Concepts in Pharmaceutical Development Project Management
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Disclaimer
The views expressed in this talk represent my opinions and do not necessarily represent the views of the FDA.
Introduction
By way of …
Small
Medium and
Large Pharma

the FDA
OND\CDER\DNP (Div Neurology Products)
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Objectives
By the end of this lecture, you should be able to:
- Describe the role of and skill sets needed for the Project Manager (PM) position
- Appreciate the different tools used by the PM
Recommended Reading

Screenshot: Pharmaceutical Project Management
Cartoon: elderly couple standing on “square one” with the caption “Well, here we go again.”
What is Pharmaceutical Development
…and why do we need a Project Manager?
What is Pharmaceutical Development
Graph showing the steps in pharmaceutical development
**What** is a Pharmaceutical Project Team Graphic showing the members of a pharmaceutical project team.
The team at the first level
Graphic showing who is on the team at the first level
What is a Clinical Development Project Team

Graphic showing what a clinical development team is.
The Matrix Model for Project Teams

Graphic showing the matrix model for project teams
INTERNAL FORCES

Graphic showing the internal forces that impact a project
EXTERNAL FORCES

Graphic showing the external forces that impact your project
Pharmaceutical Project Management

Pictures of different pharmaceutical project management teams
• What is Project Management?
  PMBOK
  “Project management is the application of knowledge, skills, tools, and techniques to project activities in order to meet or exceed stakeholder needs and expectations from a project.”
Cost of Poor Management
$ 899 MM/Each New Drug
Opportunity Costs
Failed Drugs
Marketing & Sales Costs
The Patients are Still Waiting
In other words...

Photos that show what happens when there is poor management
Benefit of Good Management

Higher NPVs
More Products per $
Identify Losers Sooner
More Successful Projects
Faster Reviews
Graphic: bar graph
The Role of the PM
Photo of a man with a confused look on his face.
PM EVOLUTION

Graph showing line driven and project driven
The Faces of Clinical Development Project Management

Graphic showing the faces of project management
• What is Project Management?:
• Who they are and what they do.
From a project manager

Masters of Business Process
Business = commercial + technical

Facilitators of interpersonal interaction

Cartoon: Man at the gates of what appears to be heaven who cannot get in. Caption reads “I’m sorry, but it appears that you didn’t meet your project deliverables.”
What is Project Management?:

Broad Knowledge
  – Experience
Interpersonal Skills
  Facilitating
  Human Factors
Ability to get the most
out of tools / technology
  Innate analytic
Communication Techniques
What is Project Management?:
Knowledge
Drug development process & benchmarking
Science/Medicine (therapeutic area)
Regulations
Business
Portfolio management
Alliance Management
Risk management
Project time management
Project cost management
Organizational dynamics
International & corporate culture
What is Project Management?:
Interpersonal Skills
Network planning
Strategic thinking
Negotiation
Meeting management
Facilitation
Communication (written & oral)
Conflict management
Issue resolution
Contractor management
What is Project Management?: Facilitating decisions

Selecting Clinical Candidates
Implementing
Tracking
Reporting
Completing /Terminating
What is Project Management?:
  Human factors
  Leadership
  Team Building
  Matrix/ Heavy-weight Teams
  Communication
  High Performance
  Education
What is Project Management?:
Tools
Planning software
PERT charts
Gantt (bar) charts
Dashboards
Budgets
Decision trees & network
Meeting minutes
Spreadsheets
e-Mail
Word processor
Teleconference
Videoconference
Cartoon of king and royal subjects. Caption reads: “Sure, we need more research in alchemy, necromancy, and sorcery, but where is the money going to come from?”
What is Project Management?:
Communication Techniques
What if analyses
Critical path analyses
Brainstorming
Challenging (devil’s advocate)
Cajoling
Nagging
Begging
Cartoon

Caption: Suddenly, a heated exchange took place between the king and the moat contractor!
Picture of a rowing team in a boat with the caption “If everyone’s not pulling together, your project’s going nowhere.”
Tools for the Project Manager
Don’t Leave Home Without It!!
The Team Minutes
The Target Product Profile
The Draft Structured Product Label
The Strategic Development Plan
The GANNT Chart
The Probability Analysis
• Why are these tools important to everyone?!
• “...Even if you do not lead a team, you lead a team of 1”.

» Christopher D. Breder, 2011

Graphic: T-shirt with the word TEiAM on the front.
Team Meeting Minutes
What they are good for
   Exquisitely organized progress review
   Concise communication tool for Senior Management
       Brings priorities and timelines up front
   Documentation of accountabilities and responsibilities
   Drives the agenda of the team meeting
Team Minutes Template

Issues (Boxed)
- Things that will cause delay, cost overrun, or that may impact a Go/No-Go decision
- Background, impact, proposals

Timelines
- With key milestones, e.g., final protocol, first patient, database lock, topline data, final report
  - Some Mgmt like planned /projected (while ongoing)/actual

Financial Summary

Progress by Dept
- Nonclinical, Clin Pharm, Clin, Regulatory, CMC, Clinical Supplies
- More granular, yet concise progress report, including finances, timelines, key deliverables met and forthcoming
Target Product Profile
A contract with the Corporation regarding the desired attributes of the Product
  Determines estimate of Net Present Value
  Forms the basis of Go-No Go Criteria
  Forms the basis of the clinical development plan (CDP; and probably all other DPs) and draft label
Target Product Profiles
Graphic: Guidance for Industry and Review Staff. Target Product Profile – A Strategic Development Process Tool
Chart
Chart
Screenshot: Product Labeling: New Format Highlights Section
Product Labeling: New Format

Highlights Section

Product Labeling: New Format

Full Prescribing Information

Boxed Warning

1 Indications & Usage
2 Dosage & Administration
3 Dosage Forms & Strengths
4 Contraindications
5 Warnings & Precautions
6 Adverse Reactions
7 Drug Interactions
8 Use in Specific Populations
9 Drug Abuse & Dependence
10 Overdosage
11 Description
12 Clinical Pharmacology
13 Nonclinical Toxicology
14 Clinical Studies
15 References
16 How Supplied/Storage & Handling
17 Patient Counseling Information
Why is Labeling Important

It is considered the preferred method to convey information about your drug

- Has profound impact on advertising, claims, compensation
- Often the first source of information for doctors and consumers

If you want claims in your label, you need to study it

- Sometimes things you don’t want get put in, e.g., class labeling
Strategic Development Plan
Chart: Adapted from Kennedy’s “Pharmaceutical Project Management”
GANNT Chart
Screenshot: GANNT Chart
GANNT Chart

Allows review of timetables
  Allows one to double check assumptions
Identification of resources
Allows recognition of critical interdependencies
  e.g., need to clear a product with QA before shipping
Forms the basis of Go-No Go Criteria

Identifies critical path tasks
  a critical path is the sequence of activities which add up to the longest overall project duration. This determines the shortest time possible to complete the project. Any delay of an activity on the critical path directly impacts the planned project completion date. Those activities that can be done at anytime are “not on the critical path”
Graphic: Critical Path Analysis: GANTT Chart
Cartoon: Woman reading a map to her kids.
Caption: “KIDS! This stop is on the CRITICAL PATH and is scheduled to take exactly 43 minutes! So no slack time!”
Probability Exercises for Project and Portfolio Planning Graph
Summary
Clinical Development is complex, both in its science and relationships
The CDPM plays a pivotal role facilitating the planning and execution of CD
Various tools are at the disposal for organization and communication

*Project Leader* is the one who takes the reins!