Project Management of Scientific Research-Phase Projects

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SIUE PM Symposium

Agenda

- Characteristics of Early Phase Research Projects
- Challenges of Research Projects
- Characteristics of Research Teams
- Challenges of Research Teams
- Birth of a Research Project
- Useful Project Manager Skills
- How Project Management Can Help
- Some Things That Have Worked
- Conclusion

Characteristics of Research Projects

- Characterized by uncertainty and risk
- Not readily predictable
- “It’s never been done before”
  - Difficult to establish estimates/timelines
  - Difficult to know what will be needed up front
- Demands the flexibility to change courses based on results
- Historical information is not always a consistent guide
  - Science changes constantly

Challenges of Research Projects

- High level of “failure”
  - The answer to the question is “no”
  - The answer is “insufficient data at this time to answer the question”
  - There is no answer – inconsistent results
  - There IS an answer, but we don’t have enough time or money to figure it out

- Logistics
  - Requires many experts in multiple disciplines
  - Equipment/supplies
  - Facilities
  - VERY expensive
  - Long timelines

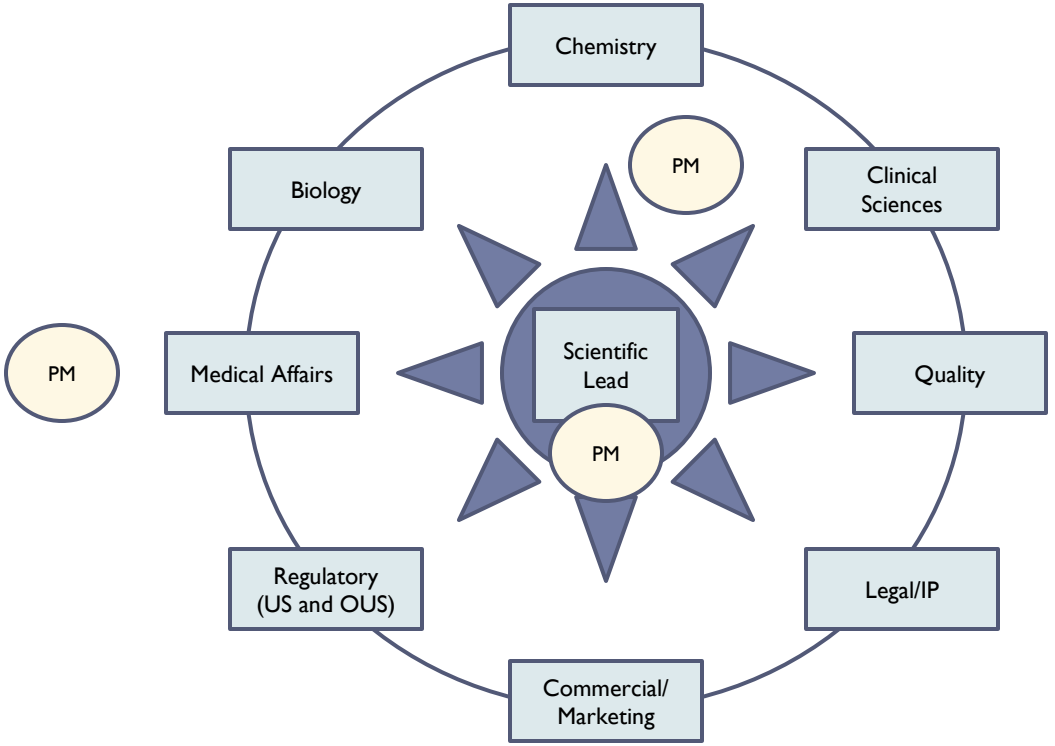
Characteristics of Research Teams

- The team is a group that meets regularly to discuss data related to:
  - A specific project
  - Their area of research
- Includes most of the scientists working on the topic
  - Multiple internal and external experts
- Will assign next steps based on the research, not necessarily on the stated project goals
- Often lacks process
  - No consistent, centralized timeline – “Science can’t be scheduled”
  - Unclear roles/responsibilities in some cases
  - Objectives are very fluid
- Difficult to generate and maintain team cohesion

Team Structure

External Groups

- Advisory Board
- KOL's and SME's
- Consultants
- External Partners
- External Vendors



Challenges – Team

- **Communication**
  - Scientists are reluctant to release information until they are sure it's "real"
    - Data vs Results
  - Difficult to get updates on status if the techniques haven't been completely worked out
  - Communications to non-scientists is usually vague
    - Complexity of the processes is difficult to convey

- **Team Cohesion**
  - Different scientific disciplines
  - Establishing effective hand-off points
  - Working with non-scientist members of the team

Challenges – Team (cont.)

