U.S. Department of Veterans Affairs

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.

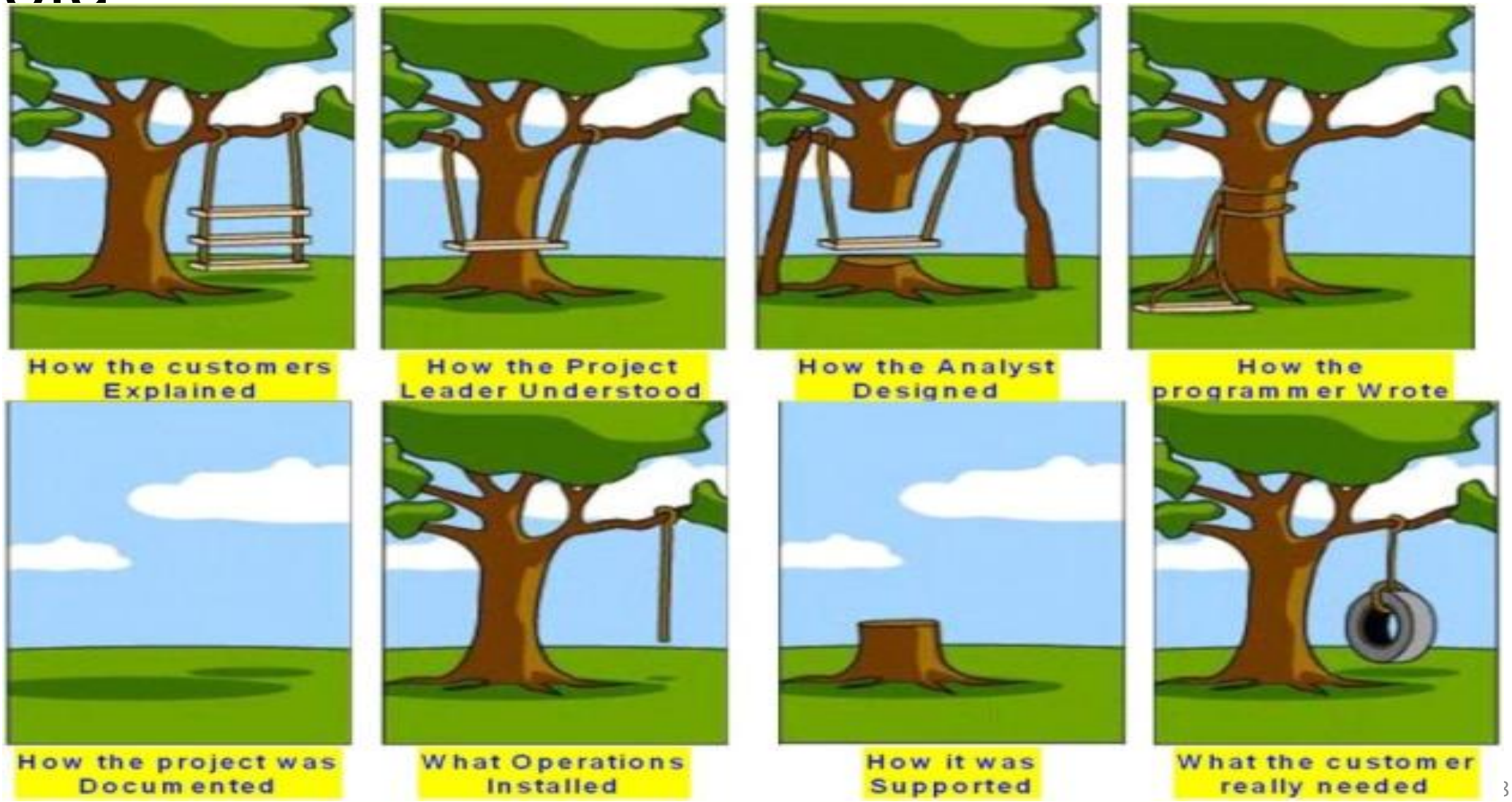
External Customers

- **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

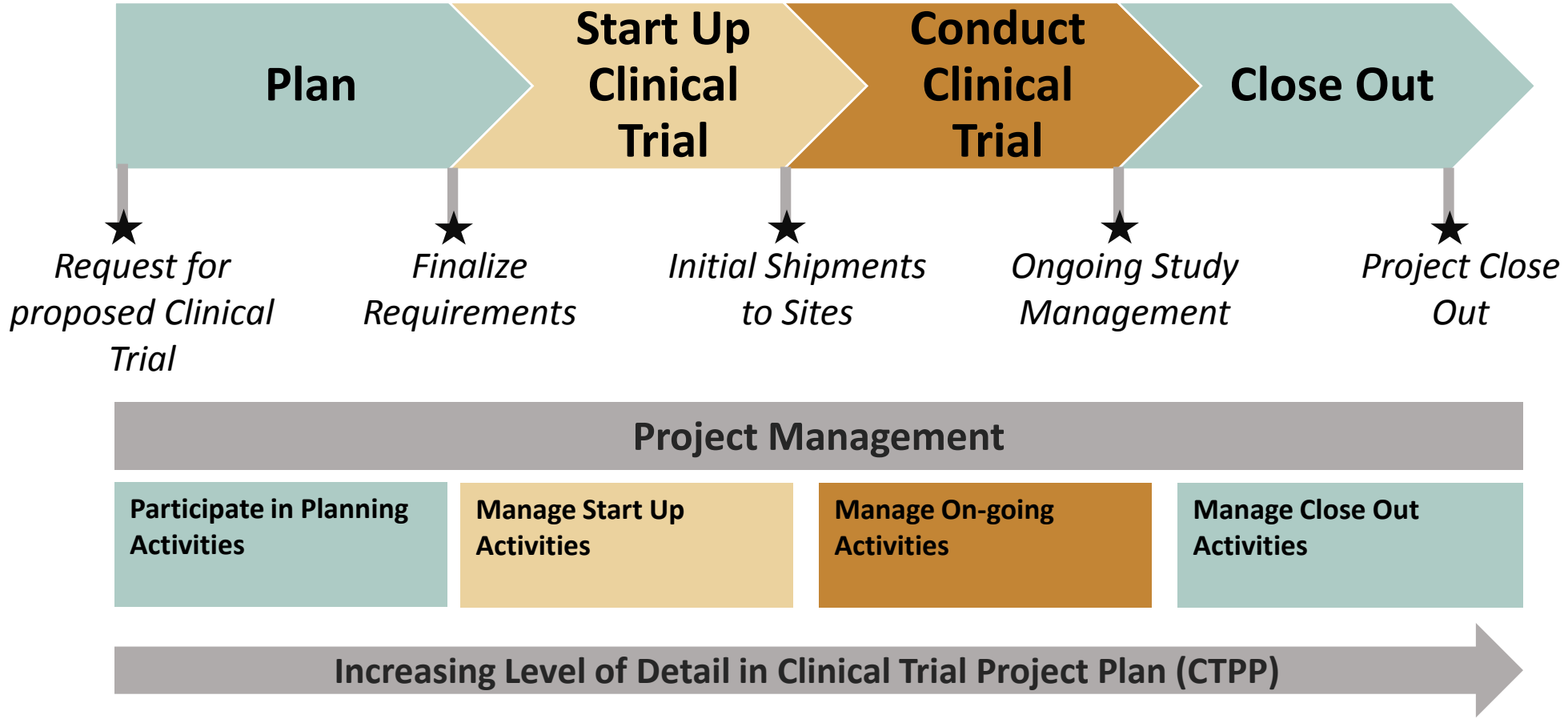
Project Management in the CT Environment

- Overview
  - Describe Concepts for Planning a Clinical Trial
  - Summarize Project Planning
  - Organizing Teams & Staff Communications
  - Managing Risk & Customer Expectations

