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Rutgers iJOBS: Successful Management of Life Science Projects

October 23, 2019 - PMI-New Jersey Life Sciences LCI:
Claudia Campbell-Matland, PMP
Reza Tehrani, PMP

Agenda

- Introductions
- Review case study exercises
- Module 1: Project Integration & Planning - Lifecycle, Processes, Knowledge Areas
  - Exercise 1: Project Charter
- Module 2: Stakeholders – Engagement & Communications
  - Exercise 2: Stakeholder Analysis
- Module 3: Risk Management
  - Exercise 3: Risk Analysis
- Wrap-Up

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Case Study Exercises

- Attendees break up into groups of 5 or 6
- Work through the high-level case study exercises and present & discuss
- Each group given 1 of these case studies
    - Develop a next-generation point of care testing device
    - Develop a new medical imaging center
- Work on exercises using templates to:
    - Develop brief list of inputs for project charter
    - Determine stakeholder categorizations
    - Develop brief list of a few key areas needing risk analysis

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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 www.pminj.org

- 2nd largest chapter in the world
- Serves all NJ, > 5500 members

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PMINJ Life Sciences LCI (Local Community of Interest) Mission Statement

To create a forum for 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

** The LS industry is intended to include pharmaceutical, medical device, biotechnology, and healthcare/medical organizations*

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Module 1
Project Integration & Planning: Lifecycle, Processes, Knowledge Areas

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"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.

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Definitions

Project*	Project Management*
• Temporary endeavor undertaken to create a unique product, service or result	• Application of knowledge, skills, tools & techniques to project activities to meet project requirements

*PMI PMBOK® 6th Ed.

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Why Project Management

Provides structure to deliver an outcome meeting objectives & stakeholder expectations

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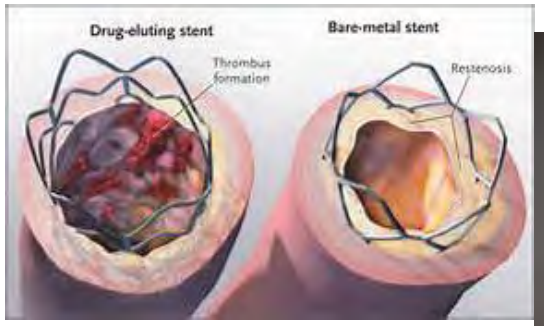
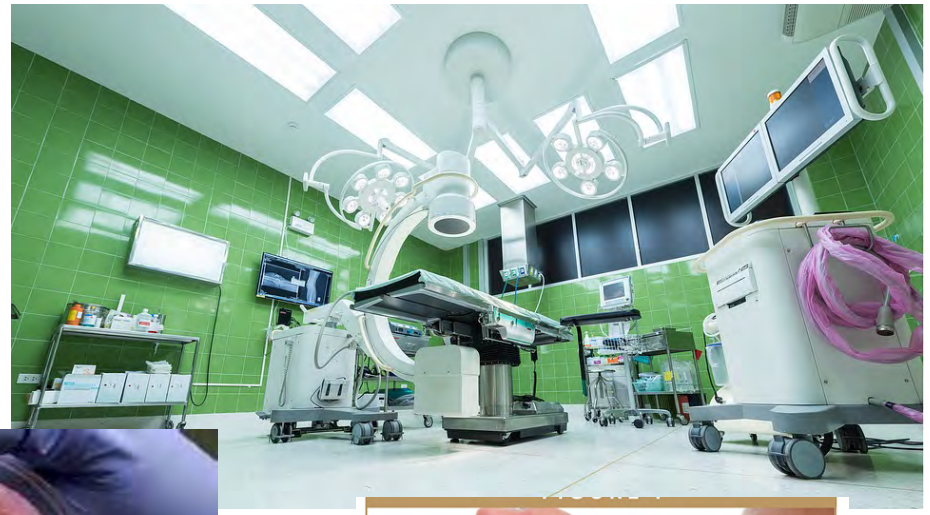
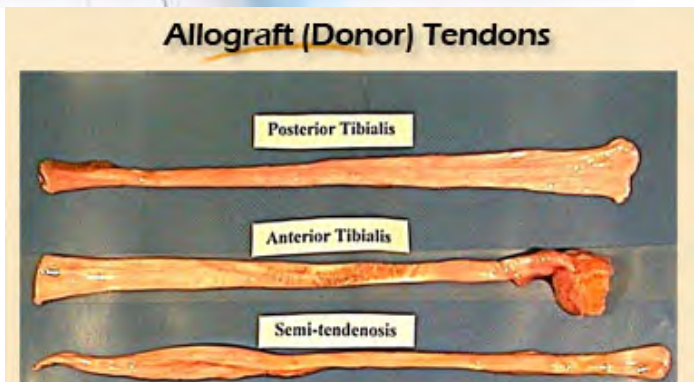
Life Science Projects Create:







Regulated Industries

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

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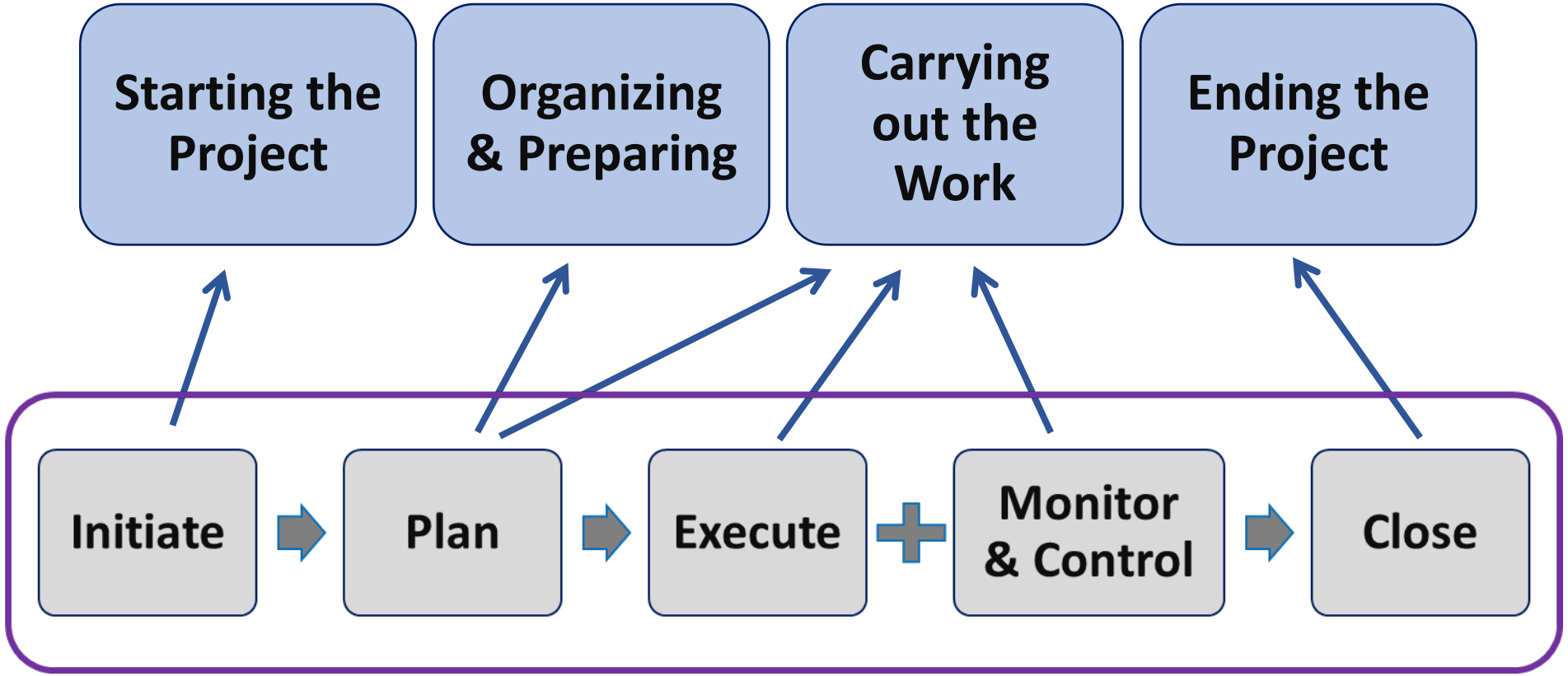
Project Lifecycle & PM Processes



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

Adapted from PMBOK 6thEd. Figure 1.5

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PM "Knowledge Areas"

Project Integration

Area/Objective	Managing …
Scope	Required work – project & outcome
Schedule	Project time
Cost	Project budget
Resources	People (and materials, equipment, services)
Quality	Success factors, metrics – project & outcome
Risk	Impacts to objectives – project & outcome
Communications	Project information
Stakeholders	Engagement for project execution & decisions
Procurement	Project's purchasing needs

