Using Lean to Improve Research Application Processes at University of Iowa, 2008 to Present

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The University of Iowa Research Enterprise for Health Care

President, the University of Iowa

Vice President for Medical Affairs
- CEO, University Hospitals
- Dean, College of Medicine
  - Principal Investigators

Vice President for Research
  - Contract negotiation occurs here
  - Research occurs here
Total External Awards

2009-2010
$466.5 million
Total Federal: $310.7 million
Total Non-Federal: $155.8 million
Total Awards By Source
2009-2010

(Millions $)
- Medicine ($225.9)
- Liberal Arts & Sciences ($56.3)
- Engineering ($50.9)
- Public Health ($39.2)
- Pharmacy ($13.1)
- Dentistry ($7.4)
- Nursing ($5.2)
- Education ($4.5)
- Graduate ($3.1)
- Business ($0.7)
- Law ($0.6)
- Other Admin. Units ($59.6)
General Process of Clinical Research Application (from UI ICTS)

- CDA and Contract with DSP
  - Signed Contract
  - Budget

- Submit to IRB
  - IRB Pre-Review
  - IRB Set Meeting
  - Modifications
  - IRB Approval
  - Study Released
  - Study Ready to Start

- Investigator Prepares Human Subjects Application, CDA if Corporate

- Cancer Center Protocol Rev Comm
  - 2009

- 2008
  - 2009
  - 2010

- Date = Lean Activity

- IBC, MOG, CIRC

- ICTS Clinical Resource Unit
  - Pathology
  - Nursing Research Committee

- Lab, Bionutrition, Physiology: Bone, Cardiovasc, Pulm, Flexible Nursing Service

- ICTS CRU Approval
  - Pathology Approval
  - Nursing Approval
Lean Process

Value Stream Mapping

Project Plan

Change Readiness

Create Flow

Eliminate Variation

Six Sigma Approach

Lean Principles

Level Loading

Reduce Setups

Create Flow

Linking suppliers

TPM

Control

Define

Measure

Improve

Analyze
LEAN SEeks to minimize the three sources of loss: waste, variability and inflexibility.
‘LEAN’ IS THE ENGINE WHICH KEEPS TOYOTA IN FRONT

The Toyota Production System developed from the 1950s

• Pursues flow throughout the entire value stream by the elimination of waste

• Builds quality in at the manufacturing process, while recognizing the principle of cost reduction

• It takes fewer man hours to make a Lexus from scratch than to re-work a German luxury car at the end of the production line – after it has been made
LEAN TARGETS THE 8 TYPES OF WASTE

1. Over-production
   Reviewing all contracts without master agreements

2. Transportation
   Sending paper contracts between multiple groups

3. Inventory
   Wasted Grant Opportunities in process (funding expires)

4. Waiting
   Contract changes sitting with various parties

5. Over-processing
   Asking for signatures that are not required

6. Rework
   Multiple contract logs (db) for managing the contracts

7. Motion
   Walking contract around for review

8. Intellect
   Failure to leverage other unit’s contract knowledge
Value-added and NVA

- **Value-adding** activity: transforms product, information or service to meet customer requirements
- **Non-value adding** activity: takes time, resources or space, but adds no value from the customer’s perspective
The Continuous Improvement Process

Understand the current process as it really is

At Least Three Versions
(Usually)

What You Think It Is...  What It Actually Is...  What You Would Like It To Be...

[Diagram showing processes and decision points]
Corporate-Funded Clinical Trials Value Stream Map
Study Coordinator/Principal Investigator Perspective
Some Elements occur in Parallel, with Decisions

Approach from Sponsor:
- Confidentiality Disclosure Agreement: C/T: 30 days, VA: 2 days
- Budget Preparation and Negotiation: C/T: 45 days, VA: 2 days
- Create Protocol Plan specific to facility: C/T: 4 days, VA: 1 day

Move forward with Project?
- Move forward with Project?
- Human Subjects Consent Generation: C/T: 50 days, VA: 2 days

Cleared to Proceed?
- Cleared to Proceed?
- Contract Negotiation: C/T: 140 days, VA: 2 days

Internal Preparation:
- Internal Preparation: C/T: 30 days, VA: 5 days

Enrolling Subjects:

Some Elements occur in Parallel, with Decisions:

- Enrolling Subjects
Ideas from Lean Events for Improvement, and the Steps they Effect

- Checklists
- Improved website content presentation
- All-Research Database
  - Entire Enterprise
  - All Research
  - Cradle-to-Grave

Confidentiality Disclosure Agreement

C/T: 30 days
VA: 2 days
Ideas from Lean Events for Improvement, and the Steps they Effect

- Advocates
- Electronic Submission with business rule guidance
- Metrics on website

Human Subjects Consent Generation

C/T: 80 days
VA: 2 days
Ideas from Lean Events for Improvement, and the Steps they Effect

- Face-to-Face Initial Meeting
- Metrics
- Electronic submission

Contract Negotiation

C/T: 140 days
VA: 2 days
Ideas from Lean Events for Improvement, and the Steps they Effect

