

Are We Playing Dice With Informatics Projects?

Bridging Pharma & IT Conference
October 1, 2007

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In response to Heisenberg's Uncertainty Principle, Einstein responded "God does not play dice with the universe."

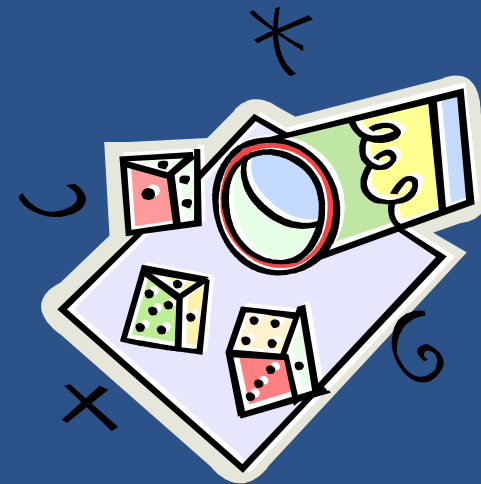
Are we playing dice with Informatics Projects?



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- Part II – Stepping Back– Project & Process Assessments
- Part III – More Certainty / No More Dice - What are we doing differently now
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*Laboratory Information Management System

Part I – Playing Dice

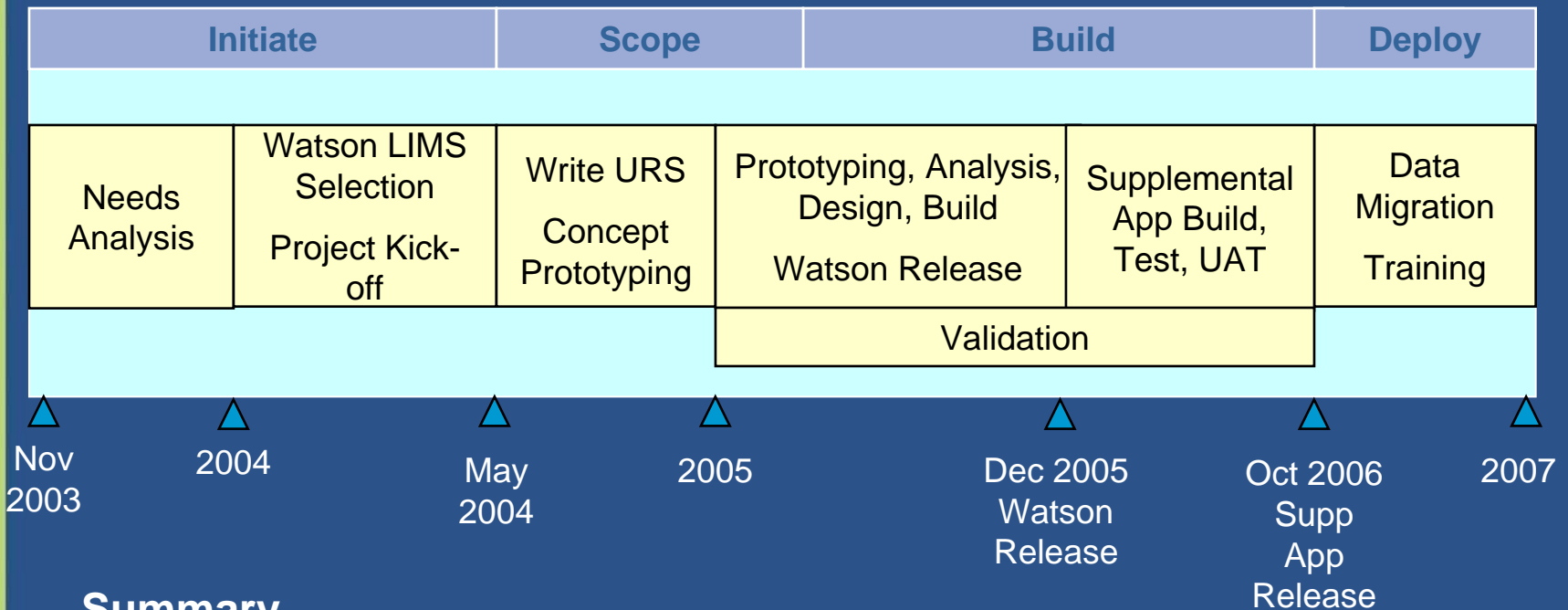
Clinical LIMS Implementation Project

Catalyst for Change - LIMS Implementation



- Clinical LIMS Project Started in November 2003
- One of the largest IT projects undertaken at Centocor in many years
- Business Needs
 - Replace an aging, compliance-challenged LIMS
 - Support business changes and increased throughput

