

**NEXT SESSION**

# STAKEHOLDER ENGAGEMENT & COMMUNICATION IN BIOPHARMA

Michael Federman

Director, CMC Project Management

**This session will be  
recorded.**

**University of Maryland**  
Project Management  
Symposium



**PROJECT MANAGEMENT  
CENTER FOR EXCELLENCE**

A.J. CLARK SCHOOL OF ENGINEERING  
Civil & Environmental Engineering Department





# Stakeholder Engagement & Communication in BioPharma

*Mike Federman*

*CMC Project Management, BioPharmaceutical Development, R&D,  
AstraZeneca Gaithersburg MD, USA*

*2023 Project Management Symposium*



# Outline

1

What is Biopharmaceutical Development?

2

Who are the stakeholders?

3

What role does governance play?

4

How do project managers engage?

5

What do partnerships and alliances require?

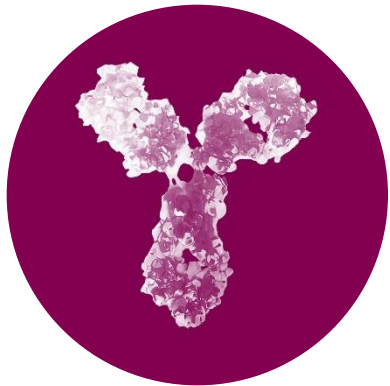


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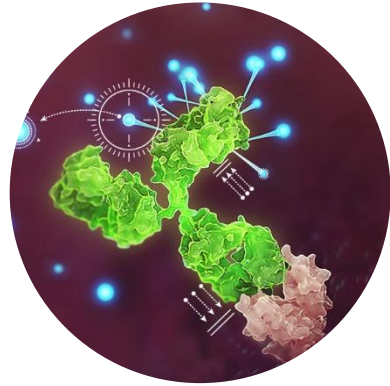


# What is a Biopharmaceutical?

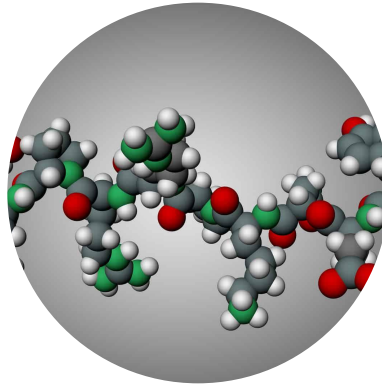
A biopharmaceutical is often referred to as a “biologic” or “biological product,” contains an active substance derived from or extracted from a biological system (living organism). They are often administered as an injection or infusion.



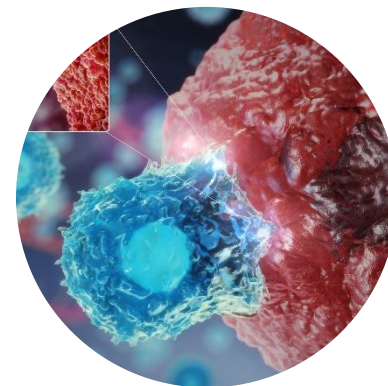
Antibodies



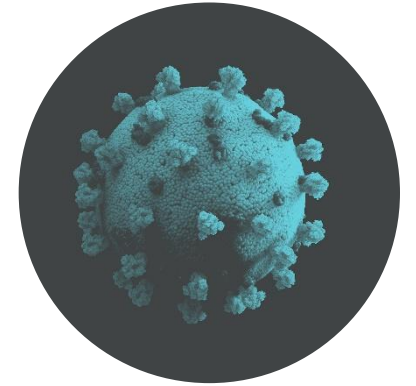
Antibody-Drug  
Conjugates (ADC)



