Concepts in Pharmaceutical Development Project Management

Christopher D. Breder, MD PhD
Medical Officer, US FDA
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 composition of a drug development team
– Discuss the role of the Project Manager
– Discuss the different skill sets needed for the PM position
– Compare the different tools used by the PM
Recommended Reading

"...is not a simple process"

"...depends on the quality of the development strategy"
"Well, here we are again."
What is Pharmaceutical Development

- Unmet Medical Need
- Innovation
- Market Potential
- Resource Limitations
- Statutory Constraints

R&D
COMMERCIAL
REGULATORY
Corporate Infrastructure
Why of Pharmaceutical Development

• **CMC [21 CFR 312.23(a)(7)]:**
  To assure the proper identification, quality, purity, and strength of the investigational drug.

• **Nonclinical [21 CFR 312.23(a)(8)]:**
  To assure that it is reasonably safe to conduct the proposed clinical investigations.

• **Clinical [FD&C Act Sec. 505]:**
  To establish efficacy and safety of a drug for use in humans, in a dose range and schedule that provides an acceptable risk benefit relationship.
How of Drug Development Process

**IND**
- **pre-IND**
  - Discovery & chemical synthesis
- Non-Clinical: Research Lab & Animals
- Clinical Phase I: Pharmacological Studies
  - Pre-IND Mtg.
  - EOP1 Mtg.
- IND Phases
  - EOP2 Mtg.
- Pre NDA Mtg.

**NDA**
- Clinical Phase II: Efficacy Testing & Dose Determination
- Clinical Phase III: Confirmatory Studies
What is a Pharmaceutical Project Team

Marketing

Non-Clinical

Clinical

Regulatory

CMC

Drug
What is a Clinical Development Project Team

- Clinical Research
  - Clinical Ops
  - Clinical
  - Data Mgmt
  - Early Devt
  - Safety Team
  - Post Marketing Surveillance

- Biostats

- Safety
  - Epidemiology
  - Safety

- Medical Affairs
  - Med Comm

- Clinical
  - PK
  - Modeling
  - Biometrics
  - Clin Pharm

- Med Affairs
  - Med Affairs
  - Health Econ
  - Liasons
The Matrix Model for Project Teams

- Higher Efficiency and Ownership
- Managing by Influence (No Line Authority)
INTERNAL FORCES

Evaluation, Team, Quality, Time, Decision Making, Selection, Strategic Intent, Turf, Marketing

YOUR PROJECT
EXTERNAL FORCES

- Competition
- Commercial Potential
- FDA/BoH
- Time
- Activists
- Congress
- Reimbursement

YOUR PROJECT
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
Benefit of Good Management

• Higher NPVs
• More Products per $
• Identify Losers Sooner
• More Successful Projects
• Faster Reviews
Shrinking time to second in class requires that you get out of the gates fast & hard

Years Between Drug Launch and First Competitor

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- Increased competitiveness
- Must maximize opportunity from day one

Source: A.T. Kearney, The Economist 09/20/97
The Faces of Clinical Development
Project Management

- Project Analyst (timelines, budgets)
- Project Leader (Voice to Upper Mgmt)
Project Management
Who They Are and What They Do:

From a Project Manager

- Masters of Business Process
- Facilitators of Interpersonal Interaction
What is Project Management?:

- Broad Knowledge
  - Experience
- Interpersonal Skills
- Ability to get the most out of tools / technology
  - Innate analytic
- Communication Techniques
- Facilitating
- Human Factors
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

- Communication (written & oral)
- Conflict management
- Issue resolution
- Contractor management
“Sure, we need more research in alchemy, necromancy, and sorcery, but where is the money going to come from?”
What is Project Management?:

Tools

- Planning software
- PERT charts
- Gantt (bar) charts
- Dashboards
- Decision trees & network
- Meeting minutes
- Spreadsheets
- e-Mail
- Word processor
- Teleconference
- Videoconference
What is Project Management?:
Communication Techniques

- What if analyses
- Critical path analyses
- Brainstorming
- Challenging (devil’s advocate)
- Cajoling
- Nagging
- Begging
Suddenly, a heated exchange took place between the king and the moat contractor!
What is Project Management?:
Facilitating decisions

- Selecting Clinical Candidates
- Implementing
- Tracking
- Reporting
- Completing / Terminating

Adapted from “How to Keep R&D Projects on Track!” -- Robert Szakonyi
What is Project Management?: Human factors

- Leadership
- Team Building
- Matrix/ Heavy-weight Teams
- Communication
- High Performance
- Education
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
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

Guidance for Industry and Review Staff
Target Product Profile — A Strategic Development Process Tool

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document contact Jeanne M. Delanko at 301-796-0900.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2007
Procedural
## Target Product Profile Awakenol® for the Treatment of Sleeping in 410.651.82 Lectures

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<th>ATTRIBUTE</th>
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<td>• Common (&gt;5%) adverse events</td>
<td>10% Nausea, 07% Apathy, 05% Confusion</td>
<td>10% Nausea, 07% Apathy, 05% Confusion</td>
<td>1-2% less in key AEs</td>
<td>Clinically significant reduction in key AEs, Reduction in AEs with Superior efficacy</td>
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<td><strong>Indications</strong></td>
<td>Falling Asleep in 410.651.82</td>
<td>Falling Asleep in 410.651.82</td>
<td>+ Falling asleep in other JHU courses</td>
<td>+ Falling asleep in any University course</td>
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1. % patients with a score of at least 85 on the Rockville Sleep Scale (RSS)

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The views expressed in this talk represent my opinions and do not necessarily represent the views of the FDA. Any molecules, scientific concepts, or references in this paper are not necessarily real. This paper is only distributed to instruct on one way of formatting a TPP.
The low case may be the same or reasonably lower than the GS if there are other attributes in favor of you. You may not want any of a particular GS attribute, even in the low case. It is not uncommon to incorporate intellectual property positions in the TPP. Differences in numerical results are tricky to assign; be reasonable. What is clinically significant?

