Project Management in Clinical Drug Development

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    {Role, Organization}
Learning Objectives

Upon completion of this presentation, participants should be able to:

1. Define Project Management and its core principles
2. Identify the skills that a successful project manager should have
3. Apply the Project Management principles to your role in the clinical research industry
Agenda

• Introduction to Jim Deiner
• What is Project Management?
  • PM Core Principles and Practices
  • What makes a good Project Manager
• Applying PM to CR
• Review of the State of Project Management in Pharma Survey
Jim Deiner Introduction

Currently
- Project Manager in Janssen R&D
- Adjunct Instructor at Drexel & Temple Universities
  - Project Management and Engineering Management
- Project Manager
  - IT
    - Pharma, Logistics, Financial Services
- PMI
  - PMP certified
  - Volunteered with PMI’s Pharma CoP
- Six Sigma Green Belt
- *NOT* represent
  - Janssen or PMI
Project Management Institute (PMI) 

Introduction

- Professional organization promoting practice of project management
- Certifications in
  - PMP Project Management Professional
  - CAPM Certified Associate in Project Management
  - PgMP Program Management Professional
  - ... and others
- Research, knowledge sharing; networking opportunities
- Project Management Body of Knowledge *PMBOK® Guide*
  - PM Framework used here
What is Project Management?

• What is Project Management?
• Core Principles & Practices
• What makes a Great PM

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What is Project Management?

• The application of
  • Processes
  • Methods
  • Knowledge
  • Skills
  • Experience
• To achieve project objectives

• Not the *work* of the project
  • But the project management activities that enable project work

PMI PMBOK® Guide
What is a Project?

- A project is a unique temporary endeavor to achieve organization results
  - Beginning, End
  - Purpose
  - Unique
  → create a unique product, service or result
- Not
  - Ongoing operations
  - Managing a department or function
- Examples in our industry?
Importance of Project Management

- Projects
  - Vehicle for strategy execution
  - Large commitment of $$, resources
- Project Management
  - Leadership & direction to projects
  - Realistic & disciplined project planning, monitoring & control
- Going forward
  - Shorter cycle times
  - Tighter budgets
  - More complex
Project Management Principles and Practices
PM Basic Principles: The Project Lifecycle
PM Basic Principles: PM Processes

- Initiating Processes
- Planning Processes
- Executing Processes
- Monitoring & Controlling Processes
- Closing Processes
PM Basic Principles: The Planning Flow

The **What** And **Why**

The **What** and the **How**

The **How** and the **When**

**Agreement** and **Authorization**
PM Basic Principles: PM “Iron Triangle”

• Three main dimensions of a project
  • Scope,
  • Cost
  • Schedule
• “Next” Tier
  • Quality
  • Risk
• Definition of project success
  • On-time, on-Budget, To-Spec
PM Basic Principles: (some) Big Ideas

- PM is a process of Expectation Management
  - Everyone on the same page
  - Agree/Understand re trade-offs
  - Continual throughout the project
- Plan the work, work the plan
- Actual outcomes vs. Planned Baseline
- Build knowledge base over time
PM Basic Principles: Planning Quotes

- “In preparing for battle I have always found that plans are useless, but planning is indispensable.” — Dwight Eisenhower
- “By failing to prepare, you are preparing to fail.” — Benjamin Franklin
- “A good plan, violently executed now, is better than a perfect plan next week.” — George S. Patton
- “No plan survives contact with the enemy” — von Moltke (attr)
- “Plans are only good intentions unless they immediately degenerate into hard work.” — Peter Drucker
Characteristics of Great Project Managers
Characteristics of Great Project Managers

• “Hard” Skill Competency
• Build /Maintain Relationships
  • Up, Down, Across
• Communication
• Manage Expectations
  • Stakeholders
  • Management
  • Team
• Handle Conflict & Change
• Leadership
  • Build trust, articulate,/align around common vision, empower/enable

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Applying Project Management to Clinical Research
Applying PM to Clinical Research

- Project Initiation
  - Chartering
    - Formal authorization: $$, People, Objectives, Portfolio
    - Great Kick-Off
  - Stakeholder Management
  - Begin Expectation Management
Applying PM to Clinical Research

- Planning
  - Discipline of following the flow
    - WBS or standard template(s)
    - Explicitly address all PM knowledge areas
  → baselined plan
• Add practical planning suggestions???
Applying PM to Clinical Research

- Execution
  - Making good assignments
  - Monitoring risk triggers
Applying PM to Clinical Research

- Monitoring & Controlling
  - Monitor the Critical path
  - Implement risk contingency strategies
  - Monitor & report: actual variance to plan
  - Different levels of rigor
  - Reporting
  - Conduct rigorous change control
Applying PM to Clinical Research

Reporting Examples
- Dashboard
- Traffic lights
- Variance
  - Milestone
  - % complete
  - Earn v Burn
PMI Pharma CoP Survey

- Background
- PMI Pharmaceutical Community of Practice survey
  - Current state of PM practice
  - Best practices
  - Challenges
- Scope
  - Late development Pharma R&D
  - Pharmaceutical, Biotech, CROs
PMI Pharma CoP Survey
PMI Pharma CoP Survey

Project Culture

Science-focused; no PM, 12.76
Low level support, 5.6
Useful tracking; not lead, 22.45
Integral & essential, 29.08
Helpful, 27.04
Other, 3.06

Senior Management View

- They understand it...
- They use PM reporting an...
- They see little value...

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Level of project management maturity

- Level 1: Ad Hoc - No formal project management
- Level 2: Planned - Formal project management
- Level 3: Managed - Project management processes and tools
- Level 4: Integrated - Project management integrated into organizational processes
- Level 5: Sustained - Project management is an organizational standard
PMI Pharma CoP Survey

Challenges

- Collecting PM Data
- Reporting PM Data
- Team Dynamics
- Scope
- Budgets
- Deliverables & Deadlines
- On-Time
- Communication
- Non-Project Org Issues
- Delays
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Prioritization of the Four Project Constraints
Organization Improvements to Reinforce PM Processes?

- Upper Mgmt Support
- Formal Methodology
- PM Training: Team, SH, Mgmt
- Training in Finance
- Other

PMI Pharma CoP Survey
Summary/Close

Hopefully,
• An understanding of
  • Project management
  • How it can be useful in clinical research
• An idea of the state of project management in Pharma
Thank you!

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