Peptides



Cell Therapy



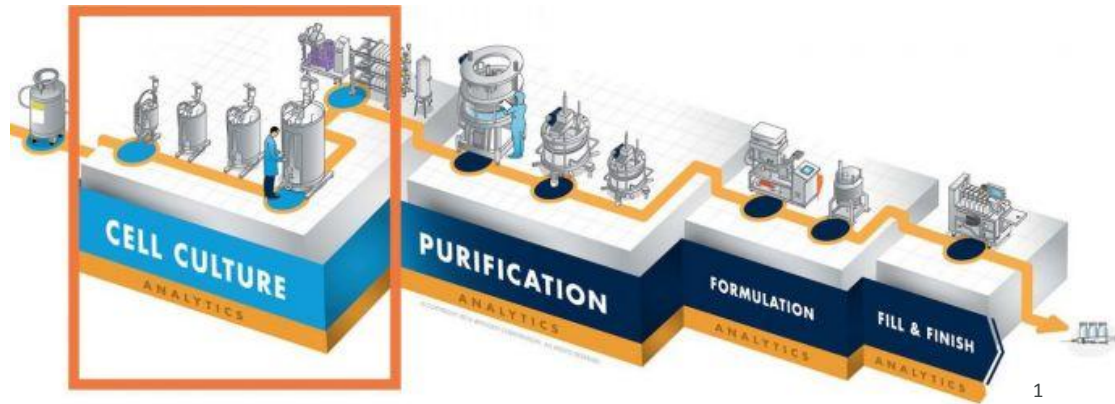
Virus / Nucleic Acid



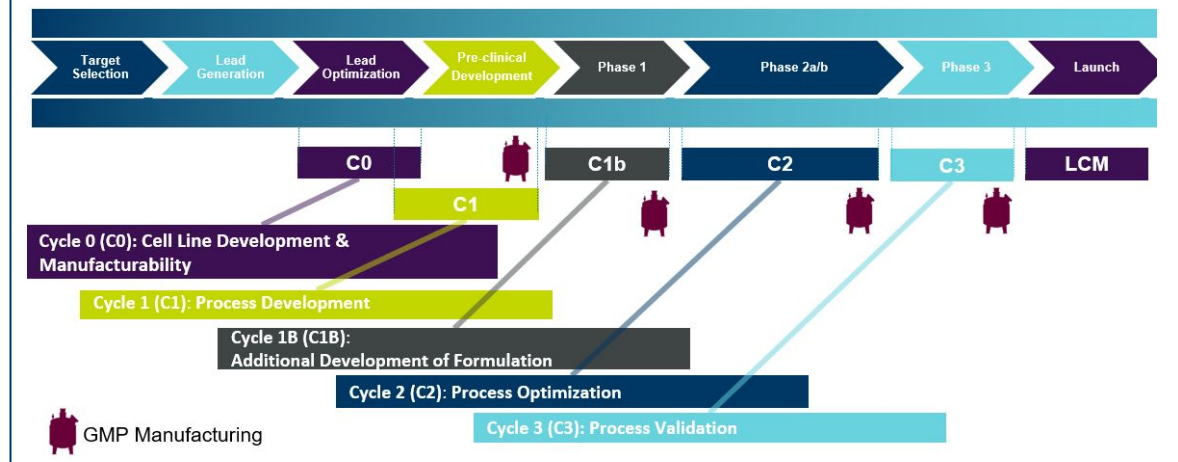


# Developing and Manufacturing a biopharmaceutical incorporates efforts from many disciplines, strategies, quality oversight and tools

## Manufacturing



## Development



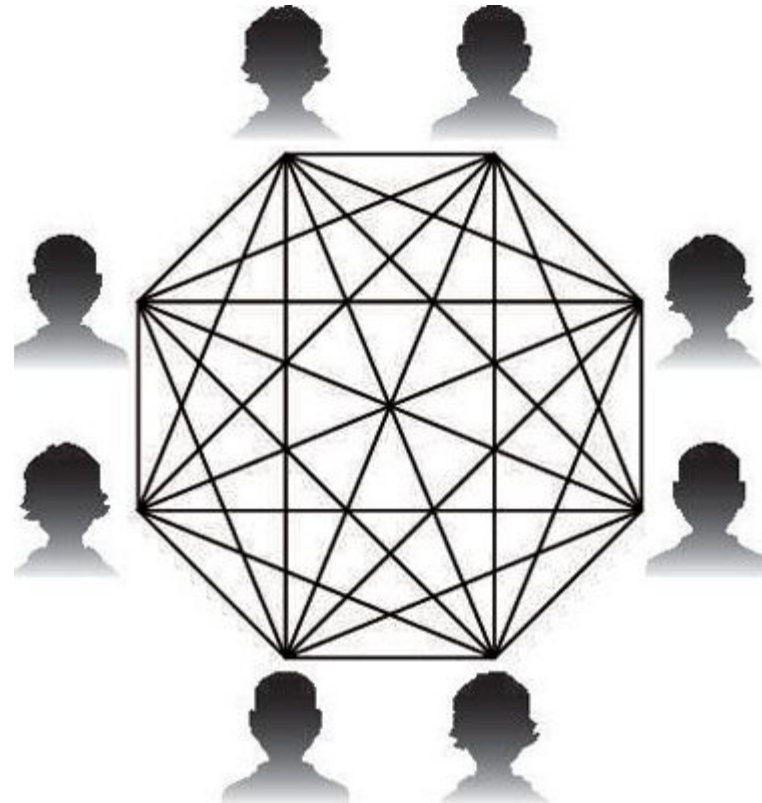
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# Stakeholder Management