CP LIMS Project Timeline



Summary

- Project took three years to complete (Watson LIMS and Supplemental Application)
- Project scope was re-defined three times
- Mid-project IT restructuring opened the door to confusion at key project hand-offs (transition to support, for example)

Initial Team Structure and Business Interaction



- Business was too busy to engage properly
 - Within the business, study workload was high
 - Prompted conscious effort to “minimize business impact”
- IT Project Team Composition
 - Program Manager/Project Manager had limited experience in end-to-end project management
 - PM tripling as functional area rep & line manager
 - Heavily reliant on contractors
- Management lightly engaged (call me if you need me)

Plan was not detailed enough;
Resources were not dedicated enough;
Consequently, the Project fell behind quickly.

Mid-Stage Project Changes and Challenges



- Phased the project looking for short / long-term wins
 - Implement COTS* LIMS / Delay customization deployment
 - COTS functionality deployed standalone to meet company goal, but never used standalone → wasted effort
 - Custom development team continued, at a slower pace, and went off-track → wasted effort
- Meanwhile, requirements were being continually added or tweaked

*Commercial-Off-The-Shelf

Good idea to salvage deployment dates;
Burden on project team underestimated;
Resulted in lots of wasted effort.

Late-Stage Project Changes



- Added a Full-time Project Manager
 - Enhanced planning - tasks/resources/timing
 - Drove tasks to completion
- Enhanced management reporting and accountability
- More involvement of business owners
- Deployed complete system (custom software / COTS)
- Many tasks / issues remained ...
 - Data migration not completed
 - Training needed
 - Confusion over operational ownership

Are We Done Yet?

- While IT struggled with issue ownership (transition to support, bug fixes) ...
- Clinical Pharmacology struggled with system adoption and change management ...
- All while critical submission timelines loomed large

Bottom line: The system was not yet being used productively by the business.



Part II – Stepping Back

Project & Process Assessment

LIMS Project Assessment



- Centocor management decided to step back and conduct a project assessment and lessons learned on the LIMS project
- Engaged ResultWorks, a management and business process consultancy, to conduct an objective assessment of the project from inception to present

Project Assessment Objectives



- Gather And Evaluate Feedback On The LIMS Project
- Include the LIMS Project Team, Stakeholders, Software Developers, Validation, and Management
- Develop Recommendations For Future Project Teams To Use In System Implementations
 - Review & Confirm - Suggested Changes To The LIMS Implementation Process
 - Identify & Review - Alternate Methods That Would Have Improved The Solution, Timing, Deliverables
 - Develop & Agree - Summary Recommendations For Consideration On Future Projects

Roles & Communications



How the customer explained it



How the Project Leader understood it



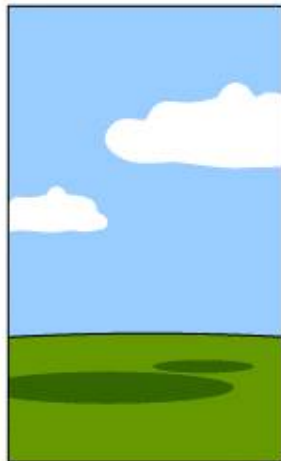
How the Analyst designed it



How the Programmer wrote it



How the Business Consultant described it



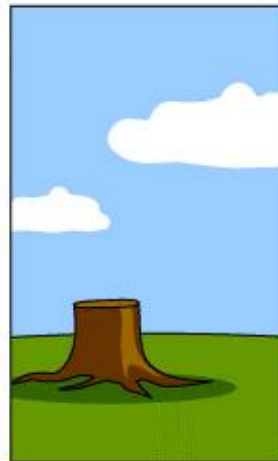
How the project was documented



What operations installed



How the customer was billed



How it was supported



What the customer really needed

Project Manager Recommendations



- Ensure a project organization is established
- Follow the project management methodology
- Create a communications plan including regular team meetings, status reporting, and escalation paths
- Establish a comprehensive project plan at the start (with team input)
- Manage the project - Micro-manage as required
- Escalate as needed – don't be afraid to push management to make decisions when needed

