



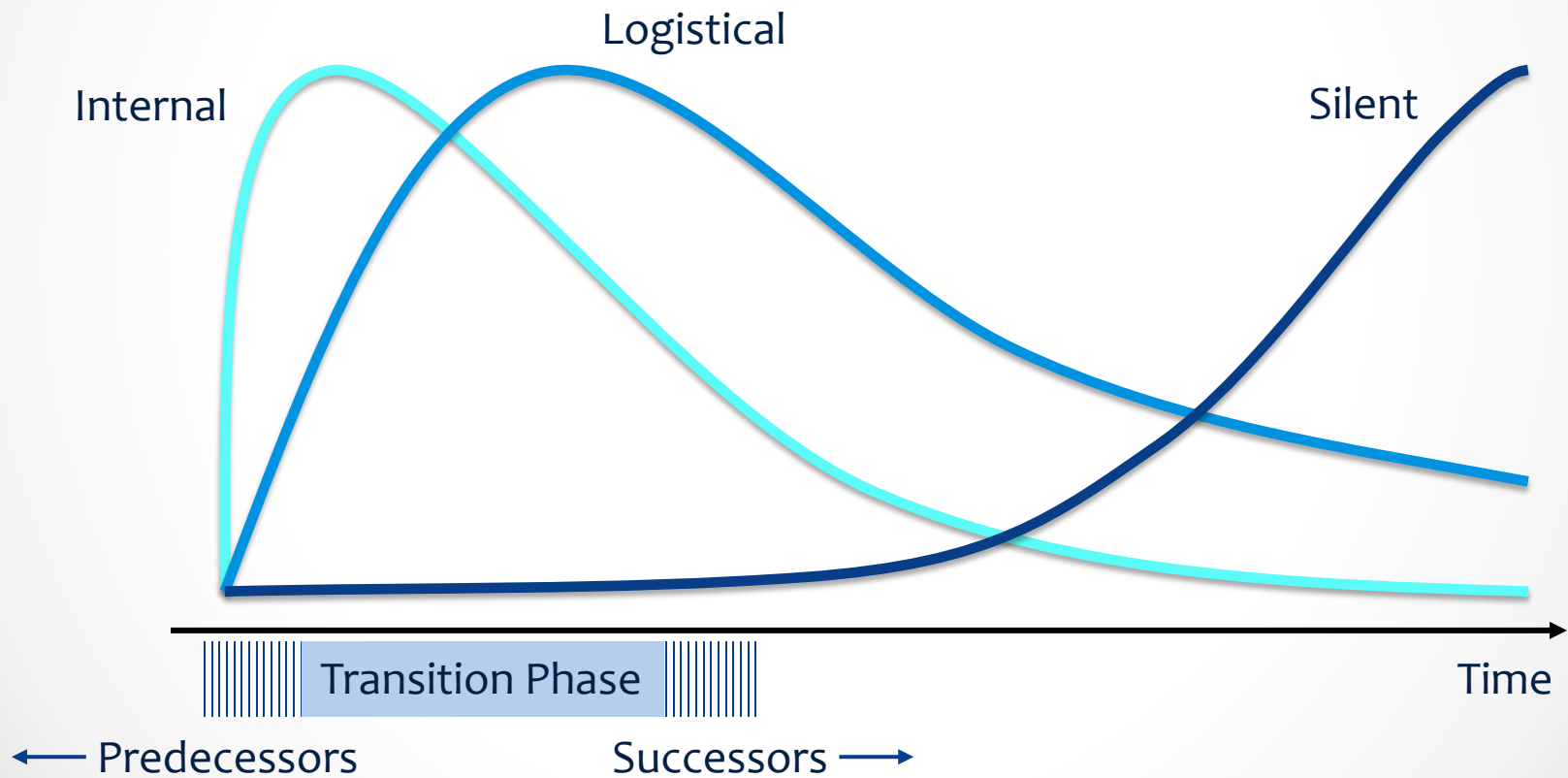
# Transitioning Projects Between Student Teams

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**Good project management practices  $\Rightarrow$  smoother project transitions**



