Overview

- Lean Process Improvements
  - Customer focused – understanding customer needs
  - Never done – seeking perfection
  - Industry clinical trial contract/budget pre-study start-up and NDA processing
  - Involving faculty and staff; daily group CT RMG
  - Began July 2015
CT Lean Initiative Advisory Committee

- Janice (Wes) Brown, Med-BMT
- Jeffrey Feinstein, Pediatrics
- Mark Genovese, Med-Immunology & Rheumatology
- Jason Gotlib, Med-Hematology
- Gregory Hammer, Anesthesia
- Stephanie Kemp, Neurology
- Terrence Ketter, Psychiatry
- Mary Beth Leonard, Pediatrics
- Ronald Levy, Med-Oncology
- Kenneth Mahaffey, Med-CV Med
- Richard Moss, Pediatrics
- Valerie Scott, Med-Pulmonary and Critical Care
- Marcia Cohen, Sr. Assoc. Dean for Finance & Administration
- Harry Greenberg, Sr. Assoc. Dean for Research
- Samuel Zelch, CFO

Clinical Trial Budgeting and Contract Process

What are the Goals?

Partnership
- Communication
- Transparency

Experience
- Efficiency
- Quality
- Timeliness
What affects Efficiency, Quality & Timeliness?

Variation  
Over processing  
Rework  
Waiting or delays

Improvement Strategies

Kickoff Meeting  
Standardization

Study Tracks  
Simplification

Partnership & Experience

Partnership  
- Communication  
- Transparency

Experience  
- Efficiency  
- Quality  
- Timeliness
Integrated Strategies

- Track 1 - Simple: 60 day goal
- Track 2 - Moderate: 90 day goal
- Track 3 - Complex: 150 day goal

Approximately 10% of studies fall outside these tracks.

Progress: Design & Implementation

- Kickoff Meetings: 95%
- Study Tracks: 50%
- Standardization: 30%
- Simplification: 20%
Testimonials

• “It’s nice to have PIs engaged in this process.” Research Coordinator

• “It really helped to have all [both PIs] present at the same time.” 2 PI study

• "appreciate explanations" "very informative" "love the guidance"

• “The kickoff meeting was so helpful – I hope this pilot develops into a program for all studies!!” Principal Investigator