User Recommendations



- Ensure right level of user participation at the right time
- Address process changes as part of the project
- Define requirements based on desired work flow
- Ensure appropriate training to meet business objectives (e.g., adopt the solution)

IT Recommendations



- Methodology (Software Development Life Cycle)
 - Ensure that the methodology is in place and followed
 - Be disciplined about moving from phase to phase with mutual approvals
- Clearly define IT roles & responsibilities
- Establish meaningful ways of assessing progress
- Keep users involved
 - Continuously relate the system to business processes
 - Ensure that the users ramp up in their knowledge and awareness of the system

Management Recommendations



- Establish a project organization; assign a dedicated project manager
- Insist on a detailed project plan with a baseline from the start
 - Align goals among all departments
 - Plan to completion of business and IT tasks to ensure true productive use of the system
- Review plan status on a regular basis (baseline vs. current)
- Insist on regular and consistent project updates
- If something doesn't feel right, insist on a project review – be prepared to stop the project if necessary

Project Assessment Outcome



- Management and project team regrouped around the project
- Reestablished project team, plans, timelines, objectives
- Concerted effort to gain productive use of the system

Six months later, the system was in production & used for all new studies.

Process Assessment

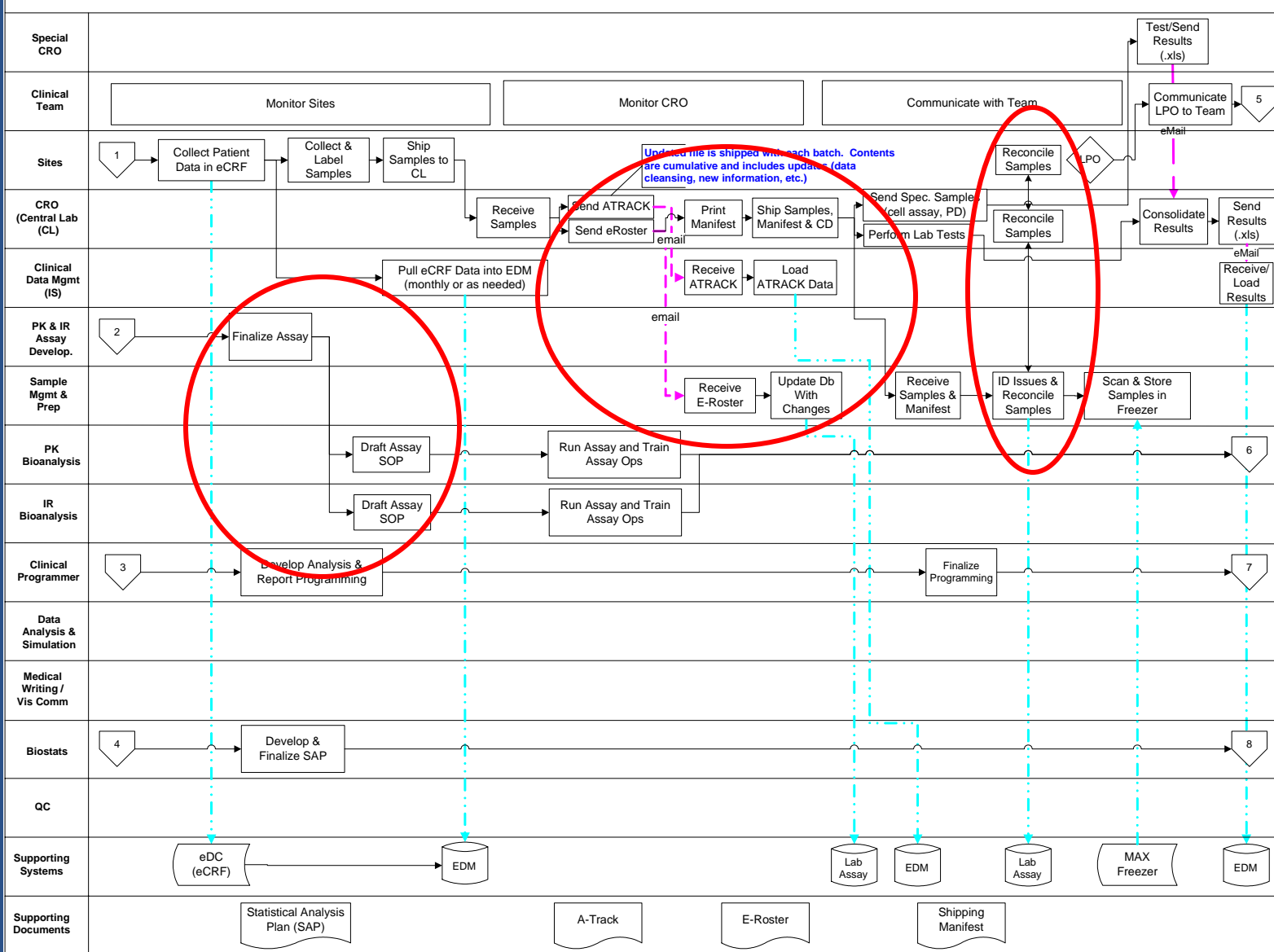
In parallel to the LIMS Project, the Clin Pharm group engaged ResultWorks for a broader process assessment. Areas served by LIMS were part of the assessment

