



Project Summary Report

C3PR
28XS103

May 13, 2009 to March 4, 2011

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1. Personnel Roster

Name	Title/Role	Contact Information
Robert Annechiarico	PI	Bob.Anechiarico@duke.edu
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Jessica Pritchard	Tech Writer	Jessica.pritchard@semanticbits.com
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Insert additional rows as needed.

2. Technical Status Overview

Insert a narrative describing the current status of the project. This section goes beyond the month's activities to include all of the activities for the entire effort. Include high-level accomplishments, future directions, and major risks and issues.

The current version of the application is 2.9.3, which is part of the Suite version 2.3. It is a fully functional web-based application for end-to-end patient registration. In addition, the Subject Management NCI Enterprise service is also part of this release. Separately, another set of services have been developed for Mayo Clinic, although it is not part of the official release. The Mayo release also includes Subject Registry service and a Study Utility service.

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In general the development work done for the project can be divided into three broad categories – web application development, which includes features for the web application; development work related to the Suite; and NCI Enterprise Service development. Other work involves supporting existing users, discussing their unique requirements, and supporting the CTMS Knowledge Center where development team input is required.

The following describes in details the activities of the project for the entire period of effort, which started on May 13, 2010, divided by the three categories of activities:

CTMS Suite

The two primary features that were developed by the c3pr team as part of the caBIG Clinical Trials Suite was decoupling of person and user, and implementing an expanded security framework which was harmonized across all the applications in the Suite. Rigorous QA was performed by the development team and then by the Suite Testing team, which was provided assistance by the development team in interoperability and regression testing.

User and Person were decoupled so that specific roles could be assigned to the user of the system as part of User provisioning and person creation would be separate from user provisioning. The expanded security framework provided for much finer grained roles which could be assigned to a user.

In addition the c3pr team also worked with PSC and caTissue to come up with a design proposal for caTissue integration into the Clinical Trials Suite. A final design and architecture was proposed for caTissue integration with C3PR, PSC and iHub.

Web Application Development

Several new features were added to the c3pr web application:

1. Additional data element related to informed consents, such as consent version, consent presentation type and status as well as the name of the person who presented the consent to the subject were added.
2. Advanced search feature based on several criteria in subject, study, and registration modules was developed.
3. Ability to take a participant off an epoch and specify the primary and secondary reason code was added.
4. Ability to find out which version the patient is consented under and re-consent if not consented under the right version was added.
5. Ability to waive eligibility criteria for participants under certain circumstances, such as when a patient fails eligibility criteria was added. A waiver number and explanation is provided and captured in the system.

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6. When a subject is registered, capability was added to take a snapshot of the subject demographics and associate it with study subject so that any future change in the master record does not reflect on the original registration record unless approved by the registrar
7. Ability to find out which version the patient is consented under and re-consent if not consented under the right version was added.
8. Ability to withdraw consent at any phase of the registration process – screening, treatment, follow up – was added with the capture of appropriate status of subject and reason.
9. OPEN Integration – significant amount of effort was spent on scoping and designing a solution for integration with the CTEP registration system OPEN with the objective of not requiring a center to install both c3pr and OPEN. But there were several technical and political challenges which prevented the implementation of solution in this performance period. The development team is of the opinion that given more time and agreement on all sides, the proposed solution could be implemented.
10. Integration with caTissue – an architectural solution was conceived for integration with caTissue for cases where studies involved biobanking, but due to time constraints it could not be implemented.

NCI Enterprise Services

The c3pr project had been assigned to develop three NCI Enterprise Services (NES) – Subject Management, Subject Registration, and Randomization services. This include writing the scope document, CIM, PIM, and PSM, and implementing the service in the technology stack specified in the PSM.

The Subject Management service was fully developed according to the process described. In addition automated testing of the Subject Management service was developed. In addition the c3pr team, along with the BRIDGE harmonization team, incorporated the information model into the Subject Registration CIM, which was based on the final C3PR BRIDG-based project analysis model.

While developing the design documentation of Subject Registration service, Mayo clinic exhibited an interest in adopting the Subject Management and Subject Registration service for integration into their enterprise wide clinical research information solution. But after reviewing the Subject Registration documents, they recommended the development of an alternate service called Subject Registry, which would only track the status of the participants on a study. A Subject Registry service was developed specifically for Mayo, but several other institutes also expressed an interest in such a service.

The Subject Registration service design documents were completed and implementation, but the implementation could not be completed due to time constraints.

For the Randomization service a scope document was completed and reviewed by the ESST.

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User Support

The current adopters of c3pr include Agha Khan University, UAMS, Baylor College of Medicine, and Mayo clinic.