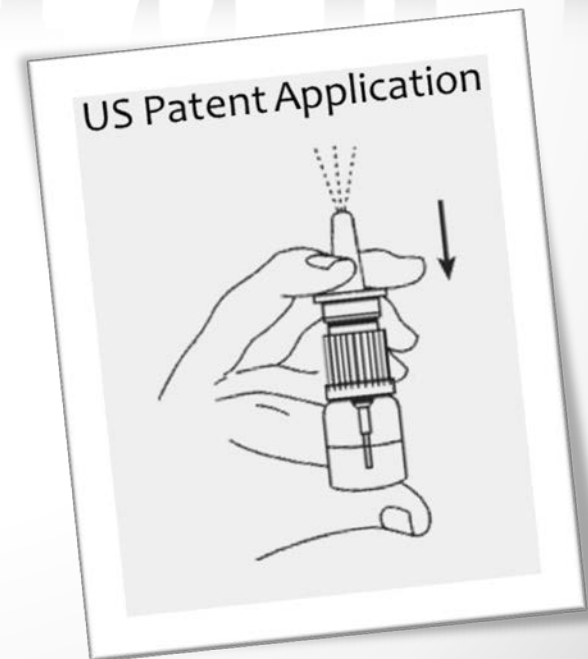
# Categorical Pitfalls

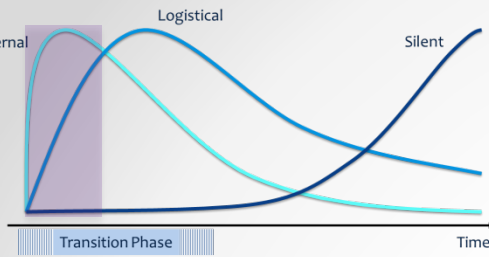


# Example



<b>Need</b>	Non-invasive drug delivery
<b>Business Model</b>	<ul style="list-style-type: none"><li>• Prescription Generics</li><li>• OTC</li></ul>
<b>Device Status</b>	Prototype Only
<b>Patent Status</b>	Provisional
<b>Funds Available</b>	\$50k





## Scenario 1: — Role Conflict —

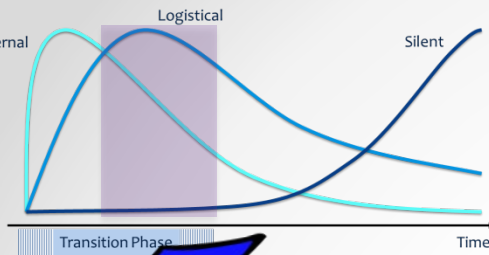


- Team overlap (1 month)
- Project handoff: Business case, DHF, Data
- **Scenario:** After further testing and discussions with industry experts, the new team members believe the product should be a unit-dose device vs. the original concept of a bi-dose and multi-dose spray, which significantly changes the marketing strategy
- **Caution:** Significant loss in project focus; rifts between teams (“us vs. them”)

### Recommended Mitigations

- Develop Project Management Structure
- Implement decision making process
- PIs aid in blending in new team members and communicating roles and responsibilities

## Scenario 2: — Loss of Project Knowledge —



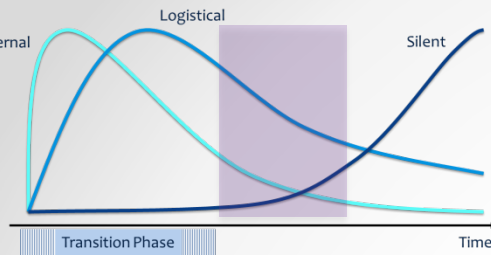
# *Baxter*



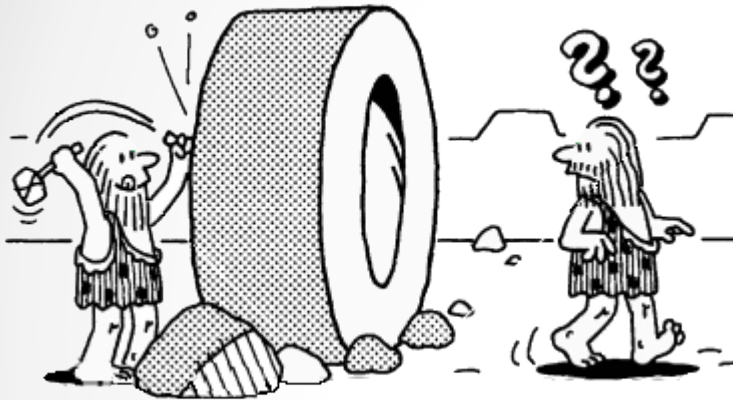
- Developing OTC caffeine nasal spray
- Loss of key personnel
- **Scenario:** The team is in the middle of conducting tests of several prototypes and has run out of a prepared 5 wt.% caffeine mixture. The team member who made the composition has accepted another job and left without writing down his methods.
- **Caution:** Incomparable data; lack of proficiencies; stalled project momentum