Process Assessment Objectives

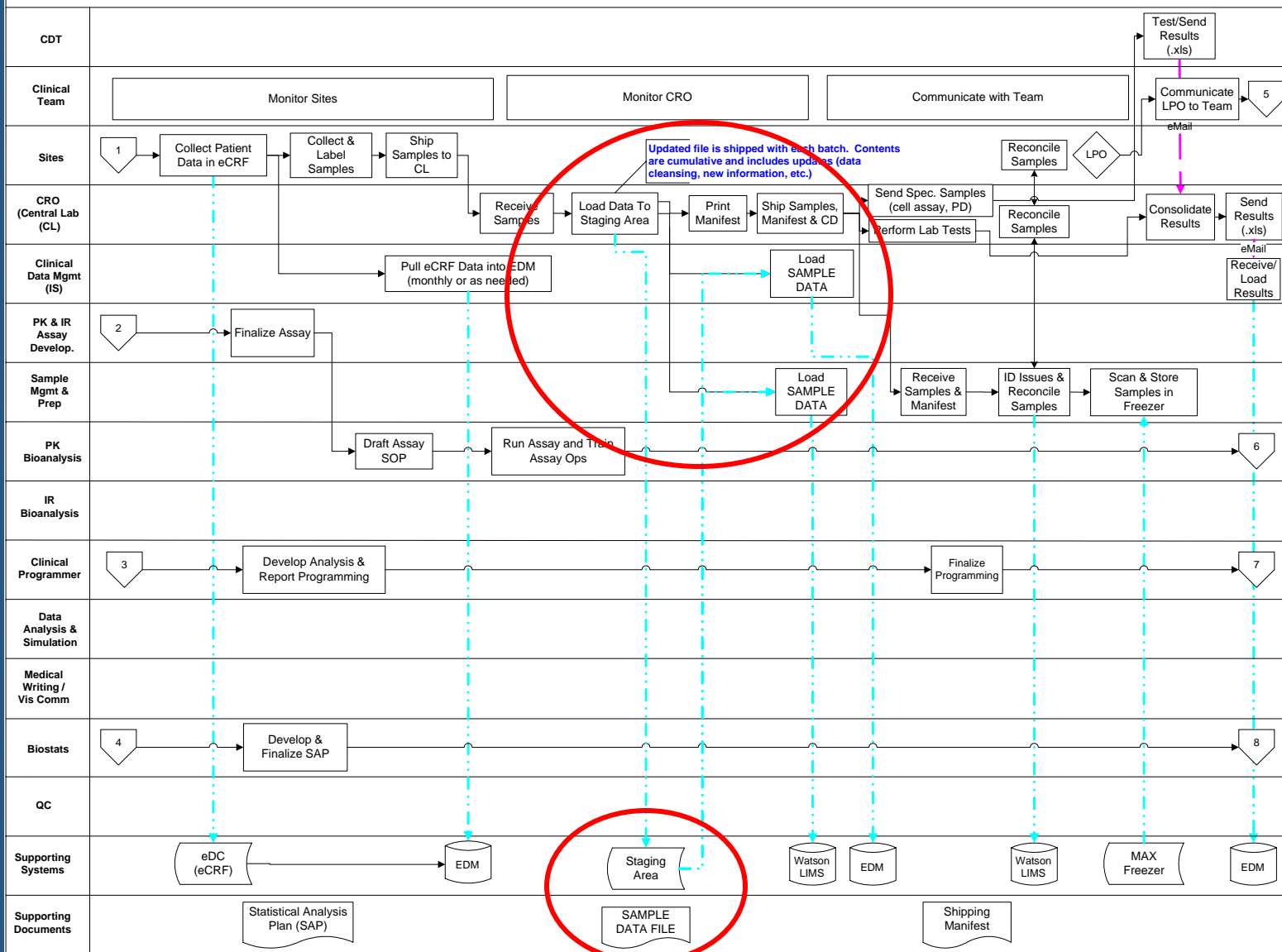


- Develop Harmonized Processes To Speed Up the Clin Pharm Analysis and Reporting Cycle
- Confirm New Processes and Data Flow Would Work With Implemented/Planned Systems (PKS, Watson LIMS, Etc)
- Improve Data Flow
 - Consistency of Data
 - Elimination of Redundant Data Handling
 - Automated Approaches For Data Transfer
- Develop Preliminary Implementation Plans To
 - Address Process Changes
 - Improve Post Implementation Adoption

Clinical Study Trial Execution – Sample Handling