- **Timeline commitments**
  - Team is averse to establishing timelines – “Science can’t be scheduled”
    - “When will we have a result” vs. “When will we know the answer”
  - Generally focused on the discovery process, not the big picture
  - Team is strongly opposed to spending time on activities separate from actual research

- **Process – if only!**
  - Team has little interest in following project-level process
  - Scientists are not focused on providing project-level documentation or updates
  - They pride themselves on a free-spirit approach – “Follow the Science”

Project Manager Skills

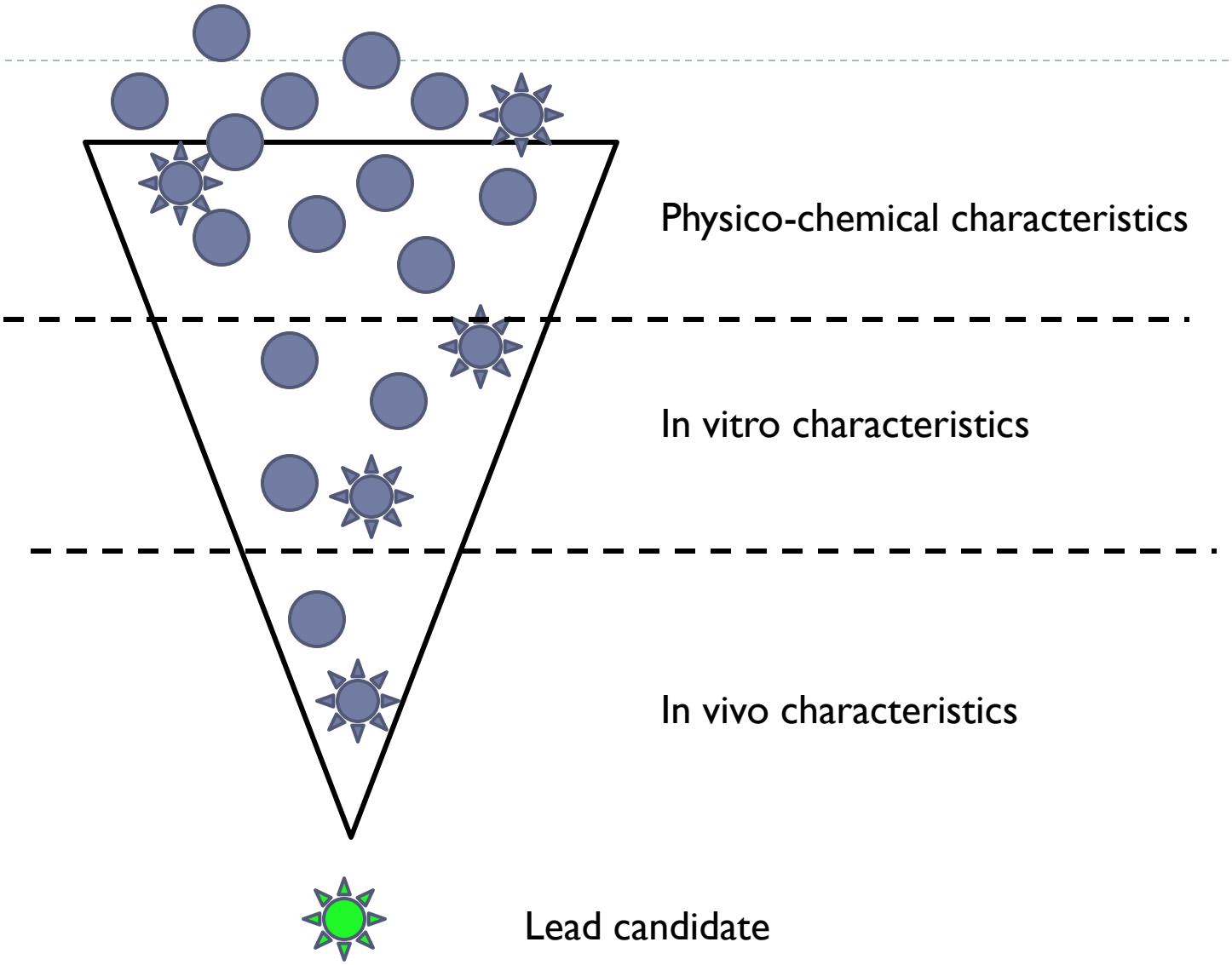
- **For research-phase projects it is advisable for the Project Manager to have a strong technical background**
  - Provide guidance/assistance to the Scientific Project Lead
  - Understand, identify, and mitigate risks
  - Necessary for providing accurate status reports and minutes
  - Provides credibility with team and their management
    - Better chance of getting information from the team