- ICTS Consolidated Application (Super Application for Clinical Research Patient Care Unit)
- Meeting Frequency
Human Subjects Review Board

EXPEDITED 01 NEW STUDIES RELEASED
Mean Days from Submission to Release

- Current Metrics: Mean Days from Submission to Release
Human Subjects Review Board

FULL BOARD 01 NEW STUDIES RELEASED
Mean Days from Submission to Release
Corporate-Funded Clinical Trials Ideal State

Approach from Sponsor

Videoconference CDA, Digital Sign Shared Electronic Document

C/T: 5 days (Schedule) VA: 1 hour

Enter Protocol Specifics into Institutional Database to quickly estimate Budget. Cost-Benefit to Team and Institution, including Standard of Care Accounting

C/T: 4 hours VA: 4 hours

Move forward with Project?

Enrolling Subjects

Consent Form Template modified to fit study; Reviewed real-time with Team, Revisions Guided and Released in Meeting

C/T: 5 days (Preparation, Schedule Review, Meet) VA: 8 hours

Contract Templates Compared and Negotiated with all 3 Parties by Videoconference, Digital Sign of Shared Electronic Document

C/T: 5 days (Schedule, Review) VA: 8 hours

Committees Review Plan from Inst. DB used to prepare Budget, Contract and Consent from Single Electronic Submission and Results of above Negotiations. Real Time Review electronically and Sign

C/T: 3 days (Prepare, Review) VA: 2 hours

All Groups electronically notified of all Status and Approvals in Single Database.

5 days .5 days 13 days Total: 18.5 days
Results: CFCT Contracts

Pre-Kaizen Average Weeks Outstanding on Contracts: 31 Weeks
Post-Kaizen December: 7 Weeks (77% reduction)
Iowa CTSA

• Current Work involving:
  – Consolidation of Application Information
    • >80% homology in question content or intent between Clinical Research Unit application questions and Institutional Review Board application questions
    • Super Application framework
  – Incorporation of Budget Development
    • Guidance and Data Capture
    • Speed application?
Clinical Research Unit Project Application Improvements

**PROBLEM STATEMENT:**
There is repetition in question content between IRB and CRU applications, which is rework for research applicants and extra paperwork for CRU staff and reviewers.

**PURPOSE:**
Changes in technology have provided query access to IRB applications. This information could be "brought in" to the CRU application process. Steps in the process could be reduced both for applicants and CRU.

**RESOURCES:**
Sponsor(s): D Blochmann, J Widness
Team Leader: E Augenackis
Team Members: E Augenackis, M Bosch, J Kline, B Kusenda, C Rebouchet, J Schappet, J Schlechte, J W
Team Facilitator: J Van De Berg, T Persoon
Other:

**CURRENT CONDITION:**

**PROBLEM ANALYSIS:**
* Re-entry of same material from IRB to separate CRU application is tedious, possibly error-prone.
* CRU needs the applications requesting their services and a way to present app description to
* ICTS has been given query access to IRB apps, but needs mechanism for presenting to CRU Review
* Applicants need to be aware of change: additional questions, notification of status of app
* CRU Staff and Reviewers need to be aware of any process changes: new SOP

**TARGET CONDITION:**

**COUNTERMEASURES:**

**IMPLEMENTATION PLAN:**

<table>
<thead>
<tr>
<th>Key Actions</th>
<th>Next Steps</th>
<th>Leader</th>
<th>Due Date</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation of Convergent IRB quest</td>
<td>Build &quot;doc&quot; version for CRU Review</td>
<td>B Kusenda</td>
<td>7/6/2010</td>
<td></td>
</tr>
<tr>
<td>Query of IRB db with CRU Requested</td>
<td>Develop and Pilot query to notify</td>
<td>B Kusenda</td>
<td>7/6/2010</td>
<td></td>
</tr>
<tr>
<td>Email to applicants that request rec'd Template email</td>
<td></td>
<td>E Augenackis</td>
<td>7/6/2010</td>
<td></td>
</tr>
<tr>
<td>Single document with CRU-specific q's</td>
<td>Develop single-page addnl q's</td>
<td>J Schlechte</td>
<td>7/6/2010</td>
<td></td>
</tr>
<tr>
<td>Email generated by IRB App, CRU Chair</td>
<td>Benchtest with IRB programmers</td>
<td>J Schappet</td>
<td>7/30/2010</td>
<td></td>
</tr>
<tr>
<td>Process for Resource Confirmation</td>
<td>Develop Pilot in SuperApp</td>
<td>Email with &quot;test investigator&quot;</td>
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</table>

**RESULTS**

<table>
<thead>
<tr>
<th>Measures</th>
<th>Baseline</th>
<th>Current</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steps in review process</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Reduction in repetitive questions in IRB and CRU applications</td>
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**FOLLOWUP:**
“I’ve Got Too Much Work To Do To Stop & Listen To You!”

“The Tools Are Available”