Clinical Study Trial Execution – Sample Handling - FUTURE



Process Assessment – Accomplishments



- Identified Process Opportunities for Clinical Studies (Phase I-II-III) From Study Setup To Reporting
 - Current Process, Issues and Opportunities for Improvement
 - Future Process Flow and Considerations
- Uncovered Data Flow/ Integration Issues & Opportunities
- Determined Management, Planning and Communications Needs

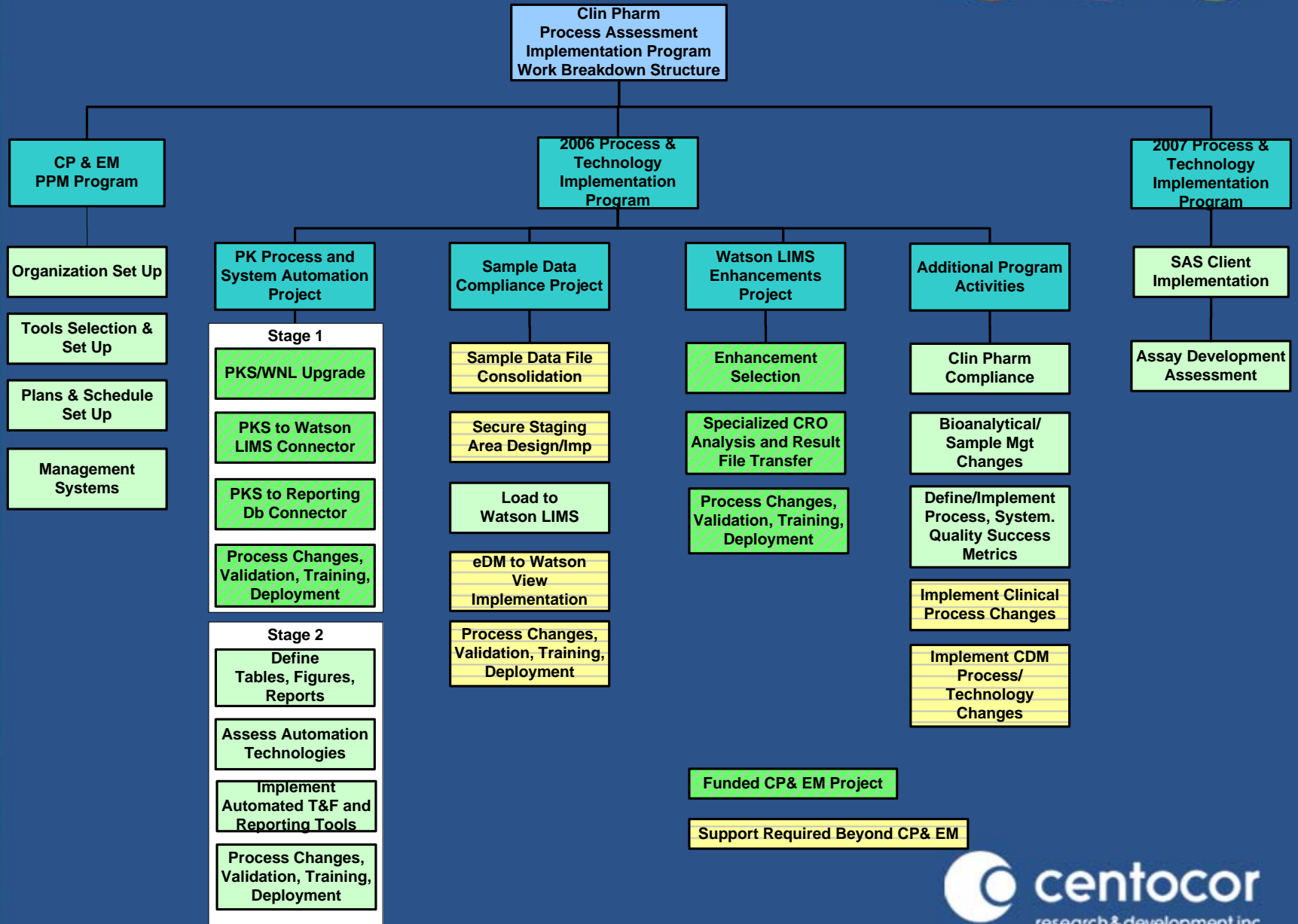
Issues surfaced in each of these areas
that impacted the LIMS Implementation