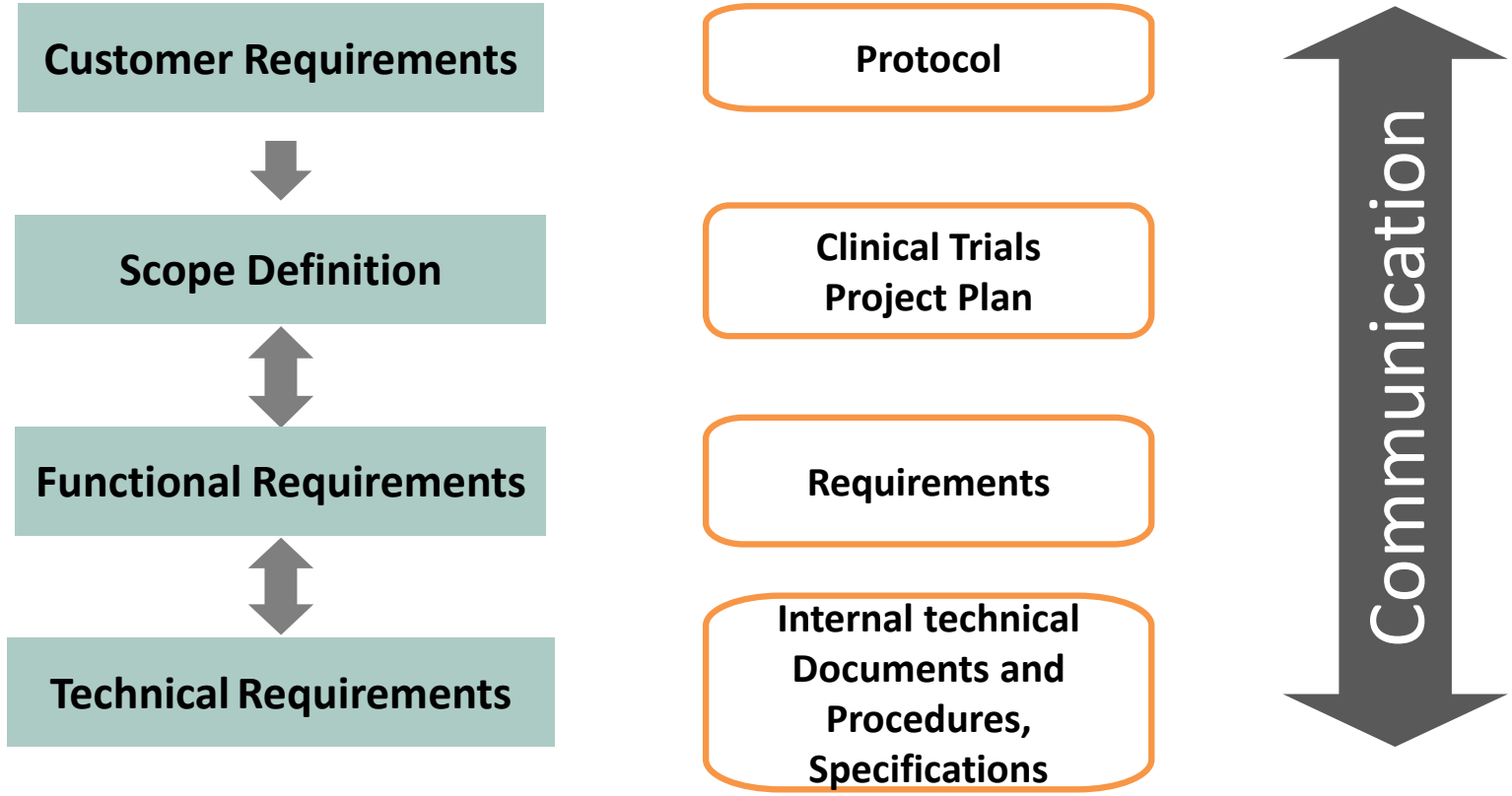
What Planning/effective PM can help to avoid



Phases of Clinical Trial



Integrating project plan, budgets and requirements with project phases



Clinical Trial Project Plan

Plan | Start Up Clinical Trial | Conduct Clinical Trial | Close Out

★

Request for proposed Clinical Trial

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

Overview | Budget Assumptions | Characteristics | Drug-Device Matrix | Key Dates | Risk Register