### Recommended Mitigations

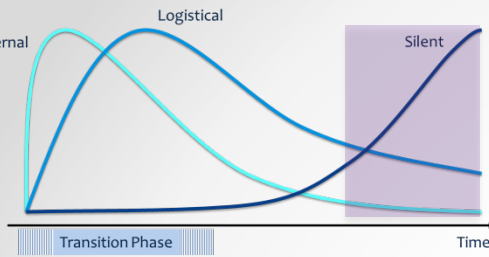
- Strive for student-to-student hand-off
- Introductory review of good documentation practices
- Contingency plan for project hand-off



## Scenario 3: — Project Loyalty—



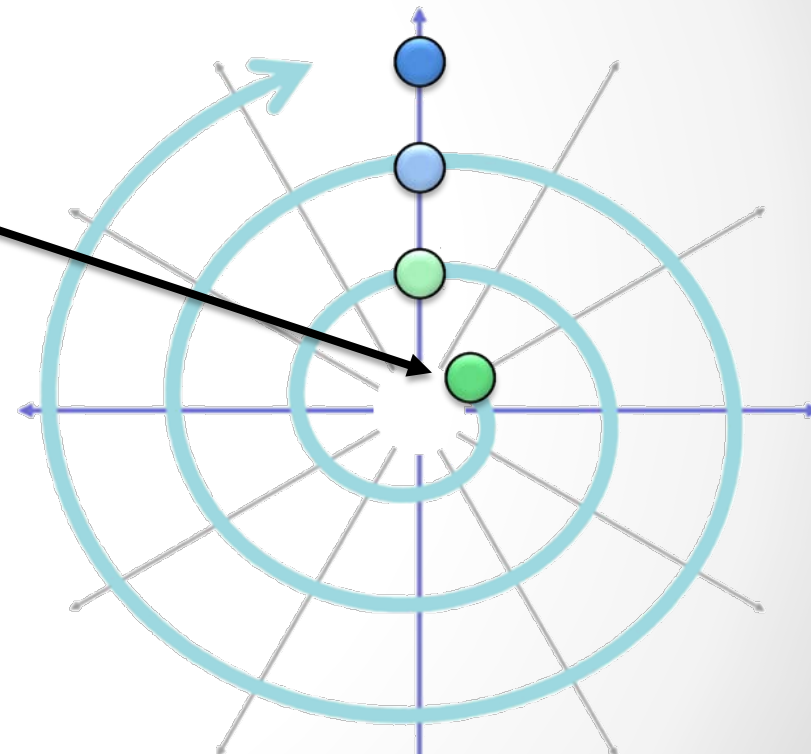
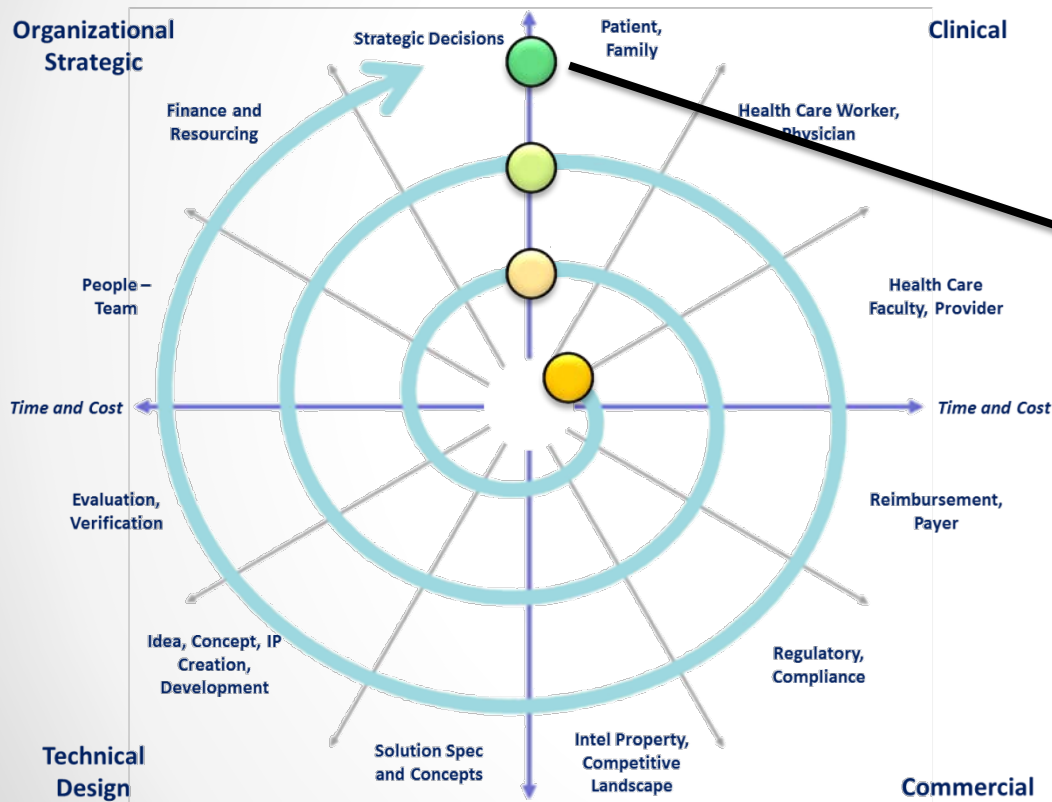
- Original team placed often in BPCs
  - 50k raised
  - **Scenario:** Continued testing by the new team reveals a technical flaw in the key feature of the design that changes the way Drug X must be loaded and disrupts the anticipated supply chain.
  - **Caution:** Micro-level design iterations (“Fixed innovation”); wrong customer needs
- Conduct an initial independent review of all major project components
  - Revisit solution landscape as major information is obtained