Program Planning and Management Recommendations



- Enhance Project Planning & Management
- Establish Logic Based Schedules Across Functions
- Establish Standard Reports To Understand Schedules, Resource Impacts, And Identify Issues Generated From Tools Used By Clinical Pharmacology Planning Function
- Refocus Management Meetings To Review Project Status & Plans
- Set Priorities Based On Approved Project Strategies & Priorities

Program Implementation WBS



Funded CP& EM Project

Support Required Beyond CP& EM

Part III – More Certainty / No More Dice

What are we doing differently now?

Systems & Process Organization



- Organizational Changes to Pharma & IT
- Implementation of Management Systems
- Continuous Process Improvement Emphasis

Organizational Changes



- Business Changes
 - Created Process & Systems Group
 - Management systems implemented to control process, balance resources across business and IT projects
- IT Changes
 - Created matrixed project teams
 - Functional leadership roles focused on business
 - Focus Technical specialties on Planning, Development, or Support aspects of project
- Management Changes
 - Improved visibility & cross-management of projects
 - Regular review meetings
 - Common scorecards

Management Systems



- Established project proposal, review, and approval process
- Common Work Breakdown Structure (WBS) across all projects – both IT and process / non-technical
 - Built in project checkpoints, approvals, and controls
- Common project reporting and dashboards
- Tracking tools and process to balance resources
- Process and Systems Group acts as Project Management Operations clearing house

Project Approval Process



Clinical Pharmacology & Experimental Medicine Project Profile

Project Name:	Requester:	Priority: (High, Medium, Low)
Start Date: Q1 2006	Interim Review Date(s):	Target Completion Date:
Project Purpose/Description:		

Resource Requests:

<i>Person Required/Skill Set</i>	<i>Suggested Role</i>	<i>Time & FTE Requirement</i>	<i>Resource Approval (by Functional Manager)</i>
Total Resource Demand:			

Project Governance:

Project Manager/Driver:	
Champion/Coach:	
Sponsor:	

Budget Request:

<i>Budget Items (Description)</i>	<i>Estimated Cost</i>	<i>Budget Approved: (by Leadership Team)</i>
Total Budget		

Is there a compliance gap that this project will correct? If yes, please explain.

What is the compliance risk if we do nothing?

Describe deliverables and how the project will be tracked and how interim reviews will be conducted:

How will success of the project be determined or measured?

Project Approval Process



TO BE COMPLETED BY LEADERSHIP TEAM:

<i>Project Approved by:</i>	<i>Date:</i>
<i>Approved with the following caveats:</i>	<i>Project will be monitored:</i>

AFTER PROJECT COMPLETION:

Was the project successful?

Why or why not?

Lessons learned for process improvement?