Requirements Document

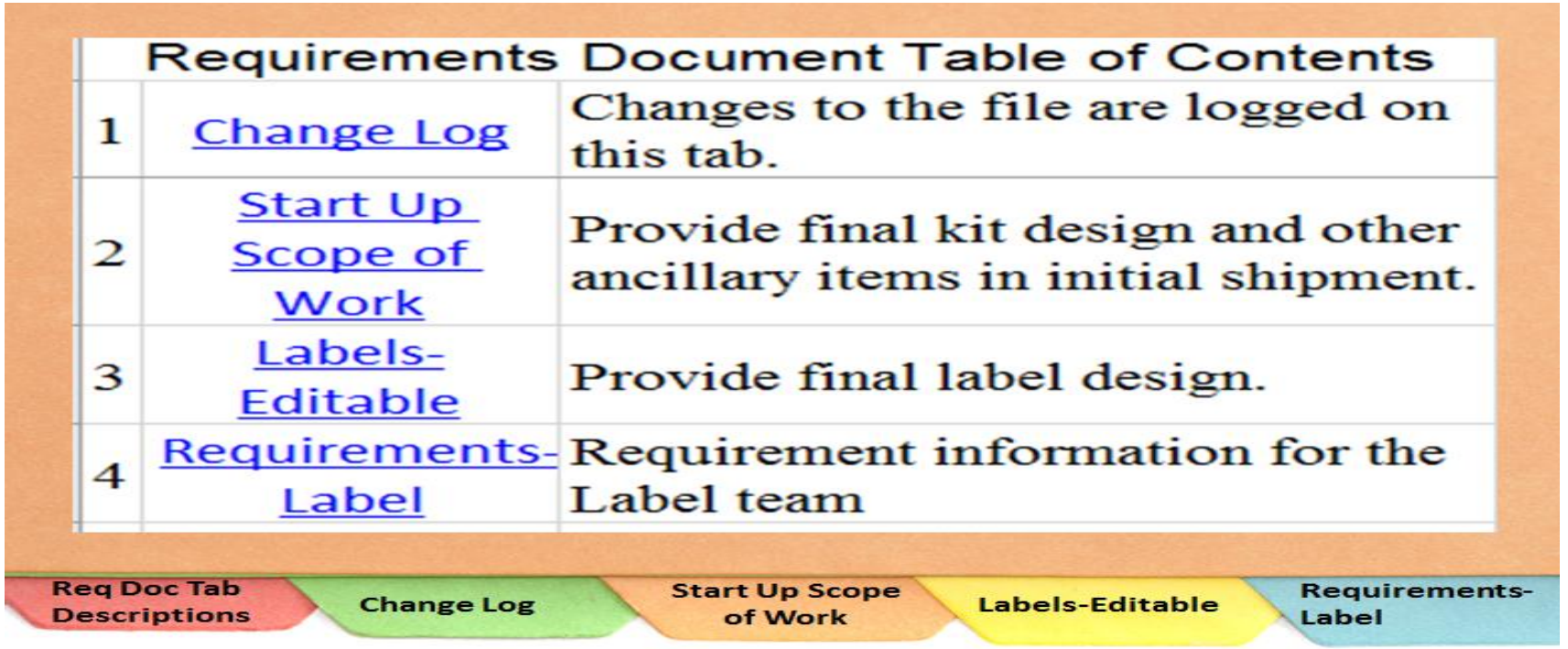
Plan | **Start Up Clinical Trial** | Conduct Clinical Trial | Close Out

★ *Finalize Requirements*

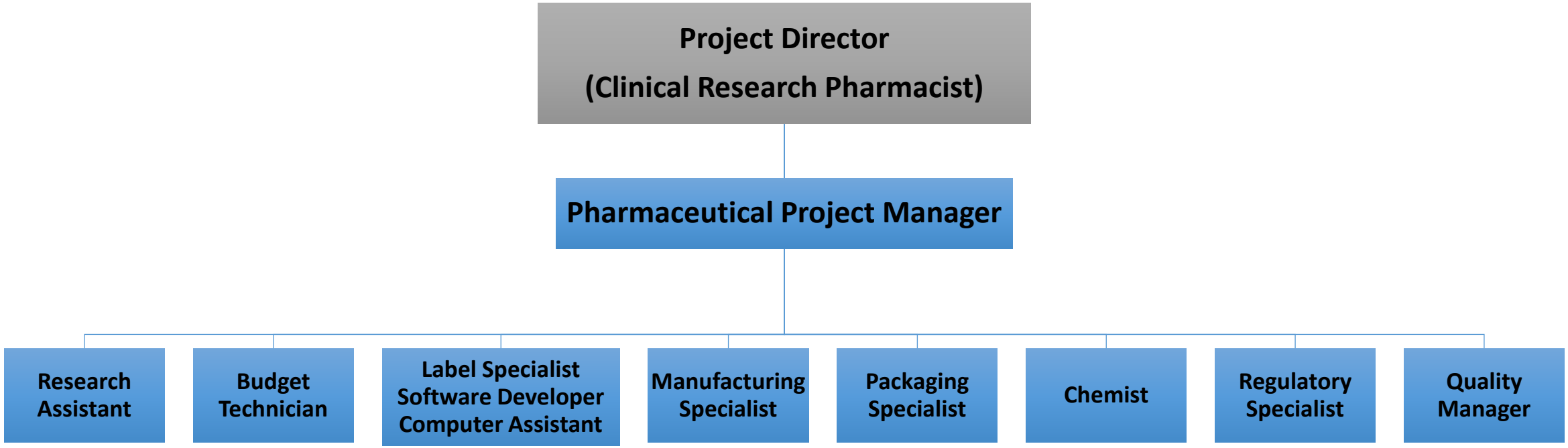
Project Management

Participate in Star-up Activities

- Gather Additional Requirements and Communicate Expectation
- Identify the Study Team
- Delegate Scope of Work to Sections