## Scenario 4: — Ownership —

Previous Class

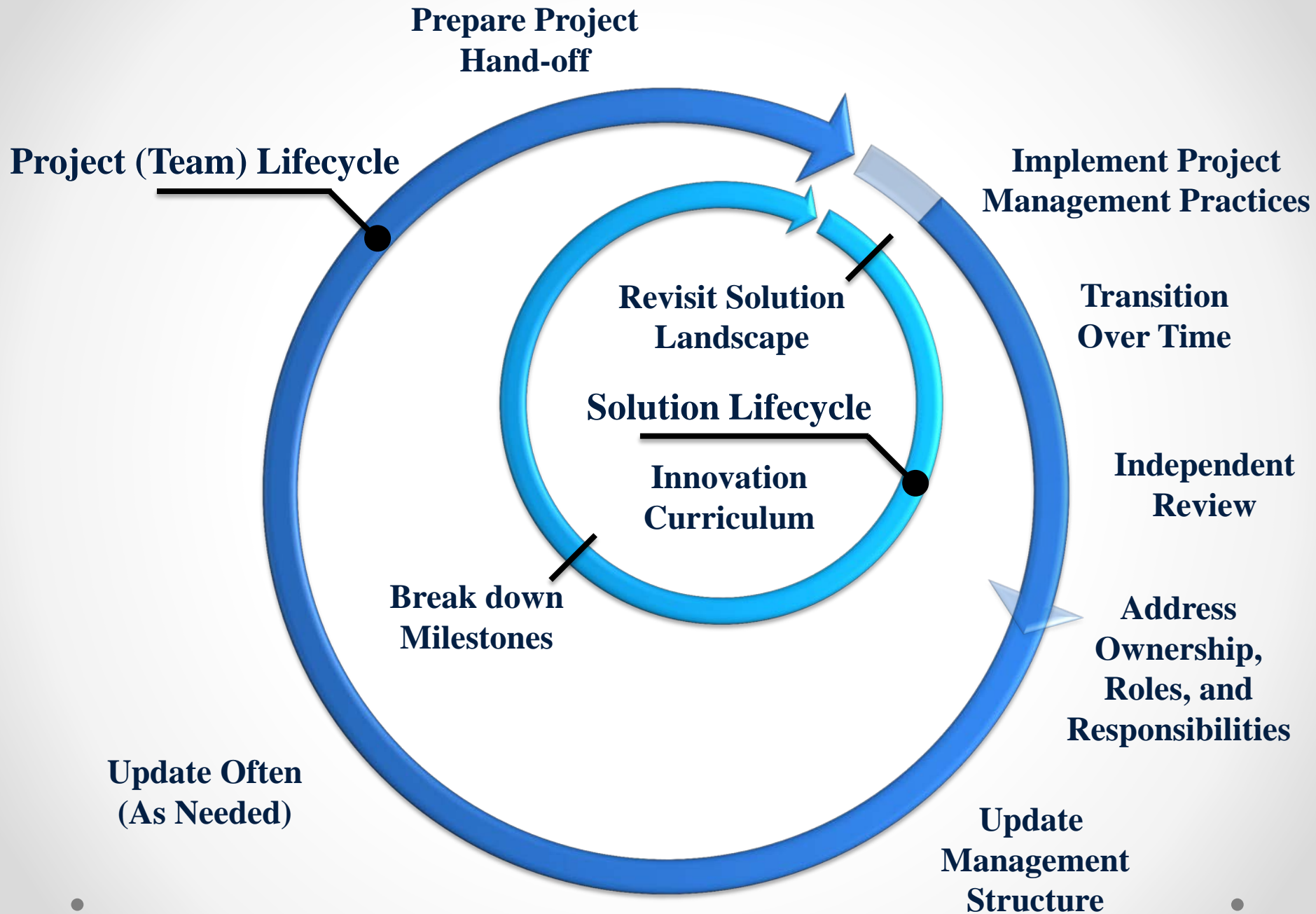
Current Class



Modified from: Yazdi, Y and S Acharya (2013). ABME 41(9):1822-33.

- Address ownership, roles, and responsibilities early
- Update often





## Acknowledgements

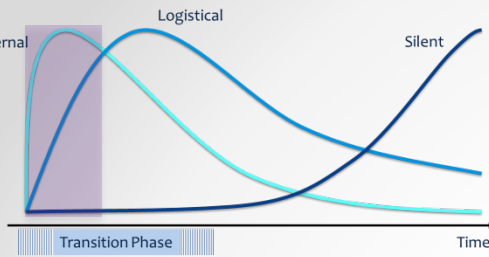
Clifford R Weiss, MD

Soumyadipta Acharya, MD PhD

## Q & A

- **Success (or failure) stories with team turnover**
- **Experience from programs where project management is emphasized and implemented**





## Scenario 1: — Role Conflict —

### Potential Causes

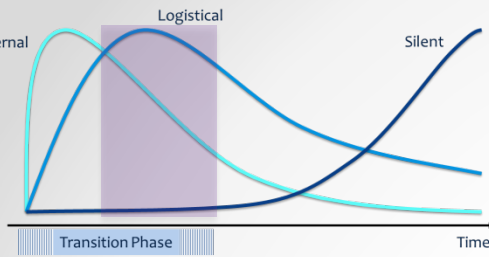
- Pivotal decisions regarding project direction
- New data modifies prior assumptions
- Changes in commercialization strategy

### Exacerbated By

- Project maturity
- Unclear project leader
- Lack of decision making process
- “Groupthinking”
- Number of students with vested interest

### Recommended Mitigations

- Designate a Project Manager, develop teams with balanced power structure
- Implement decision making process
- PIs aid in blending in new team members and communicating roles and responsibilities



## Scenario 2:

### — Loss of Project Knowledge —

#### Potential Causes

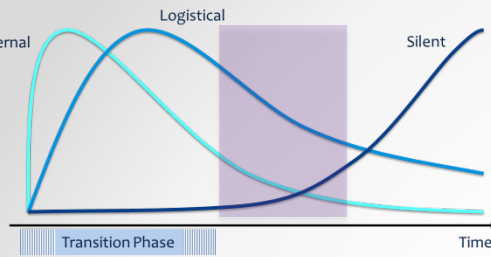
- Complete project hand-off
- New information that challenges previous results
- Loss of key personnel at critical times

#### Exacerbated By

- No overlap of teams during project transition
- Poor documentation
- Decisions required for changing project direction

#### Recommended Mitigations

- Strive for student-to-student hand-off
- Include introductory review of good documentation practices
- Incorporate contingency plan for project hand-off



