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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)

Johns Hopkins University, Center for Biotechnology Education

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

What is Pharmaceutical Development

...and why do we need a γ Project Manager?

A Peek under the Hood of the Pharmaceutical Project Team

What is
Pharmaceutical Development

What is a
Pharmaceutical Project Team

The team at the first level

What is a Clinical Development Project Team

The Matrix Model for Project Teams

Project Team

Lots of People → Lots of Ideas Change (lots) whether for reasons of

Progress

Remediation

Perception

INTERNAL FORCES

EXTERNAL FORCES

Pharmaceutical Project Management

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

27,400,000

\$ 899 MM/Each New Drug

Opportunity Costs

Failed Drugs

Marketing & Sales Costs

The Patients are Still Waiting

In other words...

Benefit of Good
Management

Higher NPVs

More Products per \$

Identify Losers Sooner

More Successful Projects

Faster Reviews

The Role of the PM

PM EVOLUTION

The Faces of Clinical Development Project Management

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?:

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?:
Communication Techniques

What if analyses

Critical path analyses

Brainstorming

Challenging (devil's advocate)

Cajoling

Nagging

Begging

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

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”.

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

Nonclin, Clin Pharm, Clin, Regulatory, CMC, Clin 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

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

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 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"

Probability Exercises for Project and Portfolio Planning

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!