Red = 6 Project Objectives / "Knowledge Areas"
Blue = 3 additional "Knowledge Areas"
10th Knowledge Area is Integration
Note: Full definitions at end of this presentation

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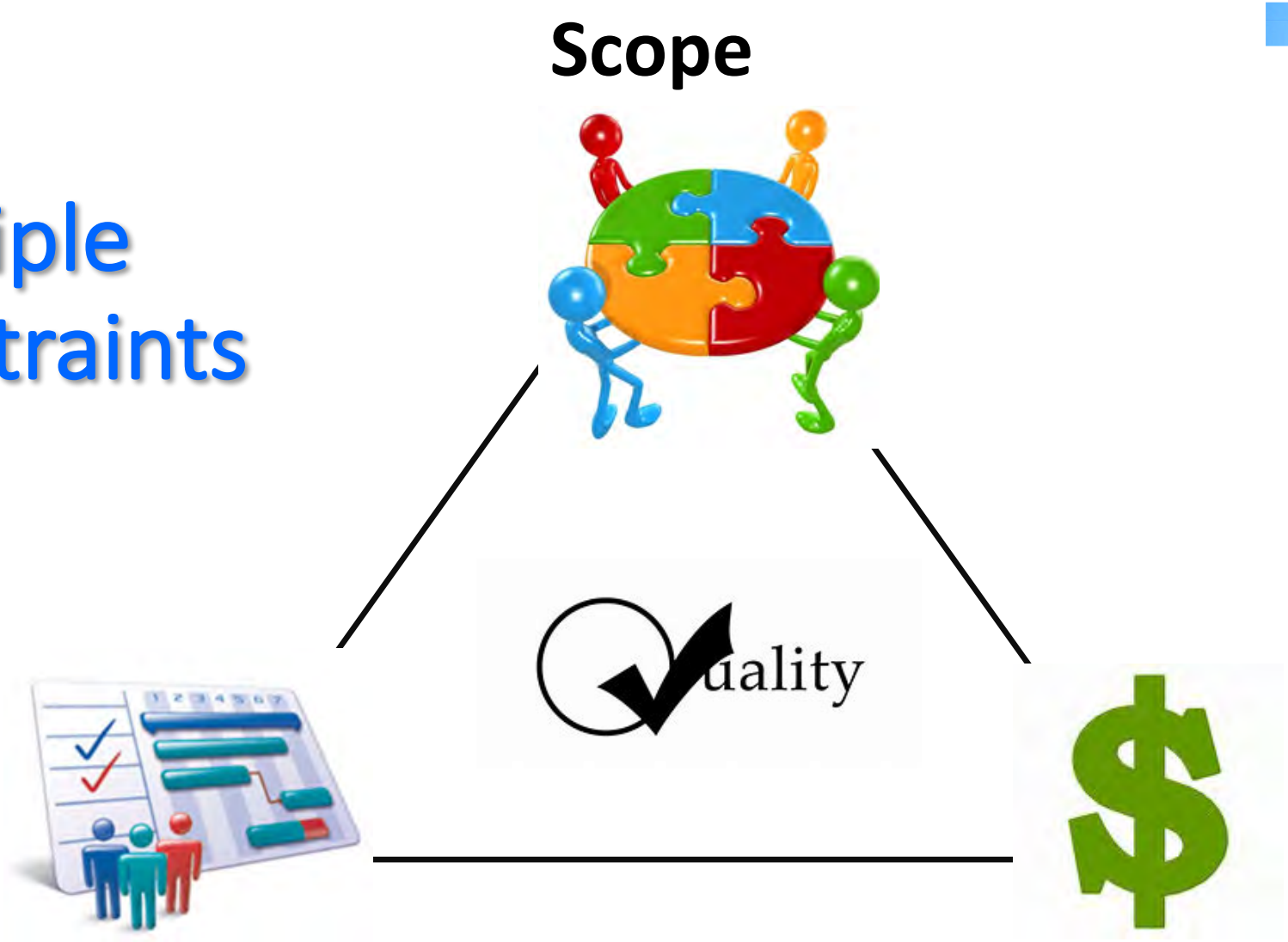
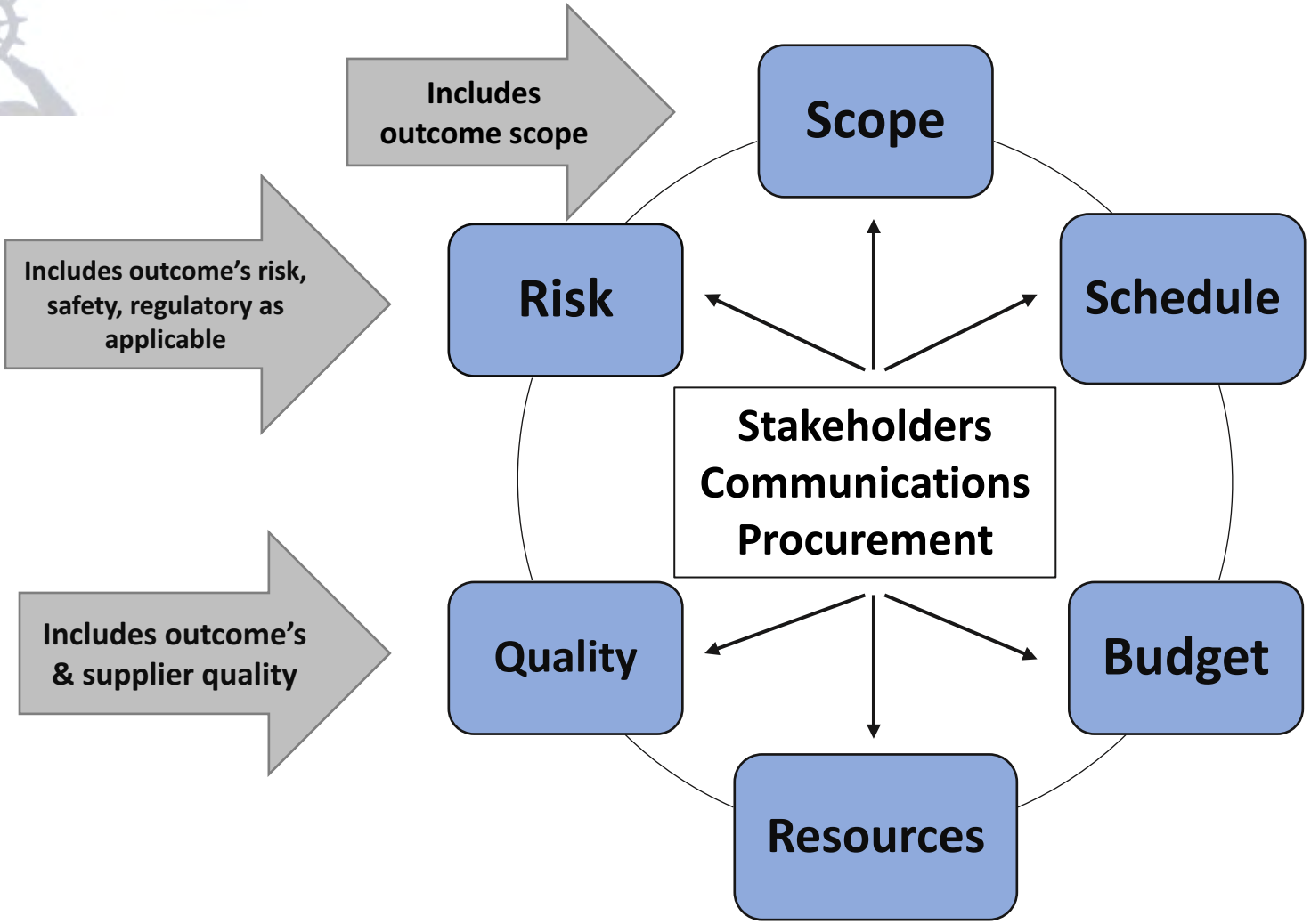
Triple Constraints