- Comfortable with a high level of ambiguity and uncertainty
- Comfortable with a low level of business process
- Project Monitor vs Project Manager
- Get your work done while leaving a very small footprint

Birth of a Research Project

- Business Decision
  - Therapeutic area – core business
  - Novel area focus or re-do existing idea
- Research Focus
  - Desired characteristics of product – what will set it apart in the market
- Research Strategy
  - Development of Candidate Drugs
  - Creation of Testing Funnel
  - Screening
  - Lead Candidate selection
- Hand-off to Development

Process Flow – Testing Funnel Example



How Project Management Can Help

"Research phase projects aren't really different from development phase projects – the team just doesn't realize it."

ORGANIZE: Manage what's manageable!

- **Provide the framework**
  - Make the big picture visible
  - Show how the pieces fit into the big picture
- **Communication**
  - Ensure that the different subteams understand their connections to each other.
  - Help establish and maintain the hand-off points –Understand the process flows of each subteam
  - Pull together status updates
  - Provide centralized organization of project information

How Project Management Can Help (cont.)

- Work with the Scientific Project Leads
- Keep track of action items
- Pull project information out of the meeting minutes
- Provide multiple schedule variations for pieces of the project
- Help ensure the team has what it needs
  - External
  - Internal
- Ensure all project documentation is in place
  - Legal documents – Freedom to Operate decision, Patents, Contracts
  - Charter
  - Project plan
  - Risk Management Plan
  - Status Dashboards

Some Things That Have Worked

- Provide tools and information that will help the scientists and their management stay informed, focused and on track

Item	Use
Project Plan	• Pulls together all the subteam components • Defines the scientific strategy • Used for project guidance • Used for information purposes – Advisory Board pre-reads, etc
Action Item lists	• Tracking • Risk Management • Schedule Management
Project Dashboards	• Tracking status • Information to Management
Strategy maps	• Tracking status • Risk Mitigation • Information to Management
Subteam process flowcharts	• Identify and manage hand-off points • Identify capacity issues • Identify project flow • Contributes to creation of project schedule
High-level task schedules	• Project tracking • Manage hand-off points
Material request tracking	• Manage hand-off points • Risk mitigation
Specialized subteams	• Manage hand-off points • Risk mitigation

- Keep it all together in a central location – e.g., Sharepoint
- Keep it updated

Action Item Lists

ID	Start Date	Title	Assigned To	Due Date	Status	Meeting Assigned	Notes	Resolution
15	2/26/2014	Work instruction and training for working with documents in SharePoint (workflows etc.)	Emily D.	7/15/2014	Open	Core Team	Leslie sent links to Emily.	
18	2/26/2014	Apply styles guides with macros to the document templates and provide training	Chris G.	7/30/2014	Open	Medical Writing		
19	2/26/2014	Begin to gather Questions for FDA meeting	Carl H.	9/15/2014	Open	Regulatory Subteam	Team will add more questions as the Strategy moves forward.	
20	2/26/2014	Draft the RACI	Denise H.	3/30/2014	Complete	Core Team		RACI approved and posted
24	2/26/2014	Provide Style guide and place on SharePoint	Susan K.	4/15/2014	Complete	Medical Writing		Style guides posted on Sharepoint.
51	4/14/2014	Follow up with Legal to see if there are any issues with managing vendors	Bob M.	4/20/2014	Complete	Core Team		Meeting with Legal held. No issues. Can proceed.
52	5/14/2014	Investigate the preferred vendor pricing	Denise H.	7/15/2014	Open	Clin Ops Subteam	CSP will do a search to gather options and details. Will present at the Core Team.	
60	6/9/2014	Meet to revise SOPs to receive materials on-site	Richard L.	8/21/2014	Open	Manufacturing Subteam		