All through the period of performance, support was provided by the development team to users of the application in the form of fixes and enhancements. Some specifics include:

1. Tested data migration from 2.5.4 to current version of C3PR (version 2.9.3) for Baylor College of Medicine.
2. Clarified requirements for Summary 4 fields with Baylor College of Medicine and added additional fields to study details related to Summary 4 reporting.
3. Worked with Mayo to develop customer services for integration into their Ptrax system and helped with the integration of services in their code.
4. Worked with UAMS to develop a few enhancements for them.

Major Risk and Issues

Some of the major risks and issues that were identified during period of effort covered by this report include:

1. Lack of resources – the resources available are always competing for work related to suite development, NCI Enterprise Services development, Web Application development, and user support. In addition, due to shifting priorities, sometimes development work often has to shift between the different areas of work before a particular task can be completed.
2. OPEN Integration – There were significant technical and political challenges involved in developing an integration solution for OPEN.
3. Support for existing adopters – when existing adopters of the application report problems, at times there are problems in allocating resources to work on those issues, which is detrimental to the adopters business needs.

2.1 Description of Work Completed During the Contract Period

Table 2.1: Technical Progress/Accomplishments

Activity	Description
Unified Security	Added several finer-grained roles and privileges which were harmonized across all CTMS Suite applications.
Off Epoch	Ability to take a participant off an epoch and specify the primary and secondary reason code.
Advanced Search	Advanced search based on several criteria in

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	subject, study, and registration modules.
Eligibility waiver	Ability to waive eligibility criteria for participants under certain circumstances, such as when a patient fails an eligibility criteria. A waiver number and explanation is provided and captured in the system.
Subject Demographic snapshot	When a subject is registered, a snapshot of the subject demographics is taken and associated with study subject so that any future change in the master record does not reflect on the original registration record unless approved by the registrar.
Consent Form Enhancement	Added date and title of consent form
Re-consent	Find out which version the patient is consented under and re-consent if not consented under the right version
Consent Withdrawal	Consent can be withdrawn at any phase of the registration process – screening, treatment, follow-up. Appropriate status of subject and reason is captured.
NES	Developed Subject Management service, Subject Registry service, and a Study Utility service. Partly development Subject Registration service. Analyzed and started scoping of the Registration service.

Describe each discrete activity on which work was performed during the month. When the activity encompasses work on a discrete task (see below), explicitly identify the task and task number.

3. Issue Management

Table 3.1: Business/Process/Technical Issues Encountered, Resolved and open

ID	Issue	Type	Status	Resolution/Proposed Resolution
1	Subject Registration NES	B	O	Given more time this service can be fully implemented
2	Randomization NES	B	O	Given more time this design documents and implementation of this service can be completed.
3	OPEN Integration	B, T	O	There were significant challenges in aligning the business process of OPEN and c3pr, as well as technical issues that prevented the finalization of a solution design and implementation. An agreement at the highest level of CBIIT and CTEP is required regarding the

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				harmonization of the business process.
4	Detailed list of issues in Jira			https://tracker.nci.nih.gov/secure/IssueNavigator.jspx?mode=hide&requestId=10398

Type = B (Business)/ P (Process)/ T (Technical)
Status=R (Resolved)/ O (Open)

4. Success stories

Table 4.1: Items that went well

ID	Items that Succeeded
1	CTMS Suite security framework implementation.
2	CTMS Suite user and person separation.
3	Implementation of the Subject Management, Subject Registry and Study utility service.
4	Implementation of several features of the c3pr web application.
5	Services development and deployment for Mayo Clinic
6	Collaboration with UAMS

5. Lessons learned/Future Improvements

Table 5.1: Lessons Learned/Suggestions for Future Enhancements/Improvements

ID	Lessons Learned/Enhancements/Improvements
1	Need better alignment of business process for OPEN and C3PR for a successful integration.
2	Need more time and resources for completion of the implementation of Subject Registration and Randomization services.
3	Need more time and resources for completion of integration with caTissue.
4	Prioritization of back logged use cases – i.e., deciding the priority from different perspectives - NCI, UAMS, Mayo, user X, etc.
5	Balancing NES development with application development was challenging and Suite development
6	Suite-level Business Analysts were not regular participants in Suite use case implementation and QC

State here possible future implementation strategy, if different from the one used in the project
Enhancements – Software changes or additions; Improvements – Process/Communication/Structure changes.