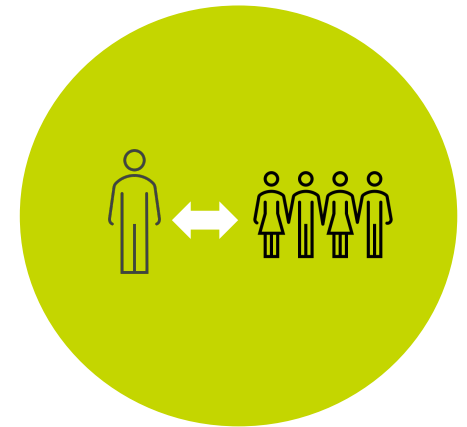
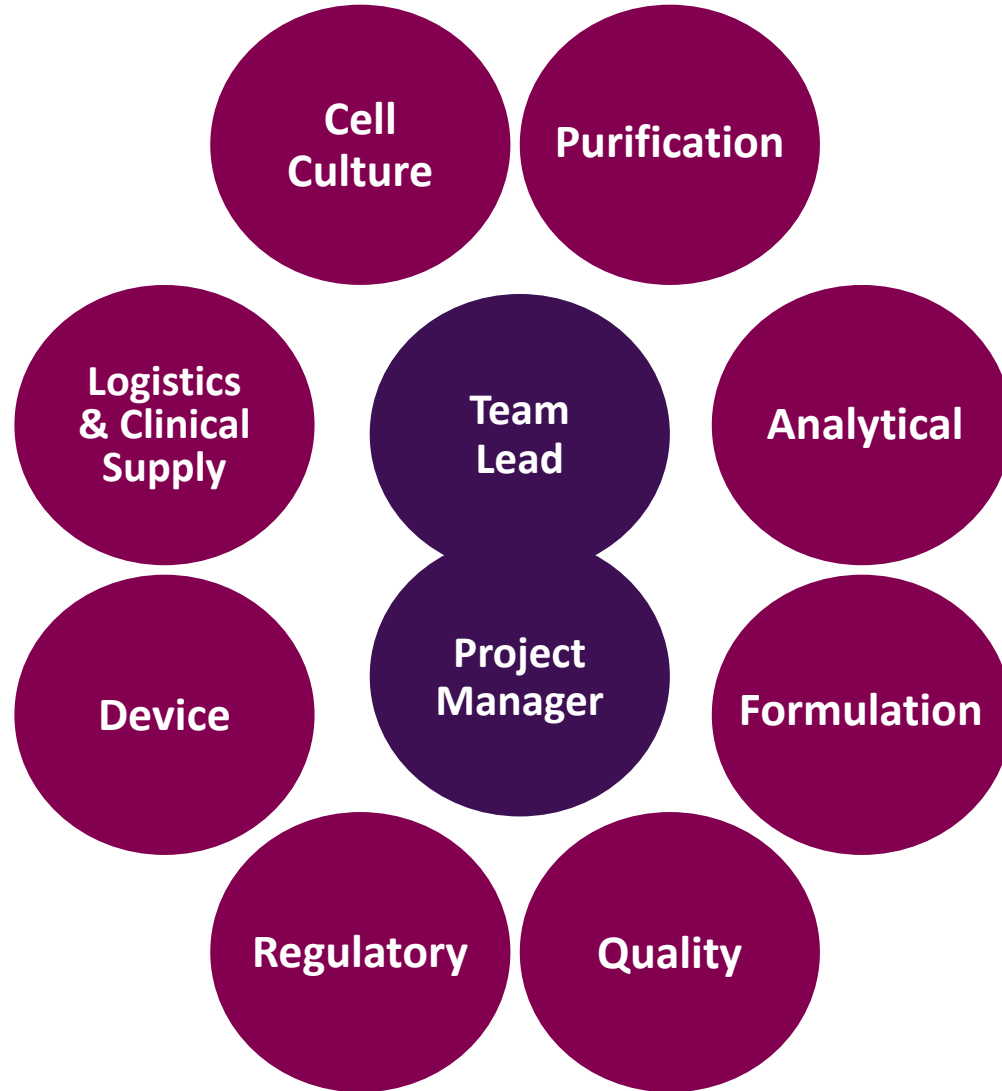
## What or who is a stakeholder?