- My first success!
- Send out the open items the day before the meeting
- Go over them at the start of each meeting

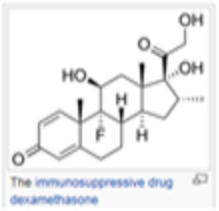
Project Dashboards

Project Scope:

- The adaptive immune system evolved in early vertebrates and allows for a stronger immune response as well as immunological memory, where each pathogen is "remembered" by a signature antigen.
- The adaptive immune response is antigen-specific and requires the recognition of specific "non-self" antigens during a process called antigen presentation.
- Antigen specificity allows for the generation of responses that are tailored to specific pathogens or pathogen-infected cells. The ability to mount these tailored responses is maintained in the body by "memory cells".
- Should a pathogen infect the body more than once, these specific memory cells are used to quickly eliminate it.

Recent Progress and Current Status:

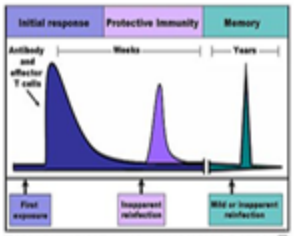
- Helper T cells express T cell receptors (TCR) that recognize antigen bound to Class II MHC molecules. The MHC:antigen complex is also recognized by the helper cell's CD4 co-receptor, which recruits molecules inside the T cell (e.g., Lck) that are responsible for the T cell's activation.
- Helper T cells have a weaker association with the MHC:antigen complex than observed for killer T cells, meaning many receptors (around 200–300) on the helper T cell must be bound by an MHC:antigen in order to activate the helper cell, while killer T cells can be activated by engagement of a single MHC:antigen molecule.
- Helper T cell activation also requires longer duration of engagement with an antigen-presenting cell. The activation of a resting helper T cell causes it to release cytokines that influence the activity of many cell types.



The immunosuppressive drug dexamethasone

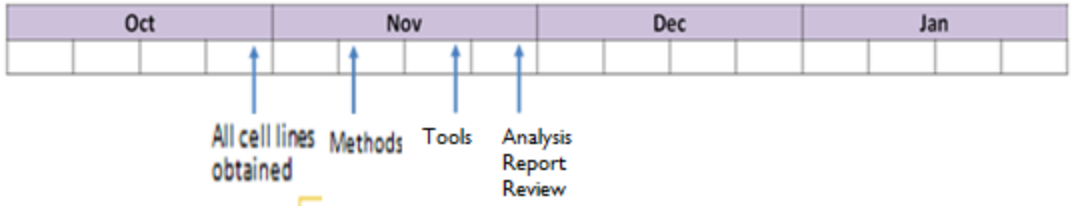
Critical Issues/Questions:

- Long-term active memory is acquired following infection by activation of B and T cells. Active immunity can also be generated artificially, through vaccination. The principle behind vaccination (also called immunization) is to introduce an antigen from a pathogen in order to stimulate the immune system and develop specific immunity against that particular pathogen without causing disease associated with that organism.[2d] This deliberate induction of an immune response is successful because it exploits the natural specificity of the immune system, as well as its inducibility. With infectious disease remaining one of the leading causes of death in the human population, vaccination represents the most effective manipulation of the immune system mankind has developed.