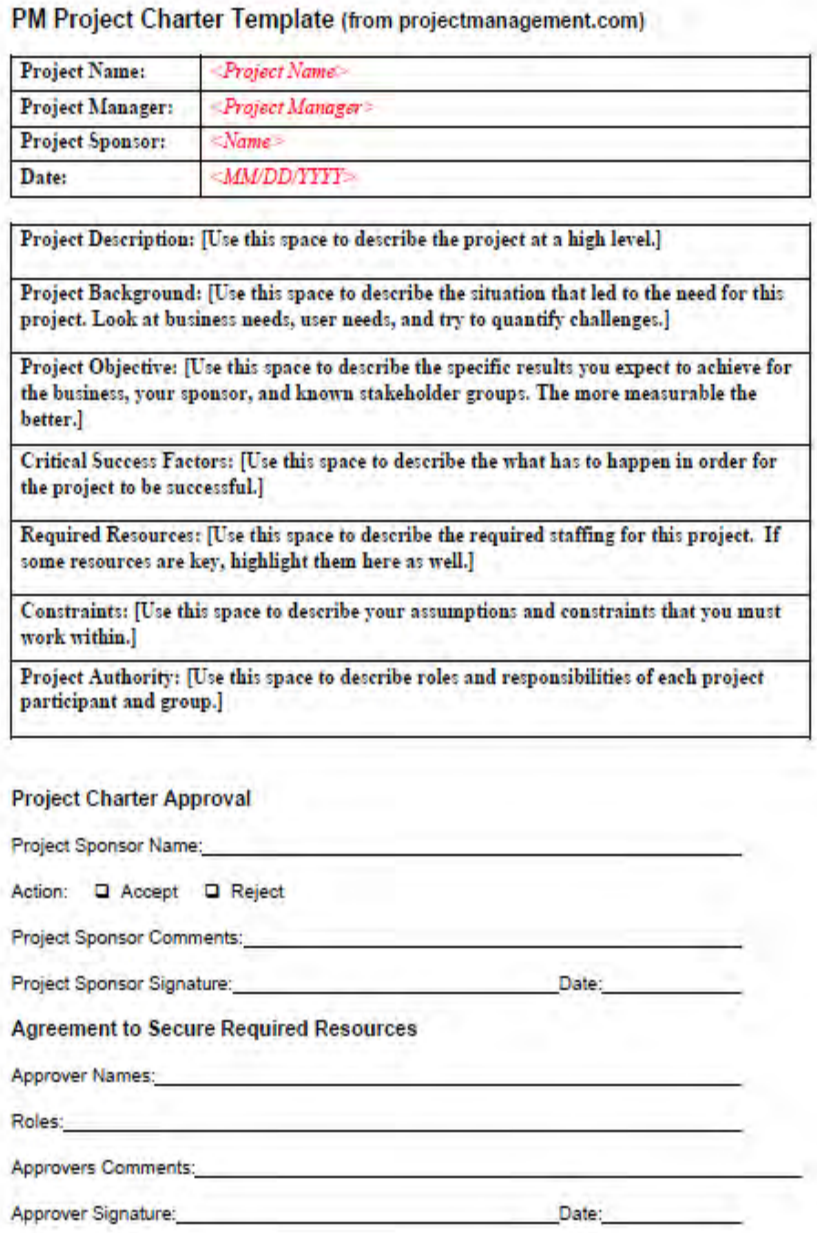


Project Objectives



Initiating the Project

- Authorize project, PM, team, objectives, with project justification
- Best practice: Project "Charter"
  - Authorization document with 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:_____

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Area/Objective	Planning Examples
Scope	SOW (Scope of Work)
Schedule	Schedule (e.g., Gantt chart)
Cost	Financial Analysis
Resources	Resource Analysis
Quality	Success Factors, Metrics list
Risk	Risk Analysis
Communications	Communications matrix
Stakeholders	Stakeholder (RACI) Matrix
Procurement	Supplier Analysis / Plan

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Breadth of Planning & Integration for LS Projects