Project closeout approved by: _____ Date: _____

Work Breakdown Structure

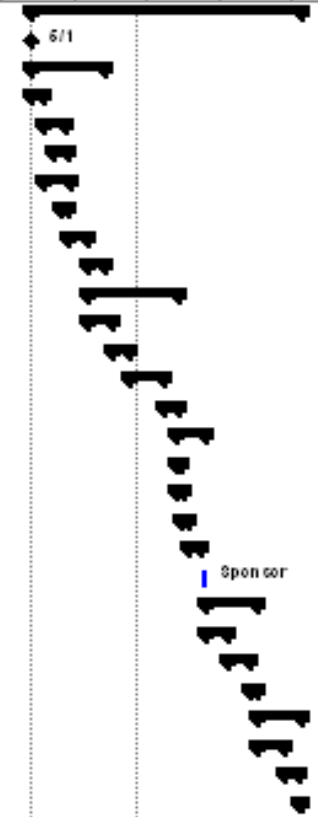


- Common Project Work Breakdown Structure (WBS)
 - Initiation
 - Implementation
 - Validation
 - Deployment
 - Completion
- Tracking at various levels of detail for
 - Custom Systems
 - Commercial (“Off the Shelf”) Systems
 - Process/Non-Technical Projects
- MS Project Schedules built around WBS for all projects

Project Plan Template



ID	Task Name	Duration	Start	Finish	November	December	January	February	March	April	May	June	July	August
					11/5	11/27	12/18	1/8	1/29	2/19	3/12	4/2	4/23	5/14
1	Centocor Project Plan Template	67 d	Mon 5/1/06	Tue 7/18/06										
2	Project Start	0 d	Mon 5/1/06	Mon 5/1/06										
3	Initiation	16 d	Mon 5/1/06	Mon 5/22/06										
4	Project Authorization	4 d	Mon 5/1/06	Thu 5/4/06										
10	Project Planning	4 d	Fri 5/5/06	Wed 5/10/06										
15	Project Team	4 d	Mon 5/8/06	Thu 5/11/06										
21	Project Communications & Controls	6 d	Fri 5/5/06	Fri 5/12/06										
30	Kick-off Meeting	2 d	Wed 5/10/06	Thu 5/11/06										
35	Functional Requirements Specification (User Requirements)	4 d	Fri 5/12/06	Wed 5/17/06										
42	Validation Planning	3 d	Thu 5/18/06	Mon 5/22/06										
49	Implementation	18 d	Thu 5/18/06	Mon 6/12/06										
50	Analyze/Design	6 d	Thu 5/18/06	Wed 5/24/06										
57	Build	3 d	Thu 5/25/06	Mon 5/29/06										
63	Test	8 d	Tue 5/30/06	Thu 6/8/06										
77	Implementation Approval	2 d	Fri 6/9/06	Mon 6/12/06										
83	Validation	7 d	Mon 6/12/06	Tue 6/20/06										
84	Final SOP/Guidelines	2 d	Mon 6/12/06	Tue 6/13/06										
88	Production Installation	3 d	Mon 6/12/06	Wed 6/14/06										
93	User Acceptance Testing (UAT)	2 d	Wed 6/14/06	Thu 6/15/06										
97	Validation Report	2 d	Fri 6/16/06	Mon 6/19/06										
100	System Release Memo Authorized	7 d	Tue 6/20/06	Tue 6/27/06										
101	Deployment	11 d	Wed 6/21/06	Wed 7/5/06										
102	End User Training	4 d	Wed 6/21/06	Mon 6/26/06										
108	Production Deployment	6 d	Tue 6/27/06	Mon 7/3/06										
115	Change Management	2 d	Tue 7/4/06	Wed 7/5/06										
119	Completion	9 d	Thu 7/6/06	Tue 7/18/06										
120	Monitor/Adjust Performance	6 d	Thu 7/6/06	Thu 7/13/06										
123	Transition System/Process Ownership	2 d	Fri 7/14/06	Mon 7/17/06										
126	Project Closure	1 d	Tue 7/18/06	Tue 7/18/06										



Starting point for planning of all projects.