## Scenario 3: — Project Loyalty —

### Potential Causes

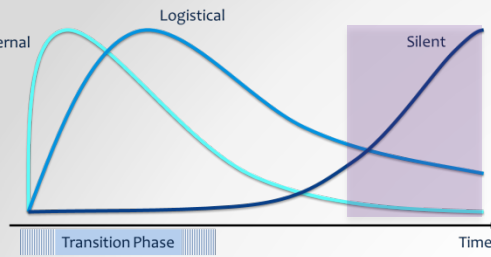
- Incoming project directives
- Information that sheds new light on technical, clinical, or commercial scope

### Exacerbated By

- Steep learning curve
- External interest about a specific solution
- Concern about maintaining “brand image”

### Recommended Mitigations

- New teams should conduct an initial independent review of all major project components
- Revisit solution landscape as major information is obtained



## Scenario 4: — Ownership —

### Potential Causes

- Formation of a business entity
- Change in active team members
- Significant shift in device design/scope by subsequent members

### Exacerbated By

- Unfiled and/or provisional IP
- Large or potential investments
- Poor documentation (DHF)

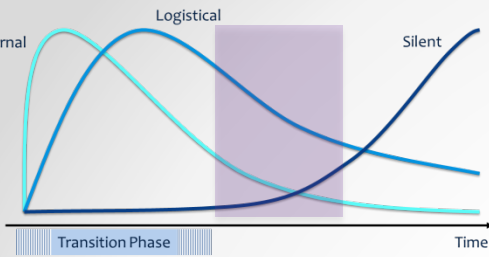
### Recommended Mitigations

- Address ownership early; roles and responsibilities of all vested members
- Update management structure often

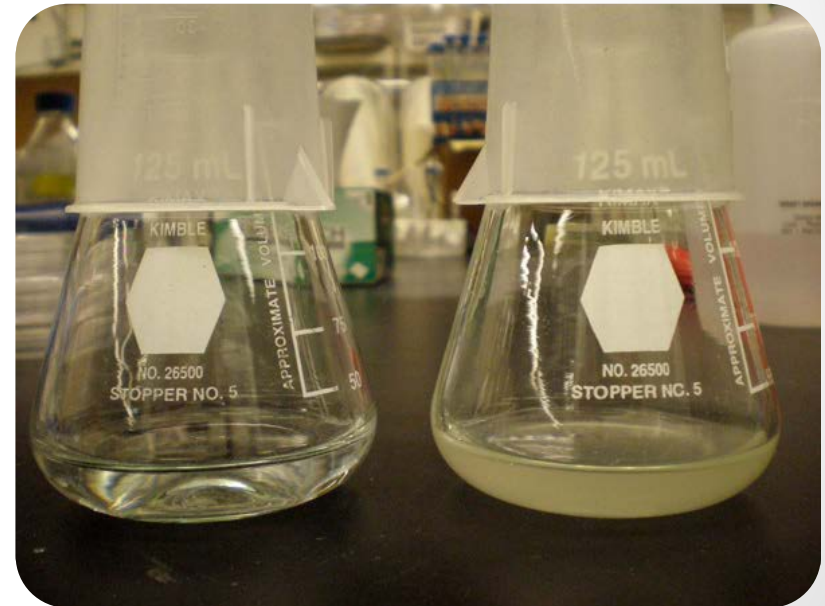




## Scenario 5: — Poorly Defined Project Scope —

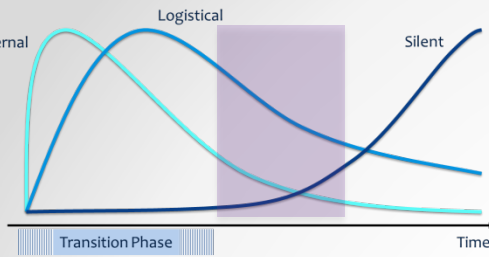


- “Aim 1: Test spray nozzle of new prototype using Drug X.”
- **Scenario:** The team finished preparing mixtures and assembling prototypes for upcoming bench studies. A few days later they notice all the samples now have a cloudy consistency.
- **Caution:** Missed deadlines; teams lacking key proficiencies



<http://www.britannica.com/>

## Scenario 5: — Poorly Defined Project Scope —



### Potential Causes

- Broadly defined project aims
- Objectives defined for devices still in design phase
- Technical aspects beyond team members' expertise

### Exacerbated By

- “Enabling” deliverables
- Existing expectations
- Unclear priority of technical and/or business objectives

### Recommended Mitigations

- Break milestones into smaller and more frequent deliverables
- Define metrics for assessing progress during a transitional period