IP

R&D

Clinical

Quality

Technical/ Customer Support

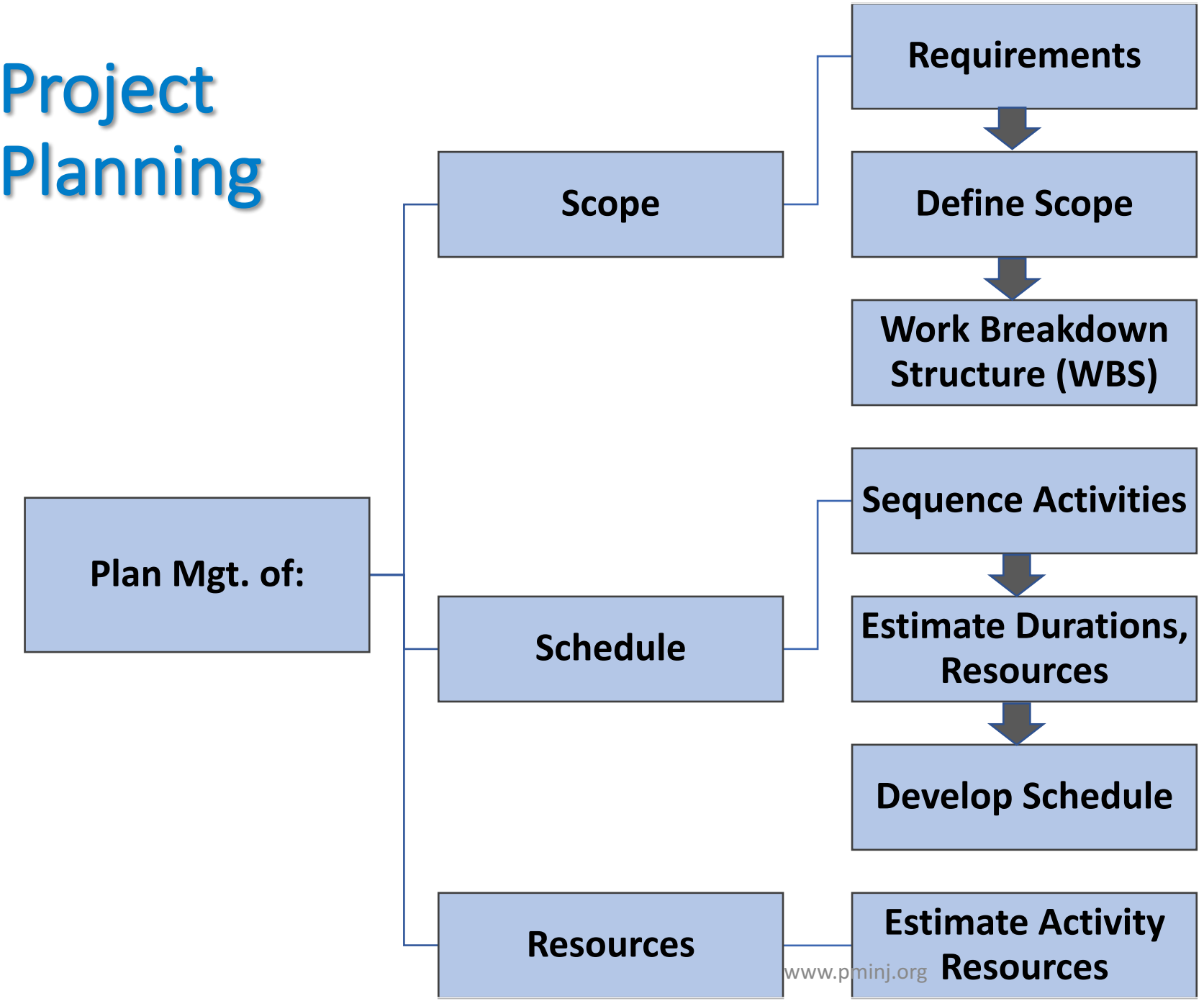
Regulatory

Supply Chain

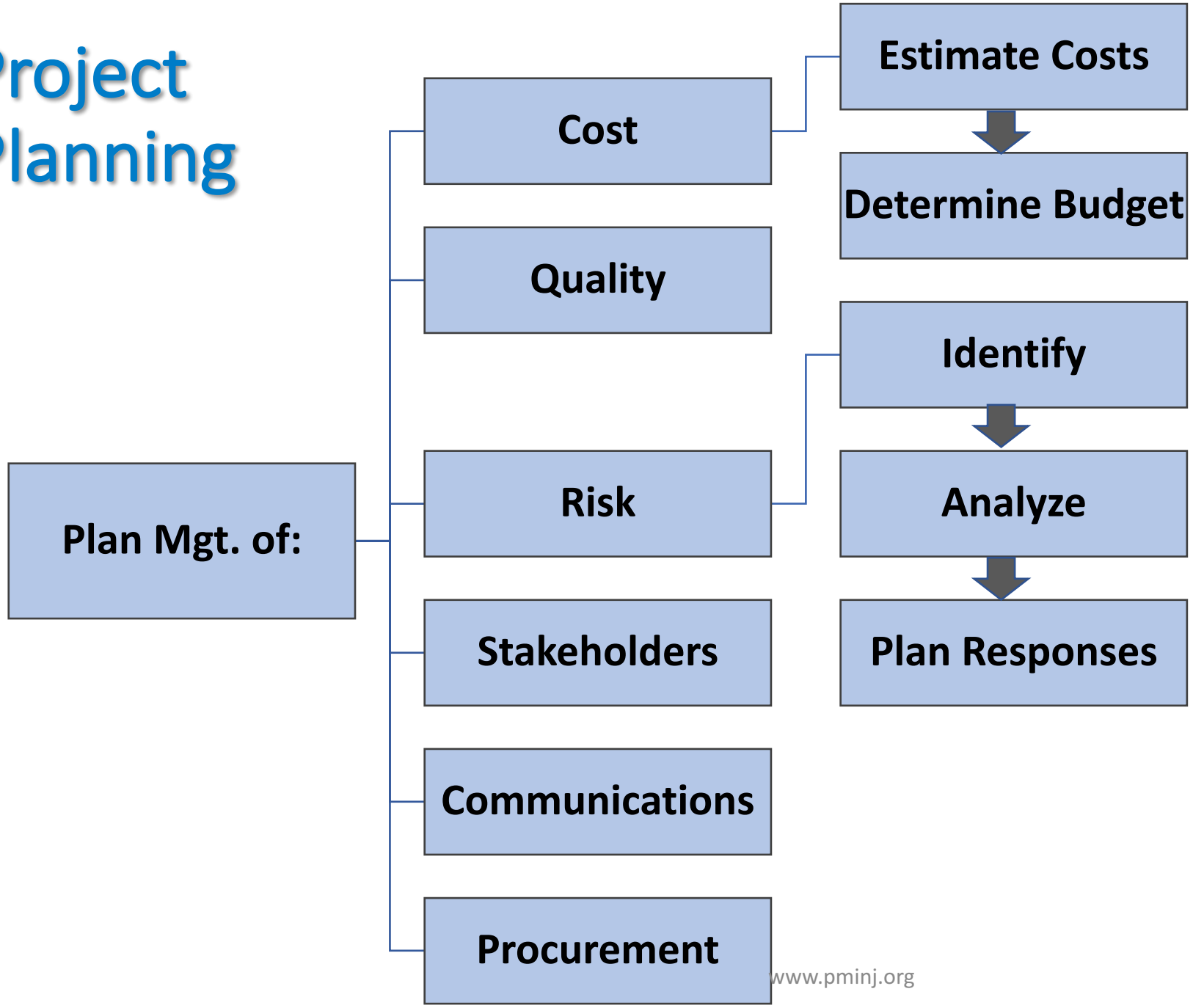
Marketing; Voice of the Customer

Operations

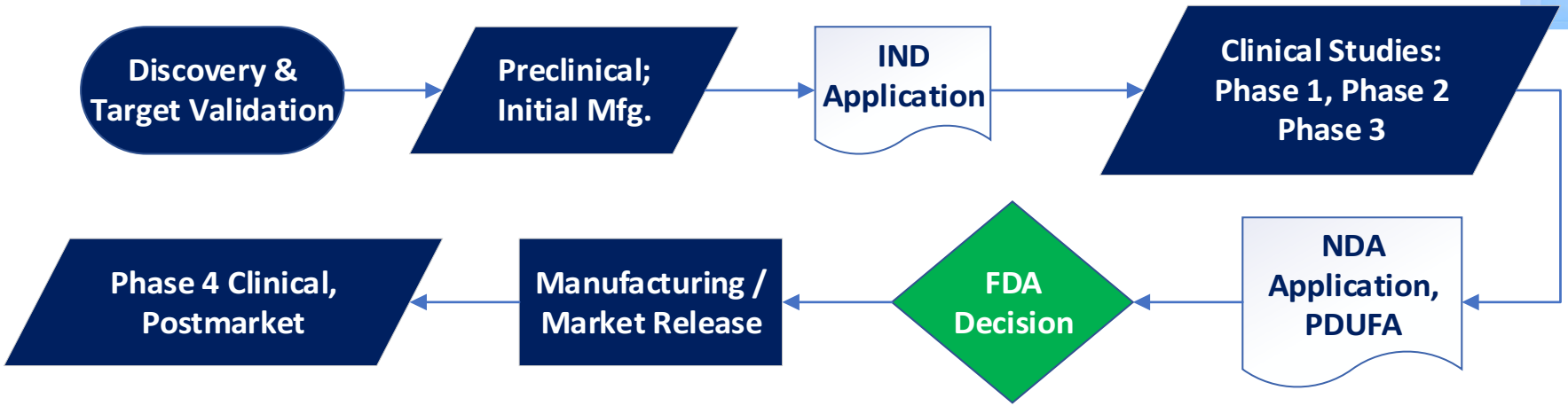
Project Planning



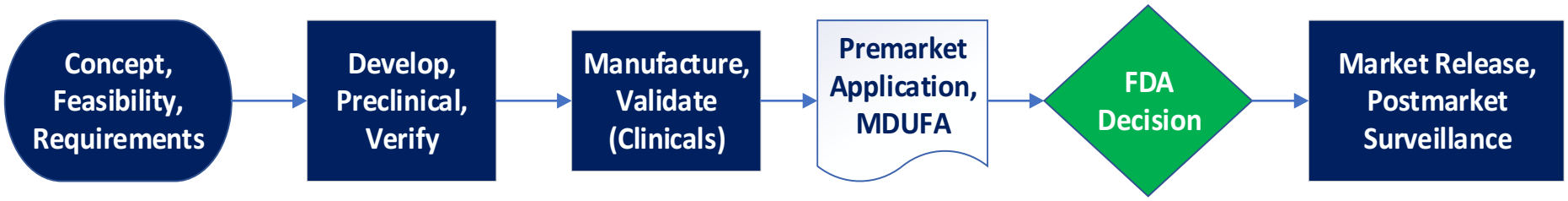
Project Planning



Pharma Drug Development Process

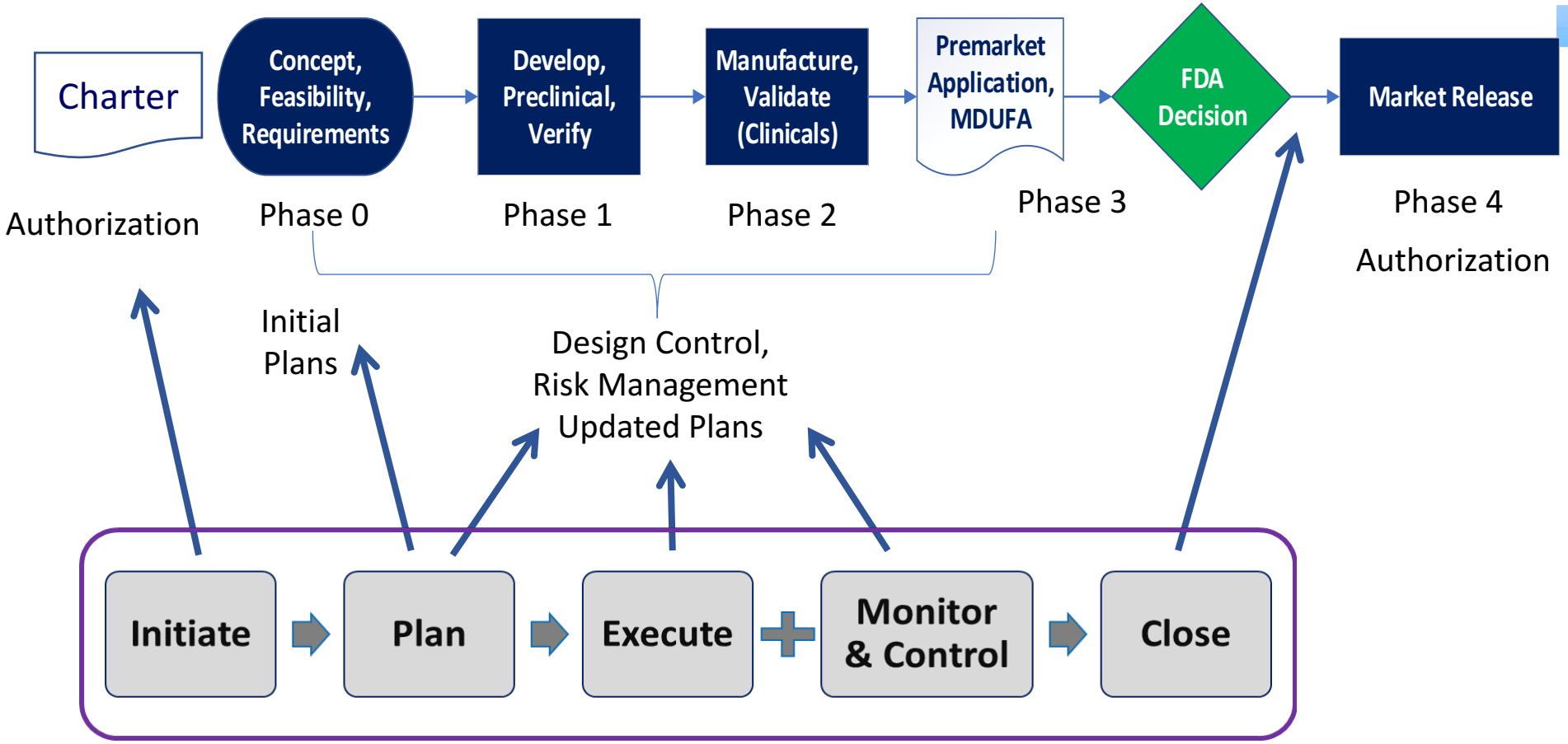


Medical Device Development Process



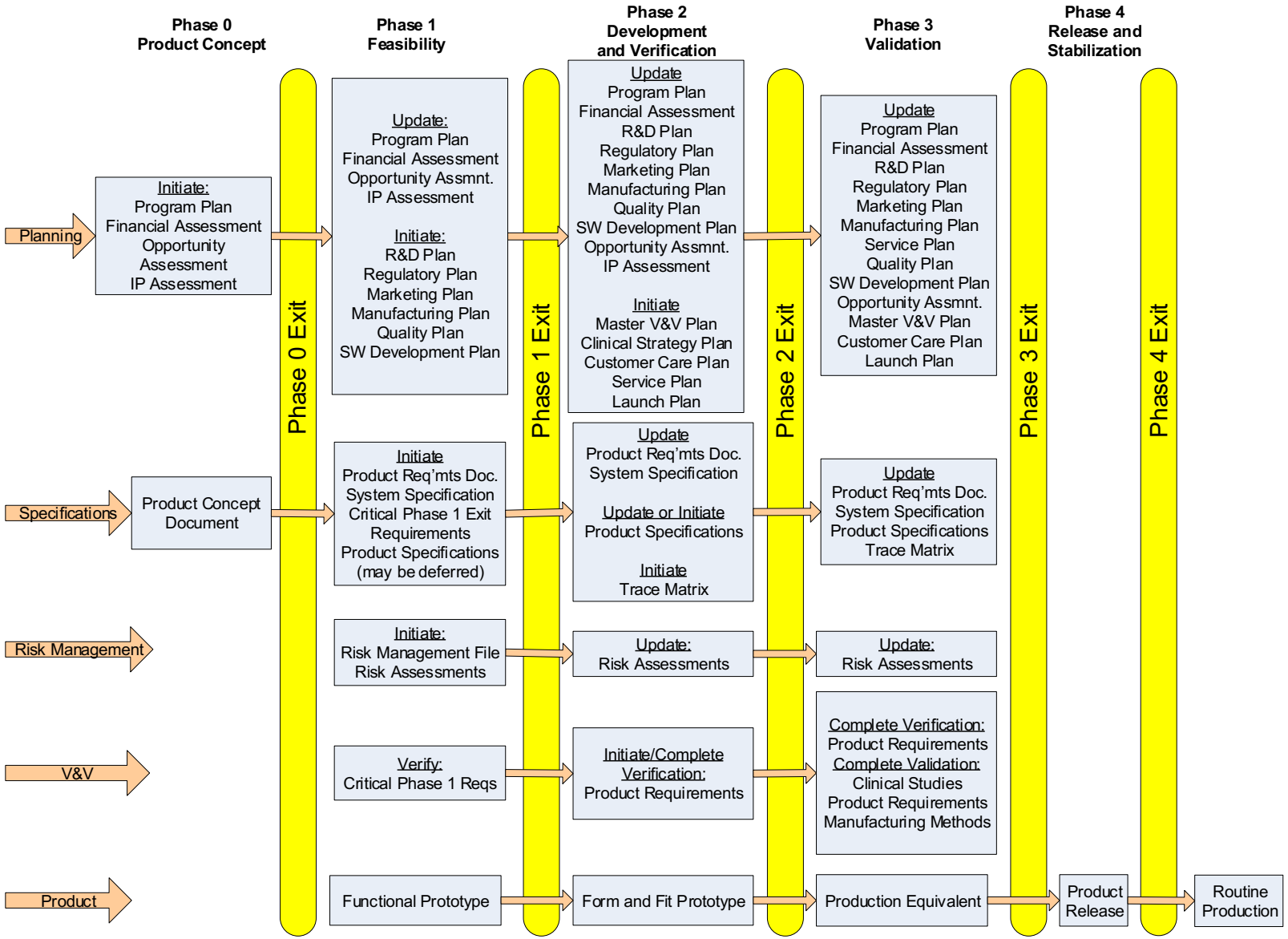
High level processes for project planning & phases

Ex: Integrating PM Processes with Device Development Process



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

Phase Gates Examples



Developing Plans

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Case Study Exercise #1
Inputs for the Project Charter

No one can whistle a symphony.
It takes a whole orchestra.”

Dr. H. Luccock

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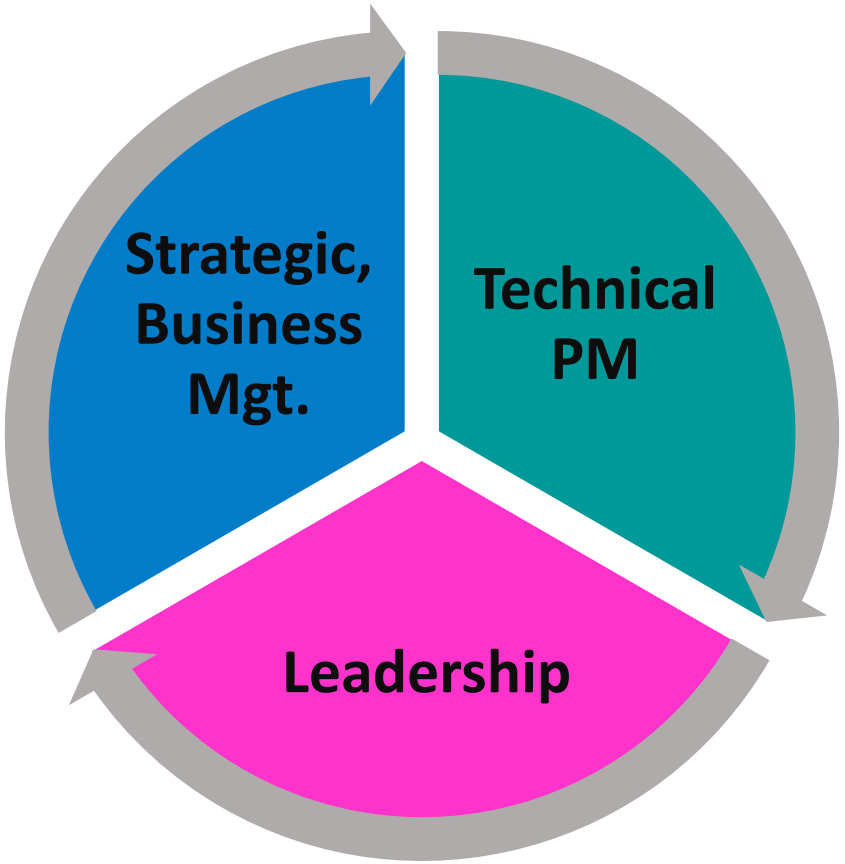
PMI – Key PM Competencies



Adapted from PMBOK 6th Ed. and PMI Talent Triangle®

PM Duties

- Leads cross-functional team & coordinates project activities
  - Accountable & responsible - with team - for achieving objectives & deliverables
    - Works to balance objectives
  - Conducts reviews with Leadership, Project Sponsor, Client, etc.
- In smaller organizations, may have additional roles
- In life sciences, expected to be SME in additional areas

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PM Skills

- Communication
- Relationship building
- Engage, Manage, Influence
- Leadership
- Conflict Management
- Decision-making, Judgement

- Techniques
- Tools
- Templates
- Schedules
- Deliverables
- Budgeting