- An individual, group or organisation who may affect, be affected by, or perceive itself to be affected by a decision, activity or outcome of a project





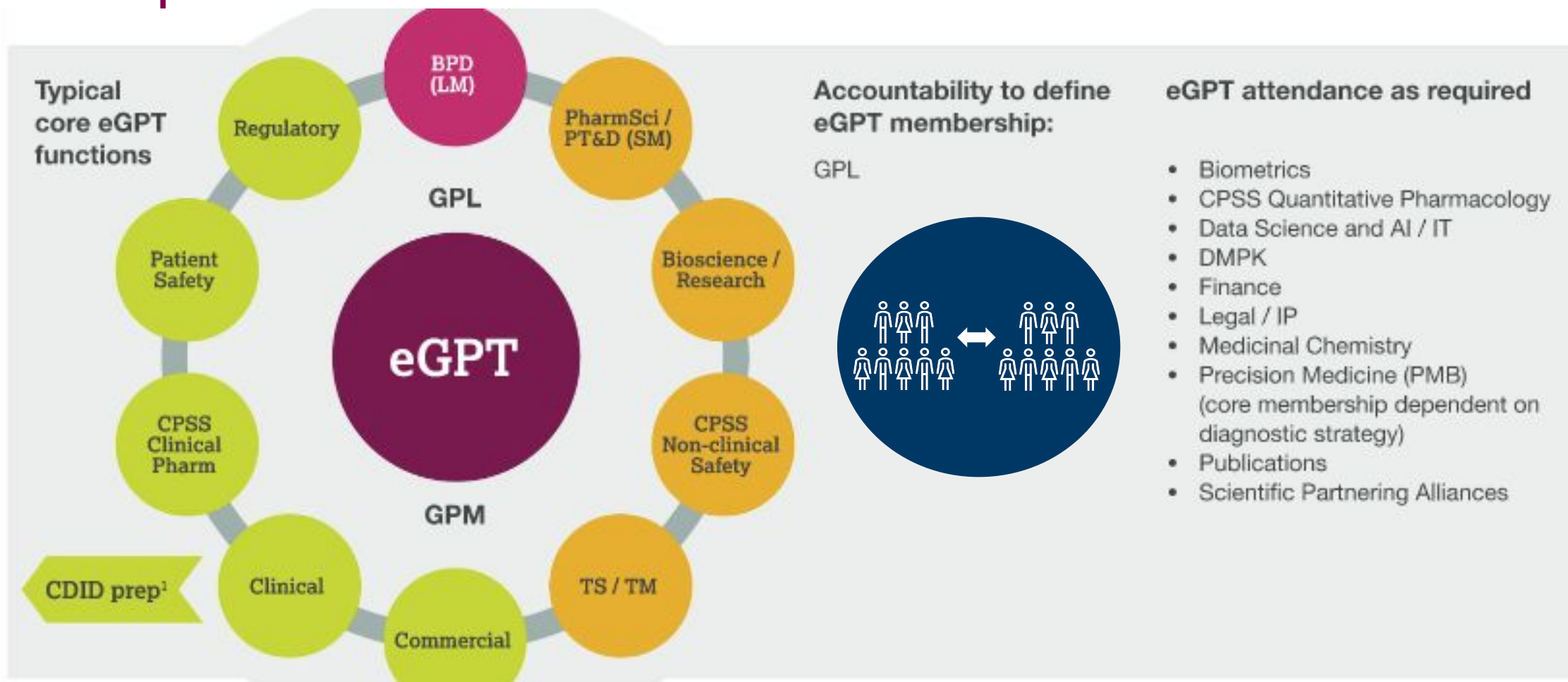
# Chemistry Manufacturing and Controls (CMC) Teams are a cross functional matrix