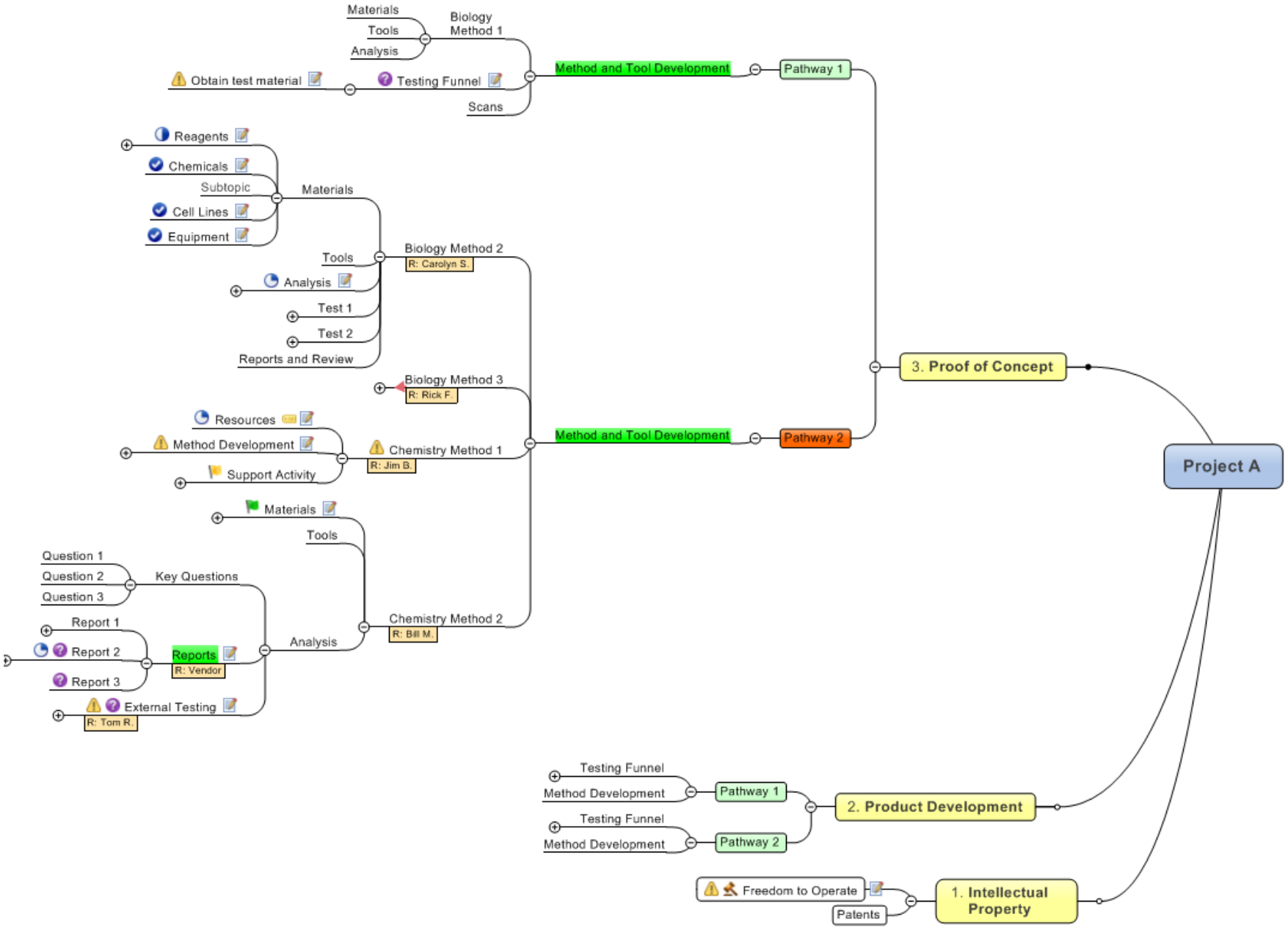
The time-course of an immune response begins with the initial pathogen encounter, (or initial vaccination) and leads to the formation and maintenance of active immunological memory.

