CTMS : C3PR Adopter Plan

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Contents

Project Summary

Project name:	Cancer Central Participant Registry (C3PR)
Start date:	March 7, 2008
Primary contractor:	Duke Comprehensive Cancer Center
Current stage of project:	version 3, elaboration phase

Points of Contact

Position	Name	Organization	Phone	Email
PI	Jamie Cuticchia	Duke	919-681-9646	
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Georgetown Adopter Lead	Jieping Li	Georgetown		

Vision and Scope

The primary adoption objective for C3PR phase 2 is to share data through C3PR in a real multi-site scenario. In such a scenario, registrations would be performed locally at affiliate sites, the registration

data would be transmitted to the coordinating site, the subject would be randomized and enrolled at the coordinating site, and this information would be sent back to the affiliate site. Currently, C3PR is not being used to run any existing trials, so we do not foresee leveraging C3PR alone to run the registration portion of a new or existing trial. Instead, we plan to run C3PR in parallel with an existing registration workflow for an existing study. We will therefore be able to exchange real registration data for a real study without jeopardizing the study.

The secondary adoption objective is integrate C3PR with with a CDMS using real study and registration data. In this scenario, C3PR would be deployed at an enrolling site, and, for each enrollment, data would be propagated from C3PR to a local CDMS. This objective is secondary and should take priority over the primary multi-site scenario.

We have performed some preliminary work to identify a study that can be used for these objectives. It is a study known as PANVAC which is a pancreatic cancer vaccine study. It is being coordinated by Duke with Wake Forest and Georgetown as two of the affiliate sites.

Success Factors

Factors that should be met to achieve overall success of adoption of the application include:

- Objective 1: multi-site adoption pilot
  - Deploy C3PR at each adopter site, including a coordinating site and one or more affiliate sites
  - Exchange real study data between the coordinating site and affiliate site(s)
  - Exchange real registration information between the affiliate and coordinating site in real-time
  - Integrate C3PR into the existing workflow setup for registering subjects on a real study
- Objective 2: CDMS integration
  - Deploy C3PR at each adopter site
  - Integrate C3PR with a local CDMS
  - Exchange real data in real-time or at specified regular intervals between the CDMS and C3PR

In the Elaboration Phase, we will address the following high-level goals:

- Determine a real study to use for each scenario
- Identify risks and barriers to adoption for each scenario
- Define a deployment model for each scenario

In the Construction Phase, we have the following high-level goals that will determine success:

- Implement data sharing scenarios that are not already implemented
- Deploy C3PR for each scenario
- Integrate C3PR into each study

In the Transition Phase, we have the following high-level goals that will determine success:

- Document lessons learned
- Document next steps in C3PR adoption

Project Dependencies

C3PR has key dependencies on existing caBIG projects:

- caGrid: C3PR is dependent on the caGrid 1.0 software for it's basic infrastructure and query language

There will potentially be dependencies on other caBIG CTMS applications (e.g. PO/PA). However, these specific dependencies will be determined as the use cases are elaborated. See the vision and scope document for a full list of potential integration (dependency) points.

Activity List and Schedule

Iteration	Task
3	Identify a protocol for the adoption scenarios
3	Identify participating sites
3	Elaborate on data sharing use cases
3	Implement data sharing use cases
4	Identify political, social, and regulatory barriers
4	Elaborate on data sharing use cases
4	Implement data sharing use cases
5	Elaborate on data sharing use cases
5	Implement data sharing use cases
6	First pass deployment of C3PR
6	First integration of C3PR
6	Elaborate on data sharing use cases
6	Implement data sharing use cases
7	Test deployment
7	Fix bugs, address issues
8	Second pass deployment of C3PR
8	Second pass integration of C3PR
9	Test deployment
9	Address issues
10	Run scenarios
11	Run scenarios
12	Run scenarios

Note: iteration 1 starts March 7 and ends March 31, iteration 2 starts April 1 and ends April 30, etc.

Staffing

Team	Members
Duke	• Jamie Cuticchia (PI) • Bob Annechiarico (Project Director, Co-investigator)

	• Pankaj Agarwal (Project Manager) • Mohammad Farid (DBA) • Peter Le (IT Analyst) • Vijaya Chadaram, RN (Subject Matter Expert) • Emily Allred (Admin)
SemanticBits	• Ram Chilukuri (Technical Director, Architect) • Patrick McConnell (Architect) • Kruttik Aggarwal (Lead Developer) • Ramakrishna Gundala (Developer) • Vinay Gangoli (Developer) • Himanshu Gupta (Developer) • TBD (Business Analyst) • Shilpa Alluru (QA Tester) • TBD (Technical Writer)
Wake Forest	• Bob Morrell (Institutional Lead, Subject Matter Expert) • Steven Cheng (Technical Tester) • Kim Livengood (Subject Matter Expert)
Mayo Clinic	• Sharon Elcombe (Institutional Lead, Subject Matter Expert)
CALGB	• Kimberly Johnson (Institutional Lead, Subject Matter Expert) • Amish Shah (IT Analyst)
Westat	• Steve Riorden (Institutional Lead, Subject Matter Expert) • etc.

Risk Identification

Number	Risk	Date Surfaced	Status	Impact	Likelihood	Mitigation Strategy	Mitigation Description