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Leadership & Management

"Of all the things I've done, the most vital is coordinating the talents of those who work for us and pointing them towards a certain goal." - Walt Disney

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Leadership	Management
Action of motivating a group of people or an organization to act towards a common goal	Process of dealing with or controlling things or people
Leader:	**Manager:**
Vision, Mission-driven	Task, Deliverable-driven
Focus people on overall purpose	Focus people on tasks/work
Transformational, takes risks	Controls the work & risks
Influence	Directs
Long-term vision	Shorter-term results
Common Qualities: Communicates, Motivates, Leads by Example	

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PM's Role in Project Execution

- Manages implementation of plans & work to meet objectives
- Ensures everyone knows their tasks & deadlines
- Tracks progress
- Reviews and communicates regularly
- Reports status to stakeholders

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PM's Role in Monitoring & Controlling

- Monitors / measures work being executed vs. objectives / metrics
- Controls work and manages requested changes
- Monitors risk triggers, issues and works with team to implement risk reduction plans / contingencies
- Works with team to verify outputs meets inputs, e.g., vs. requirements, acceptance criteria, metrics
- Conducts "lessons learned" throughout project

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Why do Projects Fail?

- Scope:
  - Inaccurate, changing, not documented / approved
- Communications
  - Lacking, ineffective
- Stakeholders
  - Not engaged / managed
- Risk
  - Not planned for, plans not used
- And more!