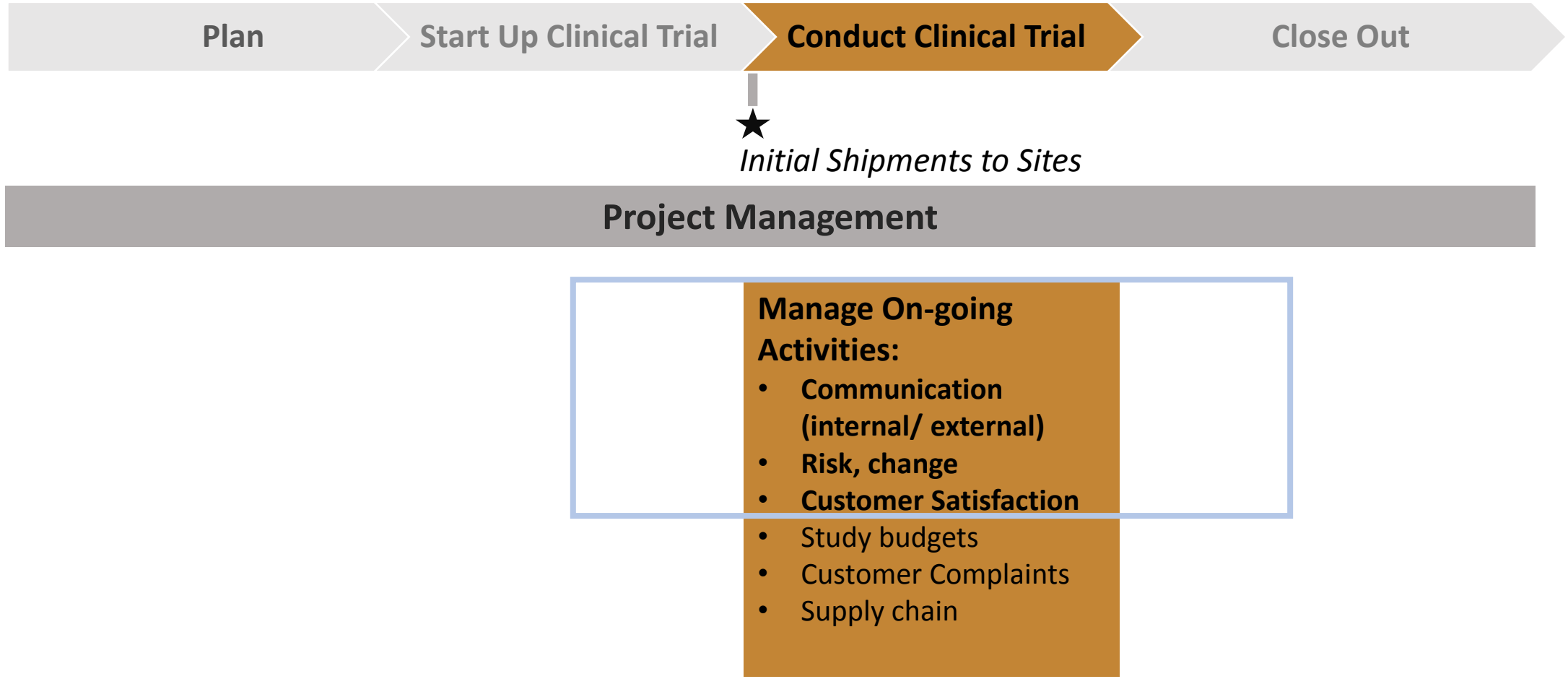


Study Teams assembled from matrix management



STRATEGIC AWARENESS WALL (SAW)
Project Director
Marcel Bizien, Pharm.D.
Donna W. Cain, B.A.
Planning
P465
Project Director
Kathy Boardman, RPh, M.S.
Barbara J. Del Curto, B.S.
Project Director
Adam Henrie, Pharm.D.
Sharon A. Jenkins, B.S.
P466
P470 - PTSD-Seen
Project Director
Mai Nguyen, Pharm.D.
Jeff Huminik, B.A.
P402
CSP#2008 - Himes cc
CSP#2017 - West Haven cc
P476 - Columbia (Afrocentric)
P478 - ASAP-SVG
P484 - HGH in Mild TBI
Project Director
Annie H. Davis, Pharm.D.
David Pittman, B.S.
P454 GWVI-BOPP (VA-NJ) JAN's
CSP 2013 PAVES Planning Mtg 10/19
Project Director
Robert Ringer, Pharm.D.BCNP
Norbert Archibeque, M.A.
Project Director
Project Director
Jolene Day
Project Director
Jolene Day
598599
595
2006
Legend
BPLS
SSS
Request for Funding
Contract Review
Order Cutoff
VA Contracting Actions
IQMU
PMRU
Retrieves/Replace
Initial Shipment
Drug Arrival
R&D Approval
Study Team Meeting
ADMS
CMMS
MedDRA
RACC
Database Development
Data Set
Forms Development
IND
SMART
Visit Start Date
GCP Training
Visit Completion Date
FTAR
Complete
Close-Out
Ongoing
Budget Due to BFMS
BRAC
Kick-Off Dates
Projects