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6. Deliverables

Table 6.1: Status of Deliverables

Deliverable/Milestone	Delivery Date	Status
Project Management Plan		In Protrac
Monthly Status and Financial Reports		Current through June, 2011
Project Summary Report		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR_v2.9.3_Final_Project_Summary_Report.pdf
Updated C3PR Scope and Vision Document		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/c3pr_v2.9.3_final_C3PR_Vision_and_Scope.pdf
Use Cases, and Software and System Requirements and Specifications or CFSS and CFAS		<p>Use Cases: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Use%20Cases.pdf</p> <p>Software and System Requirements: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20v2.9.3%20Requirements%20Specifications.pdf</p>
Updated UML Model, Architectures, and Master Design Document		<p>UML Model: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20BRIDG-Based%20Analysis%20Model.EAP</p> <p>Architecture: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/c3prv2_architecture_guide.doc</p> <p>Master Design Document: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Technical_specification_Integration.doc https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Technical_specification_Integration.doc</p>

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		v2.9.3/C3PR%20V2.9.3%20Technical_specification_core_web.doc https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Technical_specification_security.doc
Implementation Plan		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Technical%20Specification%20Core%20Web.doc https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Technical%20Specification%20Integration.doc https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Technical%20Specification%20Security.doc
Quarterly adoption support report		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20v2.9.3%20Duke_C3PR_Adoption_Report.doc https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20v2.9.3%20WFU_C3PR_Adoption_Report.doc https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20v2.9.3%20Georgetown_C3PR_Adoption_Report.doc
Updated Master Test Plan, Test Scripts and Procedures		<p>Master Test Plan: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20v2.9.3%20Test%20Plan.pdf</p> <p>Test Scripts and Procedures: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Tests%20for%20investigator.pdf https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Tests%20for%20manage%20study.pdf https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Tests%20for%20organization.pdf https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Tests%20for%20research%20staff.pdf https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Tests%20for%20study%20version.pdf https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Tests%20for%20subject.pdf https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20v2.9.3%20Test%20cases%20NES%20Web%20Services.pdf</p>

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Completed Test activity logs, test result reports, and bugs and fixes reports		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR_V_2.9.3_M3.1_Test_Activity_Logs.xls
Compatibility Review Submission Package including CDE Use Report, Annotated XML Files, API Document, Use Case, UML Model, SRSS, SIW report, Test Logs, Technical Guide etc.)		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/c3prv2_silver_review_package_final.zip
Documentation of BUGS and BUG Fixes.		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Bug%20Report.pdf
Installation Package, Source Code, and Release Notes		2.9.1: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/C3PR_2.9.1 2.9.3: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/C3PR Source Code: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/codebase/ Release Notes: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20Release%20Notes.pdf
Updated Installation Guide		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Installation%20Guide.pdf
Updated and		https://demo.semanticbits.com/c3pr/

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maintained C3PR Demonstration Web Site		
C3PR User Manual, Admin Guide, Programmer Guide, and API documentation		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20v2.9.3%20End%20User%20Guide.pdf https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20v2.9.3%20Administration%20Guide.pdf https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20v2.9.3%20Programmers%20Guide.pdf API documentation part of SLC submission zip
Enterprise Service technical approach document		Subject Management: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/design/essn/SubjectManagement/ Subject Registration: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/design/essn/SubjectRegistration/ Subject Registry: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/design/essn/SubjectRegistry/ Randomization: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/design/essn/Randomization/
CCTS release technical support document		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/CCTS%202.3%20Release%20Technical%20Support%20Document.pdf
A Deployment Guideline of Multi-Site Protocol Study		In Protrac.
Maintained and Updated C3PR Prioritized Feature List		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%202.9.3%20Features%20Final.xlsx
C3PR Compliance		BRIDG: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/

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Reports for BRIDG, BAM, and FDA regulations		v2.9.3/C3PR%20BRIDG%203.0.3%20Mapping%20Spreadsheet.xls BAM: NA. FDA regulations: https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR_FDA_Regulations_Compliance_Report.doc
Reviewed and Commented Use Case		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Use%20Cases.pdf
Critiqued Test Approach Document & Adopter Test Approach Plan		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20Test%20Plan.pdf
Test Results Report		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR_V_2.9.3_M3.1_Test_Activity_Logs.xls
Reviewed and Commented End User Guide's		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/C3PR%20V2.9.3%20End%20User%20Guide.pdf
Reviewed, Commented, and Approved Developer's Deployment Plan		https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/BCM%20C3PR%20Adoption.ppt https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/Mayo%20C3PR%20Adoption.ppt https://ncisvn.nci.nih.gov/svn/c3pr/trunk/c3prv2/documentation/v2.9.3/UAMS%20C3PR%20Adoption.ppt

Final status of each deliverable identified in the contract