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Managing Teams and Engaging Stakeholders can feel at times like…

Engaging Stakeholders

- Communications:
  - Who, when, how, how often, for what purposes, what tools?
- Opportunities to:
  - Build/cultivate interest in/support for project
  - Build your relationships
- Potential risks and how to reduce
- Project lifecycle engagement strategies

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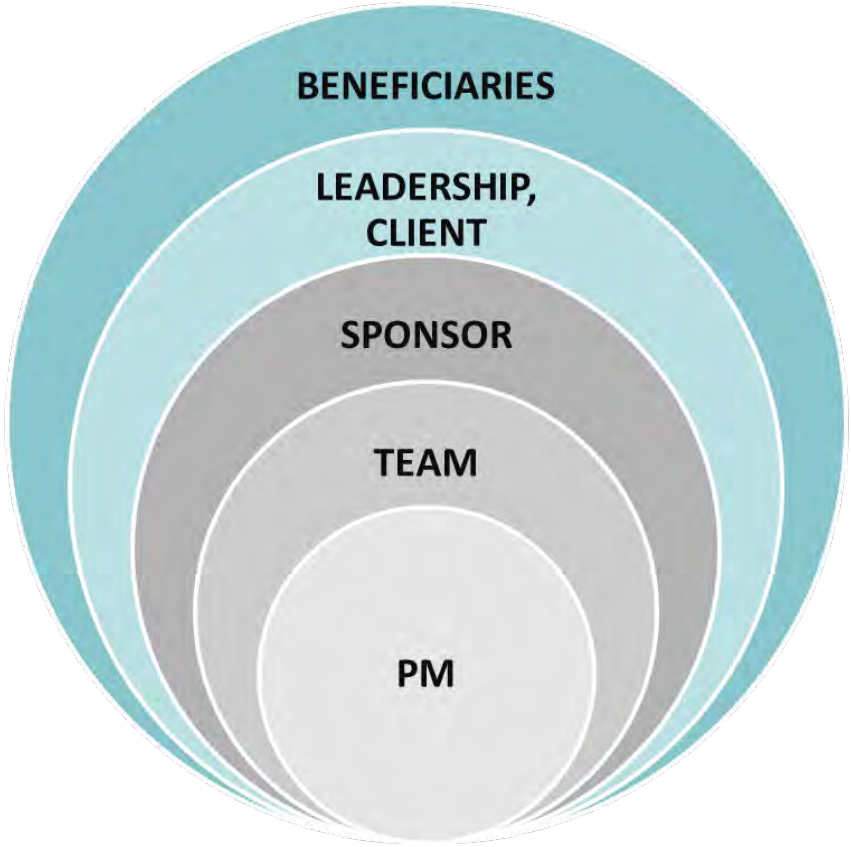
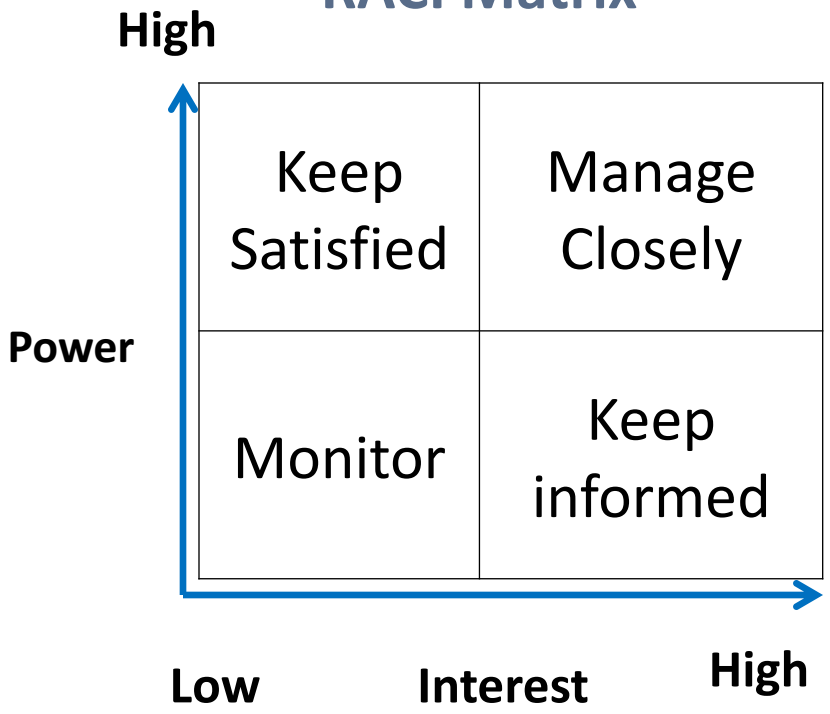
Stakeholder Identification & Analysis



RACI Matrix



Adapted from PMBOK Table 13-4

Analyzing Stakeholders - RACI Example

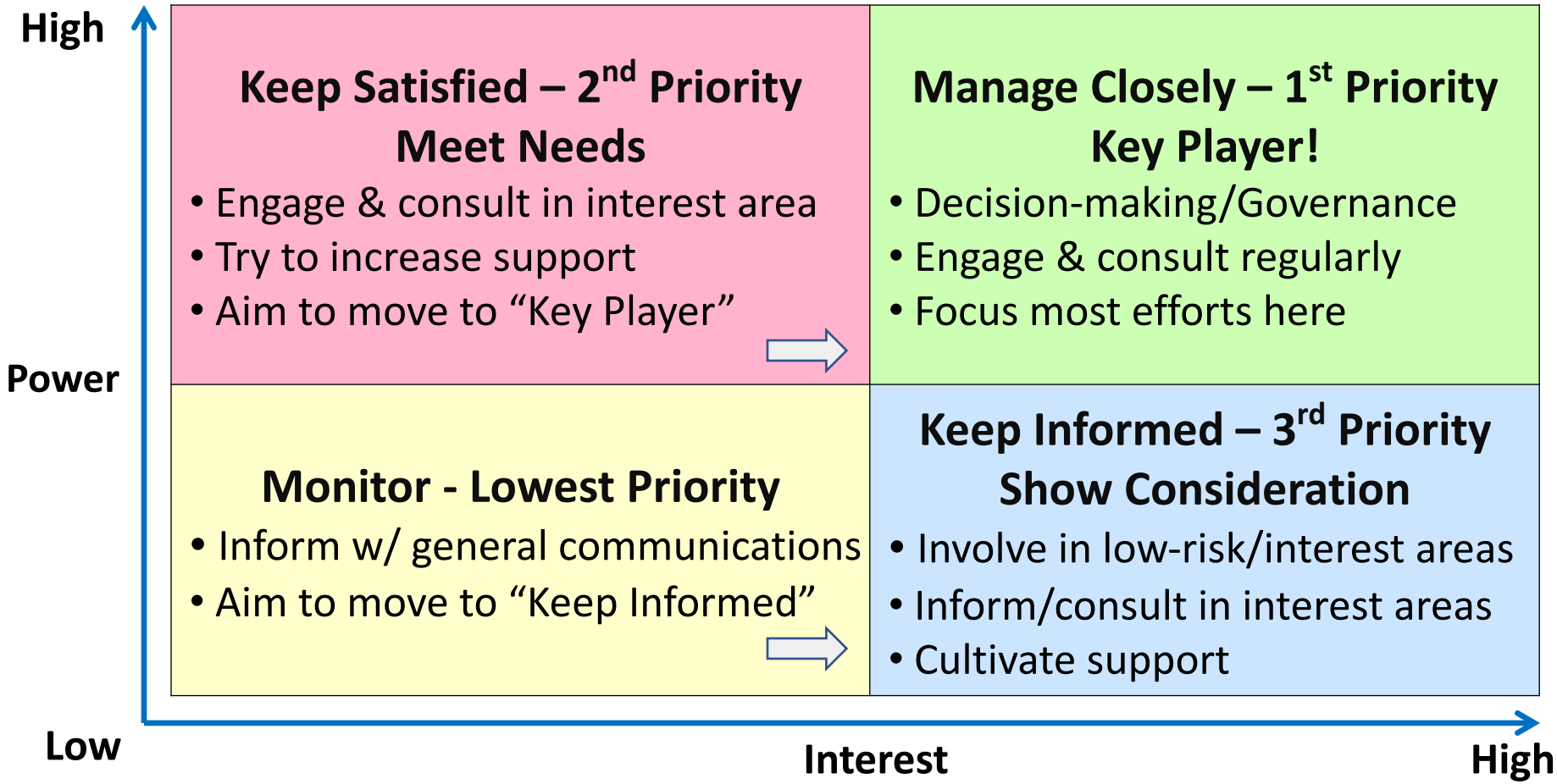


Table adapted from Stakeholdermap.com

Stakeholders Engagement Planning Example

RACI Matrix

Use to Develop Engagement & Communications Plans

Stakeholder	Goals, Motivations, Interests	Influence	Interest	Priority	Win/Win Strategies
VP	Successful project delivery, on-time, on-budget	High	High	1st -Key Player	Approve key decisions