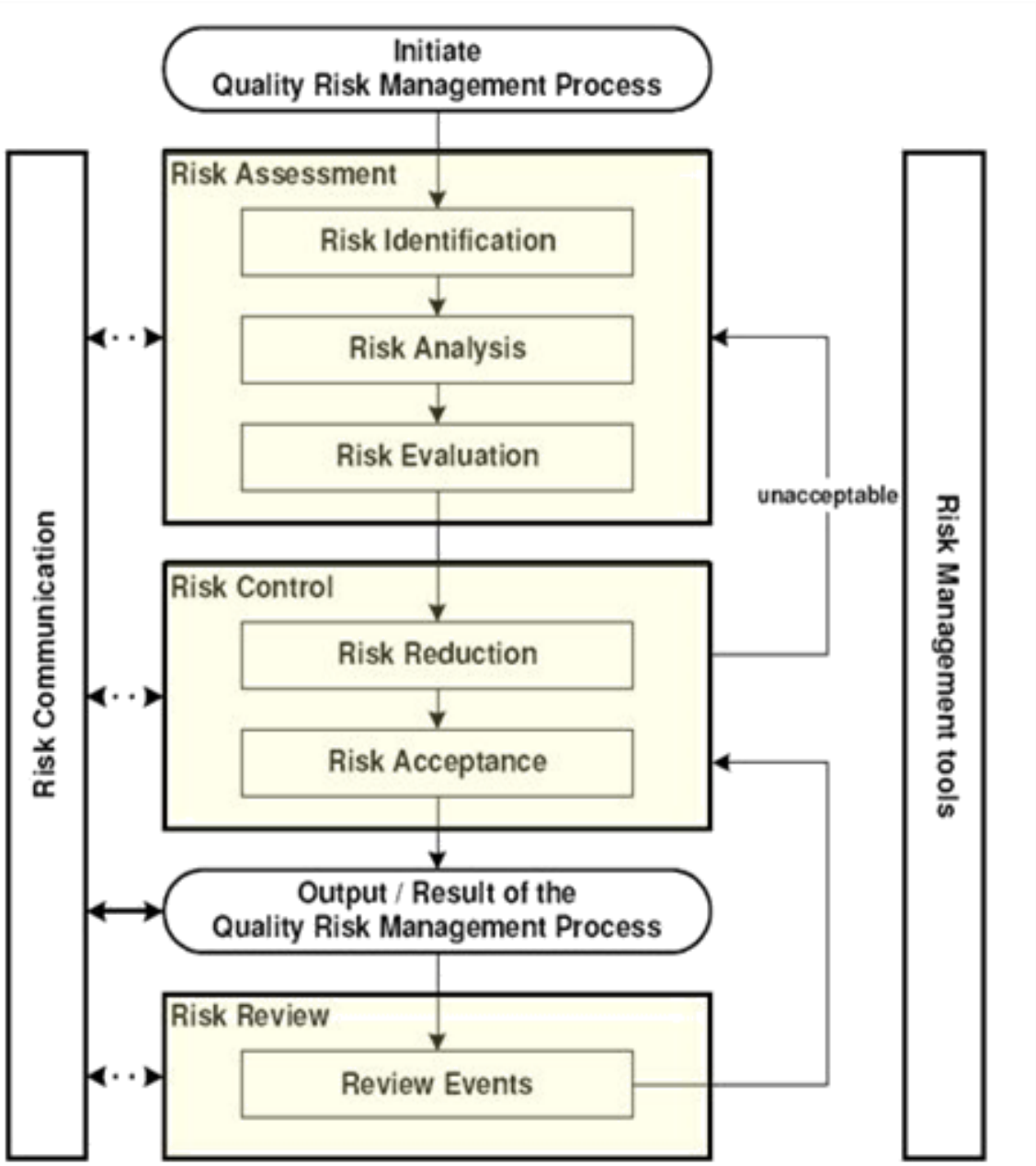
Key Focus Areas



Quality Risk Management

3 Main Categories

- Assessment
- Control
- Review

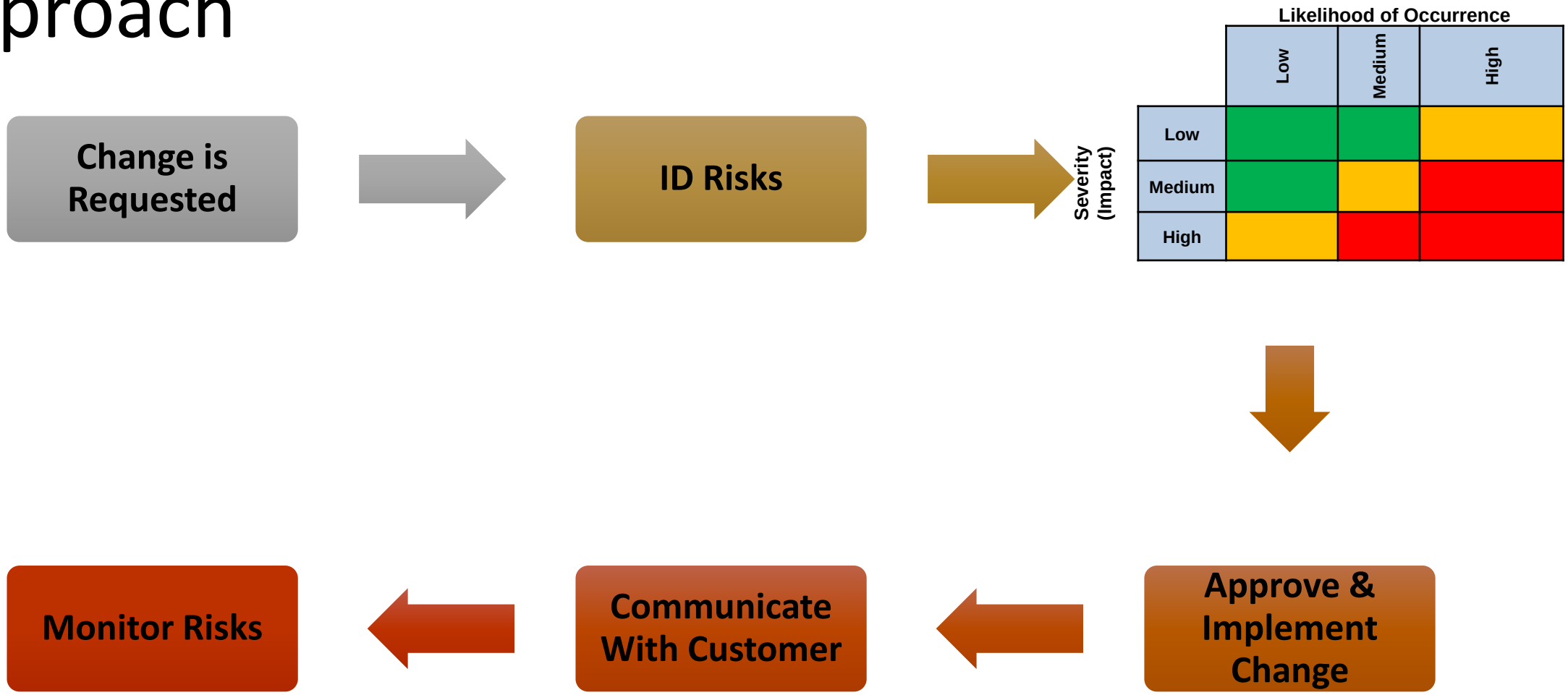


*Guidance for Industry - Q9 Quality Risk Management, June 2006, ICH

Quality Risk Management

Risk Assessment					Risk Control		Risk Review & Monitoring				
Phase Risk Identified	Risk Description	Impact Description	Impact	Probability	Suggested Response & Response Description (Avoid, Mitigate, Accept, Transfer)	Response Approval Status (Pending, Approved)	Date Occurred	Phase Risk Occurred	Occurrence Description	Corrective Action Description	Corrective Action Status
Planning	Increase Length of Trial	Labor, supplies, shipping	M	M	Accept (revise budget and supplies forecasts)	Approved					
Planning	Only one supplier of study drug	Interruption of drug supply	H	L	Transfer (inform customer of risk)	Approved					
Planning	Increase in Drug/ Device Cost	Budget	M	M	Mitigate (ID other sources, include in budget estimate)	Approved					