Key Milestones with Timelines (Oct 10 – Jan 11)

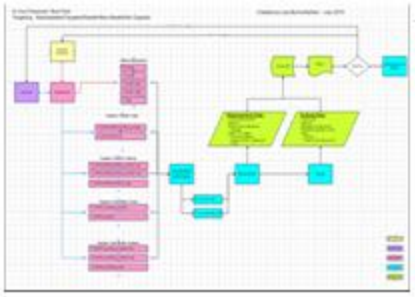


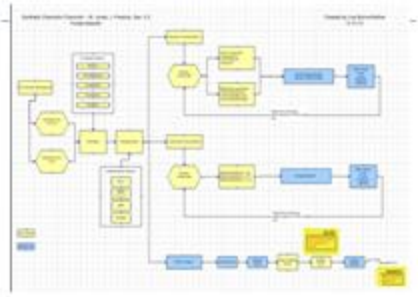
- Created for use by the Tech Leads
- Updated monthly for each subteam
- Filed on Sharepoint
- Used by Management to track status
- Used by teams to review status and plan

Strategy Maps - MindJet



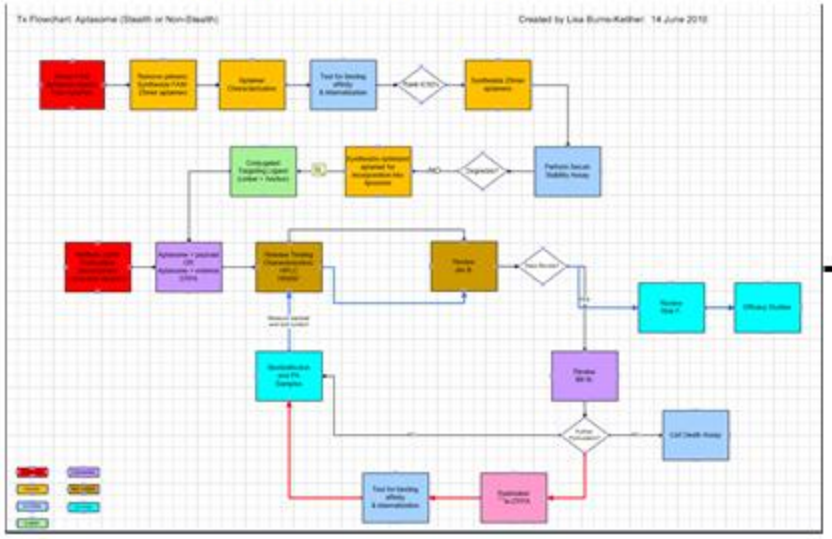
Process Flowcharts



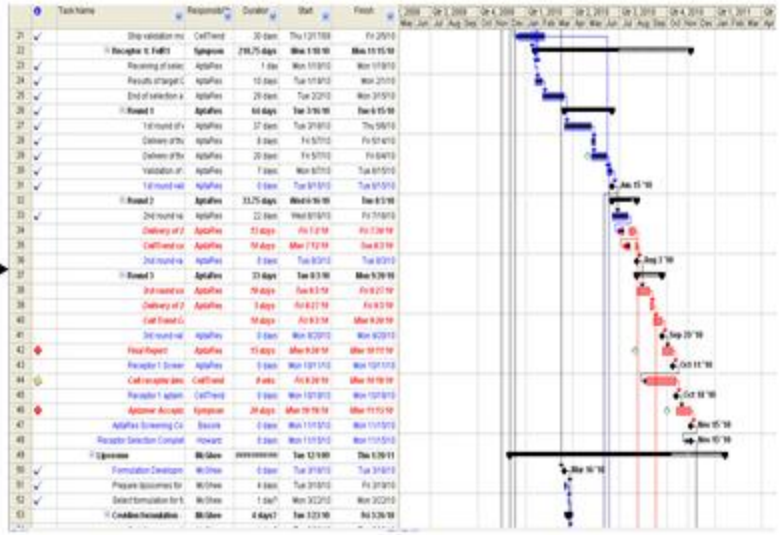


Subteam Process Flowcharts

Project Flowchart



Project Schedule



Summary

- Research-phase projects are very similar to development-phase projects, the team just doesn't realize it.
- However, there are some specific characteristics:
  - Very high levels of uncertainty and risk
  - Very low levels of process
  - Extremely difficult to estimate timelines or predict outcomes
  - High rate of "failure"
  - Challenging to organize
- Project Managers should have a strong technical background and be able to do their work with little impact.
- Get comfortable with ambiguity!
- Organization is your only hope