Table adapted from Stakeholdermap.com

Governance & Status Reviews

- Governance = Leadership
  - Build relationships
  - Enlist your manager and/or Project Sponsor for guidance/coaching in difficult situations
- Communications:
  - Report with project's business value in mind
  - Schedule regular reviews
- Progress vs. objectives, metrics
  - Major progress, milestones achieved
  - Risk to plans & recommended risk reduction methods with rationales
- *Engage your team for preparations!*

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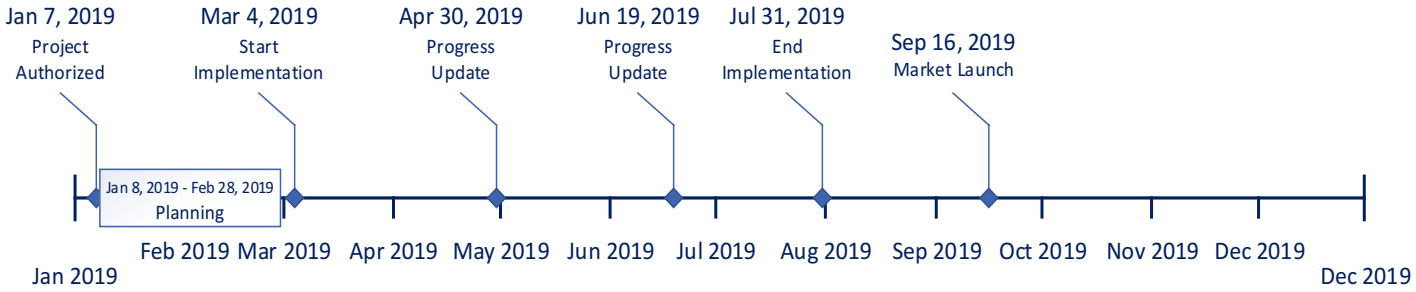
Relaying Information

- Use visual, graphical tools
  - Easy to read/comprehend, e.g., dashboards, symbols
- Level of detail appropriate to audience
- Use templates for messaging consistency



Project Lead	% Complete	Next Steps	Risk Level	Risks	Potential Mitigations

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Engaging Stakeholders

- Communicate & consult early & often
- Set & manage expectations
- Ensure they know what is needed from them and when
- Evaluate & plan for your stakeholders, including risk
- Make time for 360 relationship building
- Don’t underestimate the effort needed – lifecycle process
- Remember we’re all human!

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Case Study Exercise #2
Stakeholder Categorizations

Risk & Quality Management for Life Science Products

- Required as part of making safe & effective products
- Customers, breadth of stakeholders include:

National Medical Association

Coverage

Payment

Coding

European Commission

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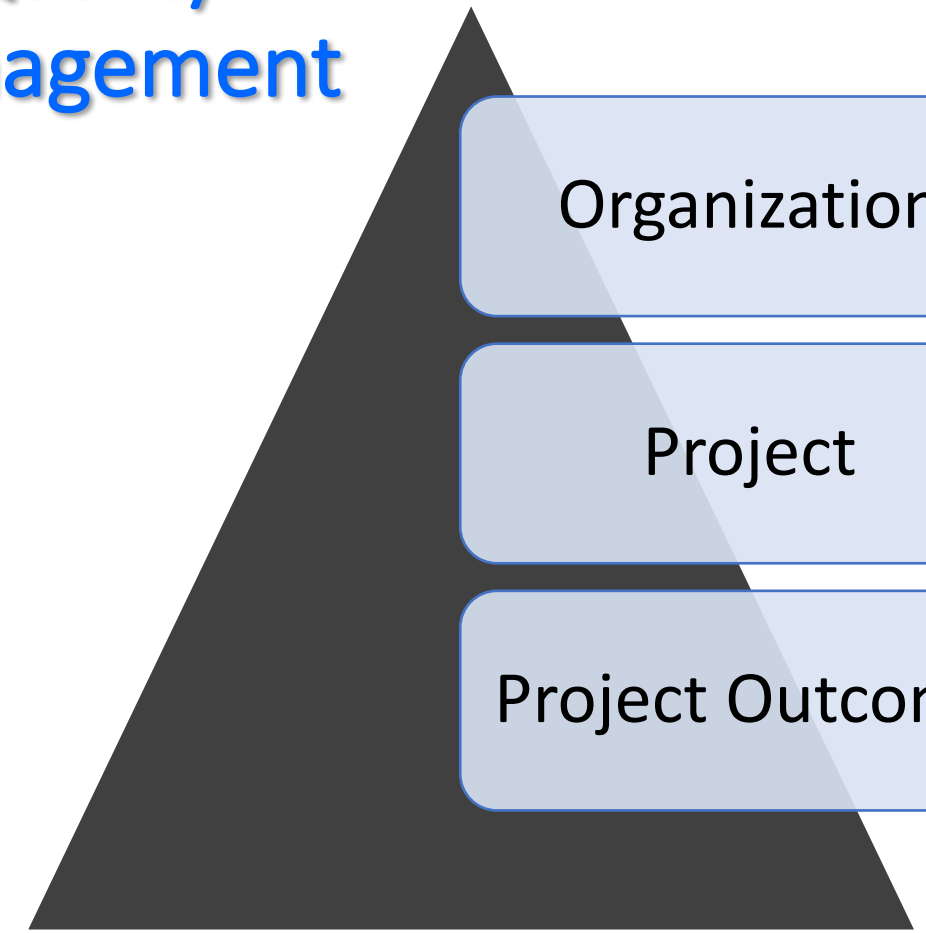
Quality Management



Organization	Quality Management System (e.g., processes & products)
Project	Customer / stakeholder requirements & expectations
Project Outcome	Metrics / success factors Verify project & deliverables / outcome meet requirements Validate outcome meets Intended Use

Device or drug will have its own Quality Plans

- Test Plans, Protocols & Reports

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How do We React to “Risk”?

“*The first step in the risk management process is to* ***acknowledge the reality of risk****. Denial is a common tactic that substitutes deliberate ignorance for* ***thoughtful planning***.” - Charles Tremper

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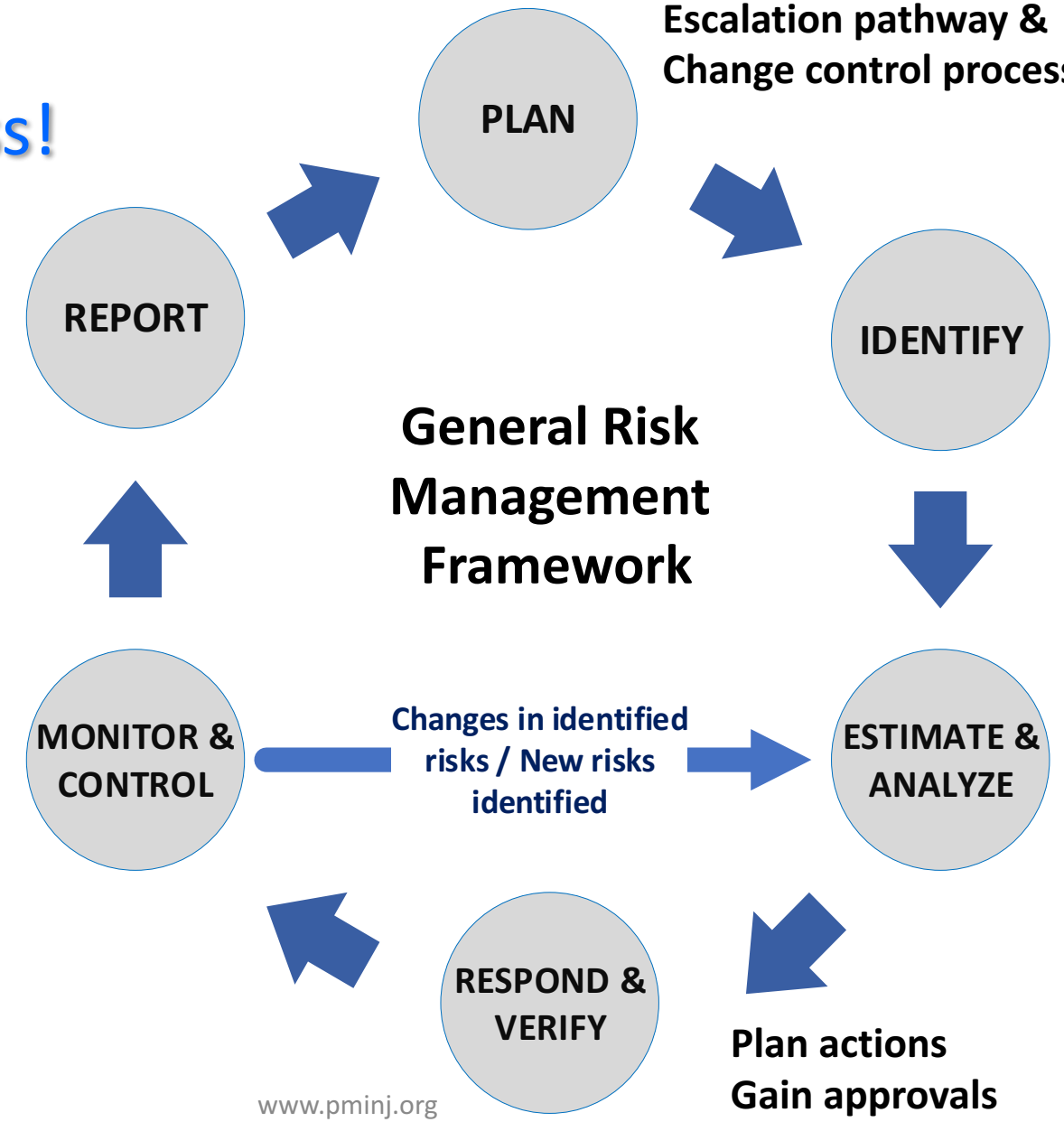
Risk Management: An iterative lifecycle process!