# Global Project Teams Drive Molecules from Start to

L

1



eGPT – early Global Project Team

CDID – Candidate Drug Investment Decision

GPL – Global Project Lead

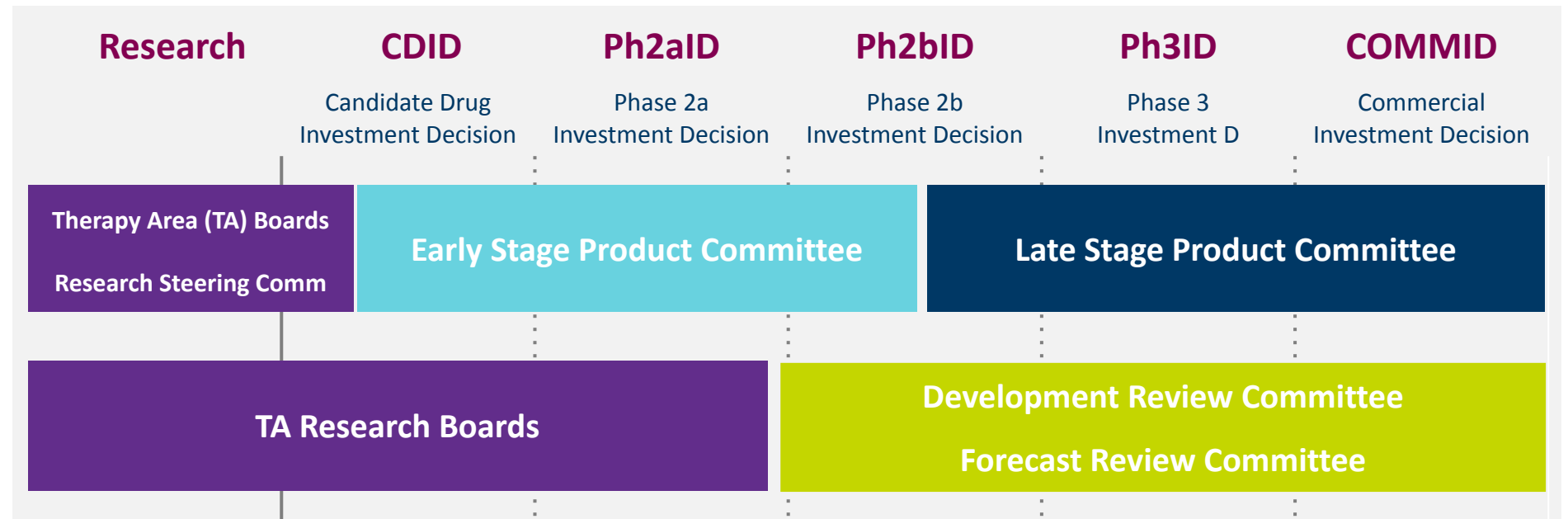
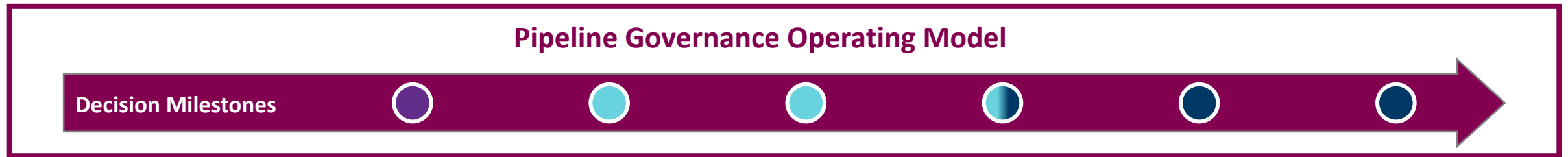
GPM – Global Project Manager



