VA Cooperative Studies Program
Clinical Research Pharmacy Coordinating Center
VA CSP Clinical Research Pharmacy Coordinating Center

- **1977** - Relocated to the VA Medical Center in Albuquerque, NM
- Manage patient safety, regulatory and pharmaceutical aspects of multicenter clinical trials
- Currently manage 34 multicenter studies in planning, 52 active multicenter studies
Certifications and Recognitions

- **1992** – Drug Enforcement Agency Facility Registration (21 CFR 1300)
- **1993** – FDA current Good Manufacturing Practices Facility Registration (21 CFR 210 and 211)
- **2003** – ISO 9001 Registration (Quality Management System)
- **2009** – Malcolm Baldrige National Quality Award – Presidential Award
- **2013** – ISO 21500 Certification (Guidance on Project Management)
Center Mission

To improve the health of our Nation’s Veterans by providing creative pharmaceutical solutions to global clinical research
Center Vision

We will become the premier provider of services for clinical research, with highly engaged employees who are focused on exceeding customer expectations.
External Customers

- **National Institutes of Health**
  - NIDA, NHLBI, NCI, NINDS, NIDDK, NIAMSD, NIMH, NIDCD, NIAAA, NCCAM

- **Coordinating Centers/Universities**
  - University of Washington, Maryland Medical Research Institute, University of North Carolina at Chapel Hill, Georgetown University, Wake Forrest University

- **Department of Defense**

- **Industry**

- **International**
  - Canadian Institutes of Health Research, United Kingdom Medical Research Council, The George Institute
Project Management in the CT Environment

• Overview
  • Describe Concepts for Planning a Clinical Trial
  • Summarize Project Planning
  • Organizing Teams & Staff Communications
  • Managing Risk & Customer Expectations
What Planning/effective PM can help to avoid
Phases of Clinical Trial

**Plan**
- Request for proposed Clinical Trial

**Start Up Clinical Trial**
- Finalize Requirements

**Conduct Clinical Trial**
- Initial Shipments to Sites
- Ongoing Study Management

**Close Out**
- Project Close Out

**Project Management**
- Participate in Planning Activities
- Manage Start Up Activities
- Manage On-going Activities
- Manage Close Out Activities

**Increasing Level of Detail in Clinical Trial Project Plan (CTPP)**
Integrating project plan, budgets and requirements with project phases

- Customer Requirements
- Scope Definition
- Functional Requirements
- Technical Requirements
- Protocol
- Clinical Trials Project Plan
- Requirements
- Internal technical Documents and Specifications
Clinical Trial Project Plan

Project Management

Participate in Planning Activities
• Gather, Document and Communicate Customer Requirements
• Assess Risk
• Develop budget

Clinical Trials Project Management Plan Table of Contents

1 Overview of Study and Link to Protocol (When Applicable) Overview
2 Budget Assumptions Budget Assumptions
3 High Level Requirements (Characteristics) Characteristics
4 High Level Requirements (Drug-Device Matrix) Drug/Device Matrix
5 Schedule (Key Dates) Key Dates
6 Risk Register (Ties to all Change Requests) Risk Register
Requirements Document

Project Management

Participate in Star-up Activities
- Gather Additional Requirements and Communicate Expectation
- Identify the Study Team
- Delegate Scope of Work to Sections

Start Up Clinical Trial

Conduct Clinical Trial

Close Out

Requirements Document Table of Contents

1. Change Log
   Changes to the file are logged on this tab.

2. Start Up Scope of Work
   Provide final kit design and other ancillary items in initial shipment.

3. Labels-Editable
   Provide final label design.

4. Requirements-Label
   Requirement information for the Label team
Study Teams assembled from matrix management
Key Focus Areas

- Manage On-going Activities:
  - Communication (internal/external)
  - Risk, change
  - Customer Satisfaction
  - Study budgets
  - Customer Complaints
  - Supply chain

Project Management

Timeline:
- Plan
- Start Up Clinical Trial
- Conduct Clinical Trial
- Close Out

Initial Shipments to Sites
Quality Risk Management

3 Main Categories
• Assessment
• Control
• Review

*Guidance for Industry - Q9 Quality Risk Management, June 2006, ICH
# Quality Risk Management

<table>
<thead>
<tr>
<th>Risk Assessment</th>
<th>Risk Control</th>
<th>Risk Review &amp; Monitoring</th>
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<tbody>
<tr>
<td>Phase Risk Identified</td>
<td>Suggested Response &amp; Response Description (Avoid, Mitigate, Accept, Transfer)</td>
<td>Date Occurred</td>
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<tr>
<td>Risk Description</td>
<td>Response Approval Status (Pending, Approved)</td>
<td>Phase Risk Occurred</td>
</tr>
<tr>
<td>Impact Description</td>
<td>Corrective Action Description</td>
<td>Occurrence Description</td>
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<tr>
<td>Impact Probability</td>
<td>Corrective Action Status</td>
<td></td>
</tr>
<tr>
<td>Planning</td>
<td>Increase Length of Trial</td>
<td>Labor, supplies, shipping</td>
</tr>
<tr>
<td>Planning</td>
<td>Only one supplier of study drug</td>
<td>Interruption of drug supply</td>
</tr>
<tr>
<td>Planning</td>
<td>Increase in Drug/Device Cost</td>
<td>Budget</td>
</tr>
</tbody>
</table>
Managing change and risk using a consistent approach
Customer-Driven Continuous Improvement

Customer Focused Culture

Customer Complaint Mgmt. Process

Customer Satisfaction Survey Process

Validation Methods
- ISO 9001:2015
- Baldrige Framework
- OPM3®
Project Management in the CT Environment

• Next steps
  – Refine Project Planning Tools & Expand to Other Groups
    • CTPP, Requirements Doc, Risk Register
  – Create Process User Guide
    • Helpful as a reference doc for new employees
  – Streamline procedures and apply LEAN techniques
Use the right tool for the right job
Questions?

- Rubiks cube timelapse
Acknowledgements And Disclaimer

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