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

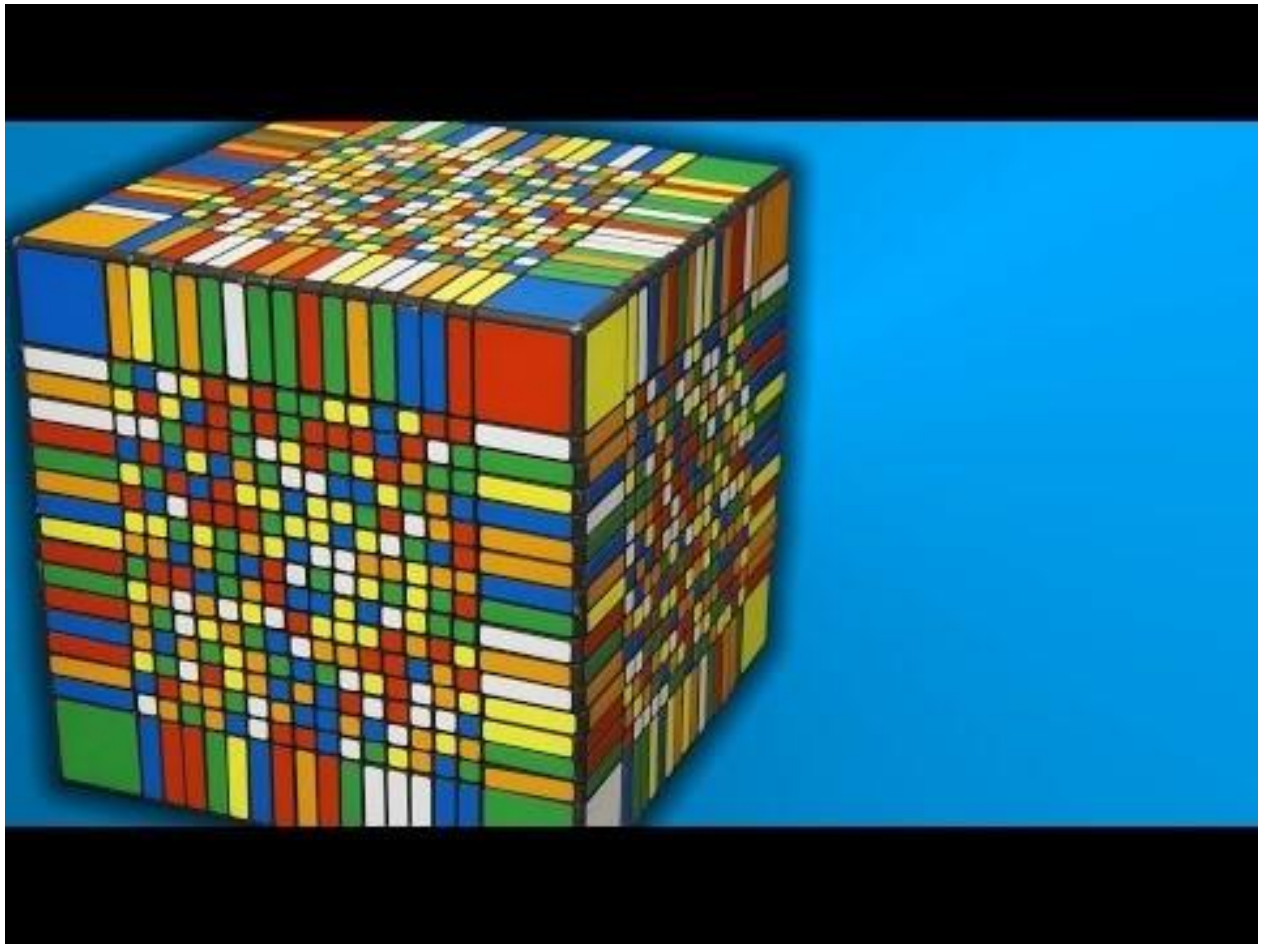
- ISO 9001:2015
- Baldrige Framework
- OPM3®

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

This material is the result of work supported with resources and the use of facilities at the VA Cooperative Studies Program Clinical Research Pharmacy Coordinating Center and the New Mexico VA Health Care System, Albuquerque, New Mexico.

The contents of this presentation do not represent the views of the U.S. Department of Veterans Affairs or the United States Government

CSP ABQ

Malcolm Baldrige National Quality Award 2009 Award Recipient