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* % patients with a score of at least 85 on the Rockville Sleep Scale (RSS)
HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Imidicon safely and effectively. See full prescribing information for Imidicon.

IMIDICON® (cholinasol) CAPSULES
Initial U.S. Approval: 2000

WARNING: LIFE-THREATENING HEMATOLOGICAL ADVERSE REACTIONS
See full prescribing information for complete boxed warning.
Monitor for hematological adverse reactions every 2 weeks for first 3 months of treatment (5.2). Discontinue Imidicon immediately if any of the following occur:
- Neutropenia/agranulocytosis (5.1)
- Thrombotic thrombocytopenic purpura (5.1)
- Aplastic anemia (5.1)

INDICATIONS AND USAGE
Imdicon is an adenosine diphosphate (ADP) antagonist platelet aggregation inhibitor indicated for:
- Reducing the risk of thrombotic stroke in patients who have experienced stroke precursors or who have had a completed thrombotic stroke (1.1)
- Reducing the incidence of subacute coronary stent thrombosis, when used with aspirin (1.2)

Important limitations:
- For stroke, Imidicon should be reserved for patients who are intolerant of or allergic to aspirin or who have failed aspirin therapy (1.1)

DOSAGE AND ADMINISTRATION
- Stroke: 50 mg once daily with food (2.1)
- Coronary Stenting: 50 mg once daily with food, with antiplatelet doses of aspirin, for up to 30 days following stent implantation (2.2)

Discontinue in renally impaired patients if hemorrhagic or hematopoietic problems are encountered (2.3, 8.6, 12.3)

CONTRAINDICATIONS
- Hematopoietic disorders or a history of TTP or aplastic anemia (4)
- Hemostatic disorder or active bleeding (4)
- Severe hepatic impairment (4, 8.7)

WARNINGS AND PRECAUTIONS
- Neutropenia (2.4 % incidence; may occur suddenly; typically resolves within 1-2 weeks of discontinuation), thrombotic thrombocytopenic purpura (TTP), aplastic anemia, agranulocytosis, pancytopenia, leukemia, and thrombocytopenia can occur (5.1)
- Monitor for hematological adverse reactions every 2 weeks through the third month of treatment (5.2)

ADVERSE REACTIONS
Most common adverse reactions (incidence >2%) are diarrhea, nausea, dyspepsia, rash, gastrointestinal pain, neutropenia, and purpura (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact (manufacturer) at (phone # and Web address) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
- Anticoagulants: Discontinue prior to switching to Imidicon (5.3, 7.1)
- Phenytoin: Elevated phenytoin levels have been reported. Monitor levels. (7.2)

USE IN SPECIFIC POPULATIONS
- Hepatic impairment: Dose may need adjustment. Contraindicated in severe hepatic disease (4, 8.7, 12.3)
- Renal impairment: Dose may need adjustment (2.3, 8.6, 12.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 5/200X
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

Adapted from Kennedy’s “Pharmaceutical Project Management”

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<td>The approval sought (scope of activities, funds, and resources)</td>
<td>A template often used so that the oversight committee has consistent “view” of the projects being presented</td>
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<td>Key risks/risk management</td>
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<td>Go/no-go checkpoint and criteria</td>
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<td>High level Gantt chart</td>
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<td>The detail increases during development phases</td>
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<td>Clinical Gantt chart</td>
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<td>Clinical issues/issue management</td>
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<td>Financial assessment of project</td>
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*Abbreviations: CMC: chemistry, manufacturing and controls; ADME: absorption, distribution, metabolism, excretion.*
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”
Critical Path Analysis: GANTT Chart

<table>
<thead>
<tr>
<th>Task Name</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Patient Last Visit (LPLV)</td>
<td>0 days</td>
</tr>
<tr>
<td>PK Data</td>
<td>60 days</td>
</tr>
<tr>
<td>Collect Bioanalytical</td>
<td>2 wks</td>
</tr>
<tr>
<td>Lock PK Database</td>
<td>10 wks</td>
</tr>
<tr>
<td>CRF Data</td>
<td>50 days</td>
</tr>
<tr>
<td>Collect CRFs</td>
<td>4 wks</td>
</tr>
<tr>
<td>Lock CRF Database</td>
<td>6 wks</td>
</tr>
<tr>
<td>Analysis</td>
<td>20 days</td>
</tr>
<tr>
<td>Analyze Data</td>
<td>4 wks</td>
</tr>
<tr>
<td>Reporting</td>
<td>85 days</td>
</tr>
<tr>
<td>Finalize First Draft Report</td>
<td>5 wks</td>
</tr>
<tr>
<td>Finalize Report</td>
<td>1 wk</td>
</tr>
</tbody>
</table>
“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

Diagram showing the probability of phase success and failure, with costs and expected values for different phases.
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!