Dashboard Report



Status ● - on target ● - alert ● - jeopardy

Technical	Project Description and Info	Subject Area Lead	Project Phases					Status Comments
			Initiation	Implementation	Validation	Deployment	Completion	
1	Complete Clin Pharm LIMS Deployment (Supplemental Piece only)	Faith Talnack				●		Went Live Oct 4
2	Watson LIMS Enhancements - Plate Management	Susan Spitz	●					Plate Mgmt is reprioritized to 2007 - Requirements gathering and clarification is underway.
3	LIMS IR Module	Gopi Shankar		●				Watson 7.3 will not release until 2007, development work at Thermo complete
4	LIMS Data Migration / Lab Assay Archive / Decommission Lab Assay and MaxFreezer	Faith Talnack		●				Alternate path being executed for large Phase IIIs in order to get data into LIMS ASAP.
5	Deploy STAAR LIMS	Marielena Mata			●			Slow progress. Access complete for one CP&EM emp.
6	Sample Data Compliance	Faith Talnack / Consultant		●				Red status due to delays based on dependencies on GCO and CRP.

Reviewed at senior management meeting monthly.
 Additional detail available for each project.
 IT and Non-IT projects reviewed jointly.
 Decisions and actions managed.

Tracking



Week of 14-May-2007 to 18-May-2007 - Message (Rich Text)

File Edit View Insert Tools Actions Form Layout Help

Reply Reply to All Forward Print Attachments Undo Redo Help

From: Rossi, Donald [CNTUS]

Sent: 21-May-07

To: DL-CNTUS Clin Phrm Lab Group; DL-CNTUS Clin Phrm TD&M; DL-CNTUS CPEM-PK; DL-CNTUS SS&PM

Subject - Project Resources - Hours Spent Week of: Week of 14-May-2007 to 18-May-2007

Project Time Tracking

Enter "YOUR" Managers
Name Here:----->

Importance: High

Instruction: Please FORWARD this form to "Donald Rossi" when completed.

Project Name:	Hours Spent	Project Number
Complete Clin Pharm LIMS Deployment	<input type="text" value="0"/>	1
Watson LIMS Enhancements - Plate Management	<input type="text" value="0"/>	2
LIMS IR Module	<input type="text" value="0"/>	3
LIMS Data Migration / Lab Assay Archive / Decommission Lab Assay and MaxFreezer	<input type="text" value="0"/>	4
Deploy STAAR LIMS	<input type="text" value="0"/>	5
Sample Data Compliance	<input type="text" value="0"/>	6
Secure Data File Area	<input type="text" value="0"/>	7
PKS Upgrade	<input type="text" value="0"/>	8
PKS Connector to LIMS	<input type="text" value="0"/>	9
PKS Connector to Reporting Database	<input type="text" value="0"/>	10
Reagent Mgmt	<input type="text" value="0"/>	11a
e-Lab Notebook Requirements and Analysis	<input type="text" value="0"/>	12a
Electronic laboratory checklist event capture	<input type="text" value="0"/>	12b
Sample data files mgmnt w/o central lab	<input type="text" value="0"/>	13
Generic specifications for Central Laboratories	<input type="text" value="0"/>	14
Transition_of NMEs from DR to CP	<input type="text" value="0"/>	15
Pharmacology Summary Report and Centralized Filing	<input type="text" value="0"/>	16
Phase I protocol templates	<input type="text" value="0"/>	19

Capturing people's time on projects is critical to planning & allocating resources, but it requires a cultural change to make it happen.

Recommendations Forward

Recommendations for Better Management of All Projects



- Management is fully engaged in Informatics Projects
- Project Managers are driving to & measured on results
- Schedules are well defined and managed
- Project Communications are frequent, frank and informative
- Project controls are in place – reporting, milestones, project reviews, change order process, escalation
- Project Team demonstrates excellent teamwork and thorough understanding of the business needs
- Business functions and IT are working side by side
- Projects are on-time, on-budget, and what the business needs

Acknowledgements

- Michael Beyer
 - Hugh Davis
 - Sandra De Guire
 - Terry Iorns
 - George Kuebrich
 - Lisa Nudy
 - Arita Patterson
 - Chris Perrotto
 - Don Rossi
 - Debbie Sisco
 - Faith Talnack
 - Karl Yorgey
 - CP&EM Colleagues
 - RIT Colleagues
- ResultWorks, LLC
- Susan Butler

Thank-you

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