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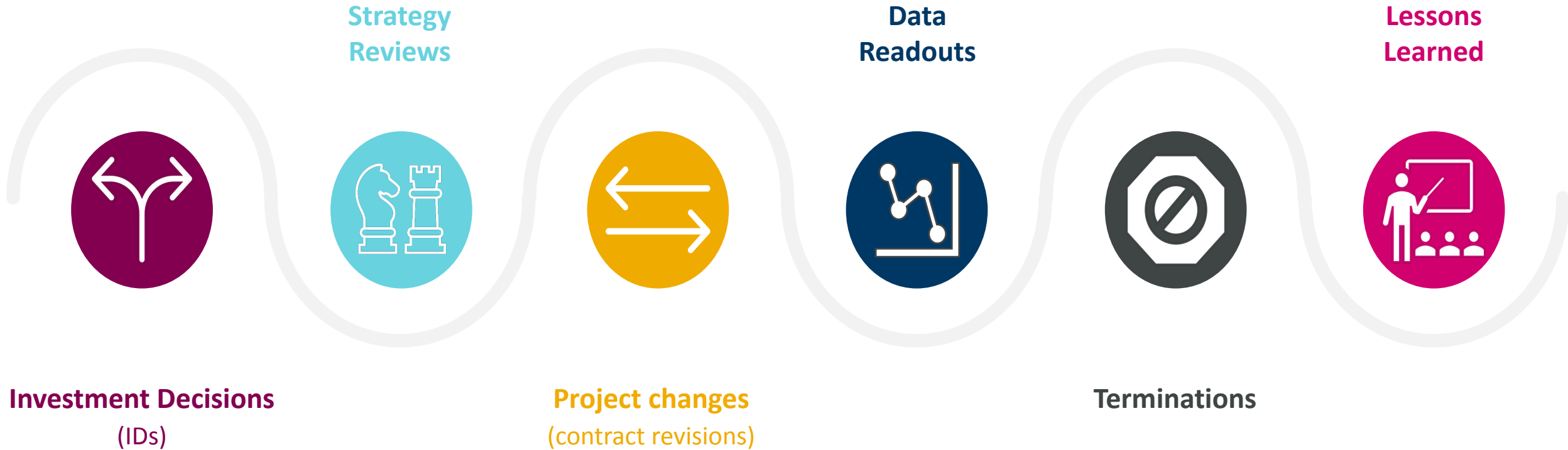
# Governance drives a comprehensive, deep review & decision to invest in a project



RBs provide scientific review & input to early-stage teams from CDID to Ph3ID review.



# What topics come to governance?



# Engagement Outside of Formal Governance



**Development Teams**



**Other Functional  
Project Managers**



**Vendors & Contractors**



**Academic and  
Community Leaders**



**Finance & Accounting**





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# Tailor to the audience

When presenting to governance - who are the committee members?

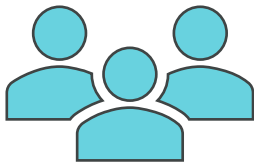


**Core Members:** SET



**Standing Members:**

R&D Heads,  
Regional Commercial EVPs



**TA / Business Heads:**

R&D, Commercial, Regulatory,  
Biometrics, Clinical, etc.



**Agenda-driven Members:**

Franchise Heads, Biomarkers,  
Legal, BD, etc.



- Simple & clear
- Tell the story
- *Less is more*
- Answer questions succinctly
- Prepare & practice
- Be confident!

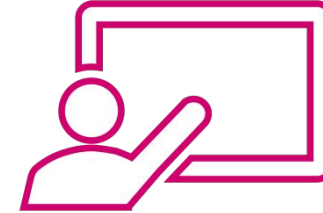


# What do people want out of governance?



## Committee Members

- **Information that enables effective decision making**
  - Executive-level of detail
  - Focus on key messages & critical issues
  - Simple, understandable slides
- Coherent strategy & supporting story
  - Reasons to Believe
  - Value Proposition
  - Comprehensive (use the templates!)
- Well-planned for executional success
- Reasonable slide count



## Presenters

- **Clear decisions & guidance**
- Alignment of advice
- Speed & flexibility
- Minimal burden; stay on critical path
- Positive experience with leaders



# Tips for presentations

## Preparing the pre-read (presentation) deck

### Single deck submission

- Indicate pre-read slides
- **Plan early!** Pre-reads due ~**at least one week** prior
- Minimal to no changes (unless LT approved)

### Include:

- Team slide
- Decisions needed (front & back of presentation)
- Clear Executive Summary
- Indicate pre-read slides
- Slide numbers

Use templates & guidance

Communicate closely with Secretariat

## During the presentation...

- Focus on key messages
- Be ready for discussion throughout
- Listen carefully to questions... and answer them concisely
- Allow 10-15 minutes at end for discussion & decisions

### Bring the right people

- Team attendance  $\leq 3$  people
- Must have clear role & purpose
- Know who is expected to answer majority of questions
- Know who is “leading” the presentation

