 - Build relationships with all levels of stakeholders
 - Regular communication is key
 - Don't operate in a silo
 - Hold team members accountable & responsible for their work, but also be ready to jump in if needed
- Being a PM can be frustrating at times, but is also incredibly rewarding – enjoy the journey and challenge yourself to grow

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Thank You