Escalation pathway &
Change control process

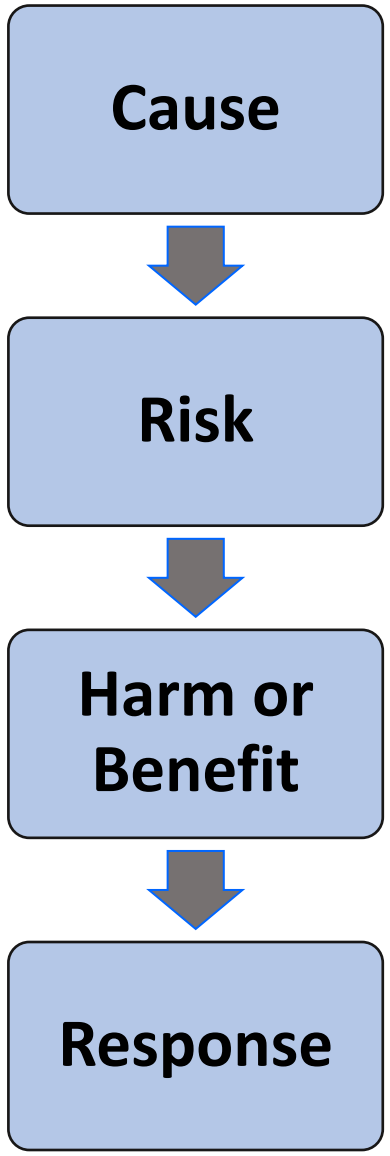
Sources
Triggers

Evaluate,
Prioritize:
Impact level
Likelihood to occur

Plan actions
Gain approvals

Monitor & control identified risks and any changes.
Add new risks / information

Analyzing Risk



Risk identified by:	**Risk ID**	**Positive or negative risk?**	
What might happen?			
What could result?			
How might that impact the project?			
Qualitative Analysis (Must be completed)			
Risk may impact (check all that apply):	Scope? Schedule? Budget? Quality?	Impact	
		Probability	
		Detectability	
		Total	
Quantitative Analysis (Must complete for highest severity threats & largest opportunities)			
Financial impact		Schedule impact	
Response approach			

Risk Analysis Template from projectmanagement.com

Ranking Risks:
Project Risk Chart (Example) - Threats

	Impact Risk Ranking			
Probability (of occurrence of the harm/threat)	**Negligible**	**Minor**	**Serious**	**Critical**
High	**Medium**	**Medium**	**High**	**High**
Medium	**Low**	**Medium**	**Medium**	**High**
Low	**Low**	**Low**	**Low**	**Medium**

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Ranking Risks: Project Impact Chart (Example)

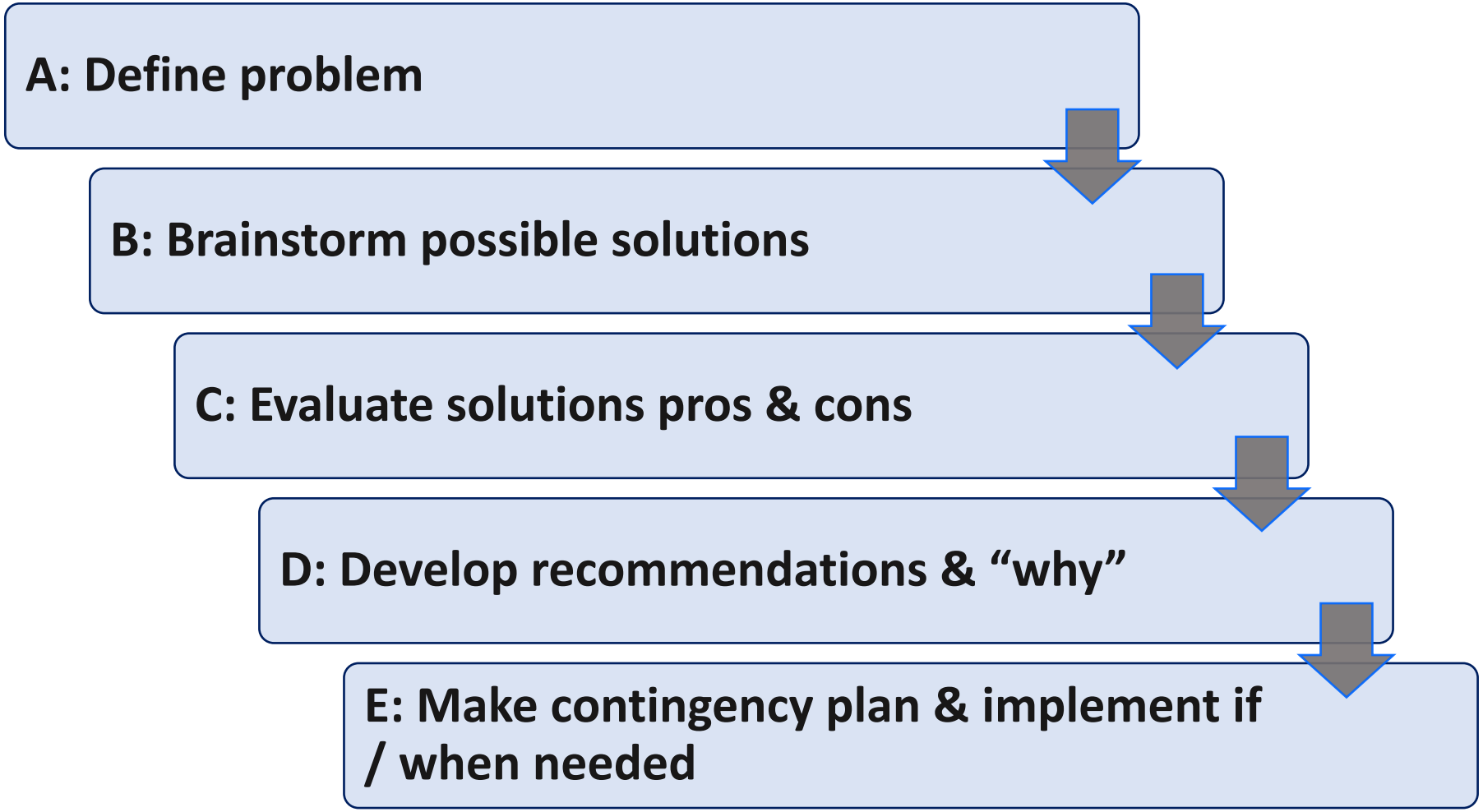
Scale	Probability	± Impact on Project Objectives		
		Time	Cost	Quality
High	61 - 99%	> 90 days	> $200K	Significant impact on overall functionality
Moderate	31 - 60%	25 - 89 days	$51K - 199K	Some impact on key functional areas
Low	6 - 30%	1 - 25 days	$11K - $75K	Minor significant impact on overall functionality/ secondary functions
Negligible	< 5%	No Change	< $10K / no change	No change in functionality

Modified from Fig. D11, *Practice Standard for Project Risk Management*

Determining Risk Responses

Risk Impact	Potential Responses based on Risk Ranking			
Negative (Harm)	Avoid	Reduce	Transfer	Accept
Positive (Benefit)	Exploit	Enhance	Share	Accept

Consider Re-framing Risk Management as Problem Solving for Contingency Planning



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Handling Risk

- Keep it Simple - use a logical, step-by-step approach
- Schedule specific team risk meetings to maintain focus
- Uncertainty is inherent - manage expectations
- Communicate! Include risk updates in reviews
- Do not treat it like a checkbox exercise

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Case Study Exercise #3
Areas Needing Risk Mgt.

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 also incredibly rewarding – enjoy the journey and challenge yourself to grow

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Thank you

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