*Did we mention.... clarity, conciseness & simplicity are key!*

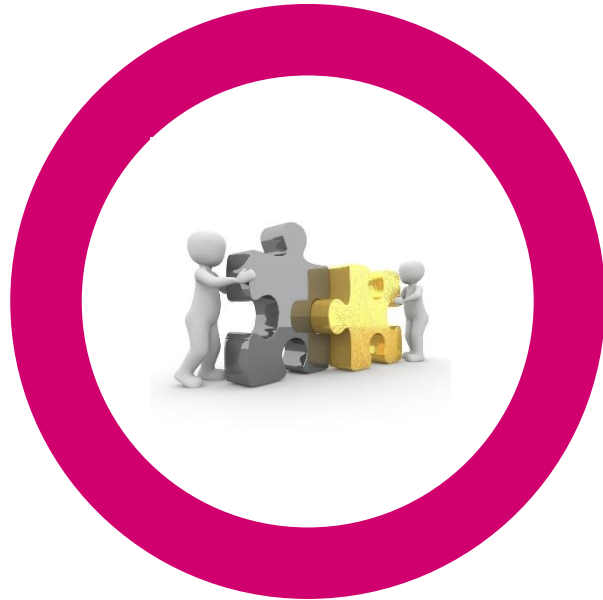


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# What Makes a Good Alliance?

Alliance Management is a known and trusted partner who:



Listens to ensure delivery models meets customer needs



Embraces continuous improvement and innovation to drive excellence in delivery



Provides governance and oversight to support inspection readiness

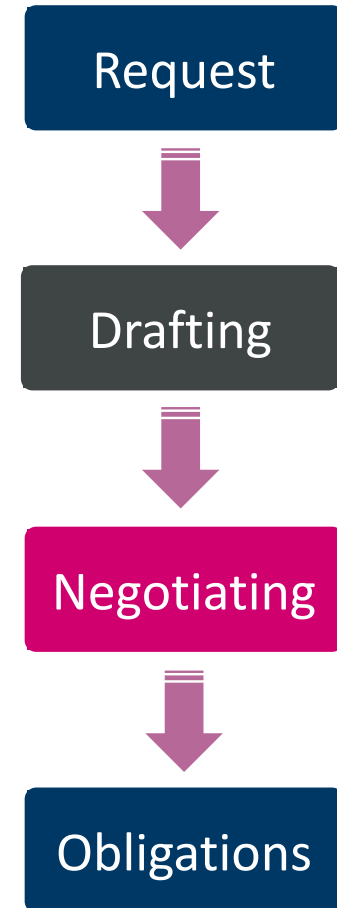




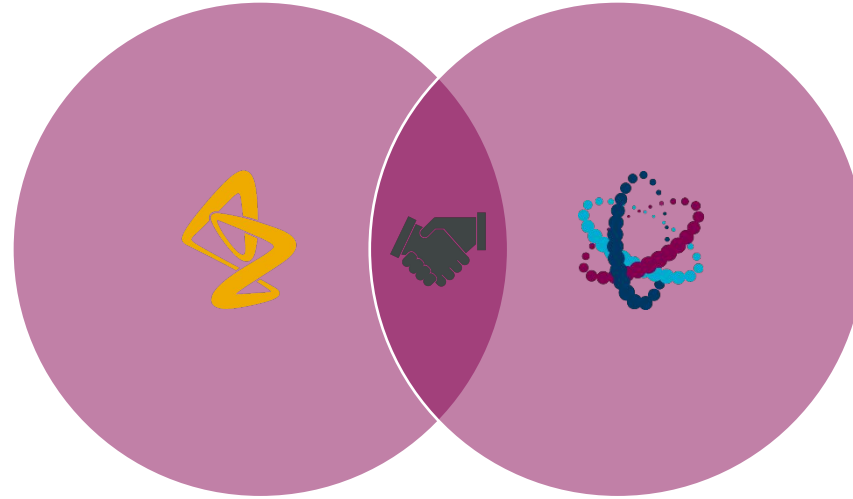
# Key Areas Within Alliance Management



# Alliance Management Contracting



# Joint Team Structures



- JSC – Joint Steering Committee
- JCC – Joint Commercial Committee
- JDC – Joint Development Committee
- JPT – Joint Project Team
- JRC – Joint Regulatory Committee



# Q&A



Evaluate Session



