

CIDMU Web System Development

Standard Operating Procedure

“How do I work with CIDMU?”

Christopher Reid
Head, Clinical Informatics and Data Management Unit
CCRE Therapeutics,
School of Public Health and Preventive Medicine
Monash University

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Introduction:

The Clinical Informatics and Data Management Unit in the School of Public Health and Preventive Medicine is a Monash University platform for the development of web based and desk-top applications for the collections and management of clinical information for the conduct of randomised trials and clinical registries.

The current suite of services offered through the Unit include;

- a) Web-based data capture and reporting systems
- b) Desk-top based data capture and reporting systems
- c) Web-based clinical trial randomisation services
- d) Telephone based randomisation services
- e) Electronic forms based data capture systems (scan, fax and email)
- f) Case record form design
- g) Clinical trial and registry development and management
- h) Clinical trial design and statistical consulting services

The Unit consists of 30 highly trained software development, clinical research project and data management professionals.

CIDMU Systems Architecture - Overview

Essentially we have a standard approach to the development of web-based systems which can be developed down various pathways. The standard approach involves;

Development using Microsoft .NET platform

- Microsoft SQL Server 2008 backend
- Microsoft Team Foundation Server - collaboration platform for application lifecycle management
- Three (3) developers assigned to each project
- One (1) designated Project Lead Developer

The architecture framework for the systems to be developed will be outlined in the Systems Requirements Specification and the decision may depend on resources, time frame and other factors. The architecture will be agreed to prior to commencement of programming work.

The Project Development Plan

1. The Project Brief

The initial requirement for “getting started” is to work up a Project Brief (See Project Brief Template). This document will be developed following the initial meeting with the Head of Department. Following delivery of the Project Brief, a CIDMU Project Manager will be identified through which all future Project related communication will be coordinated. The Project Manager will be either the;

- a) Head of Department,
- b) Systems Development Manager
- c) Senior Project Manager or Nominee

Following receipt of the Project Brief, a Systems Requirements Workshop will be planned.

2. Systems Requirements Workshops

The purpose of the Systems requirements workshops is to develop documentation regarding the functional requirements for the system to be developed. The systems requirements workshop will be led by the designated CIDMU Project Manager and will involve key stakeholders including client representatives (1 or more), systems developers (1 or more) and a business analyst. **This group forms the Project Team.** We would propose that a minimum of 2 workshops would be held following **which a Systems Requirement Document will be produced for sign off by the Project Board.** The Project Board will include the Principle Investigator for the proposed system to be developed, the designated Study Project Manager and the Head of CIDMU. Following sign off of the Systems Requirements Document, a proposed budget, payment schedule and timeline will be prepared and will be sent for approval to the Principal Investigator. No development work can begin until all documentation and signatures have been received and a contract or Memorandum of Understanding (MoU) is in place.

3. The Systems Development Cycle

CIDMU utilises an agile software development framework and will progress work in three iterative cycles. In most circumstances and depending on the scope of the work, three cycles of 2- 4 weeks duration will be required to deliver the agreed requirements specified in the Project Board approved systems requirements documentation. At each review meeting, the opportunity exists for feedback from the client and there is the opportunity for changes to be considered to the requirements specification documentation. **The impact of these changes on a) the timeline for delivery and b) the project budget must be agreed to by the Project Board and signed off prior to the commencement of the next stage.** Prior to User Acceptance Testing, CIDMU will undertake internal systems testing. This will take approximately one week.

4. User Acceptance Testing (UAT)

Following the end of the last cycle, a minimum period of 2 weeks User Acceptance Testing (UAT) will commence. User Acceptance testing is to be undertaken by a) Project Research Staff and End-users, and b) a CIDMU Testing Officer. It is the Clients responsibility to ensure that they organise and allow adequate staff and time to test the system during this phase. Following the UAT, CIDMU will undertake the following as part of the development contract; any bug fixes identified during the UAT i.e. – correction of functionality specified in the Systems requirements document that is either missing or not working. Assessment of the time involved will be given following review. Additional UAT will then be undertaken.

5. System Delivery

Following the correction of bug-fixes, the system will be “delivered” to the Project Board. We will make every effort to undertake bug-fixes within a 1 week period. System delivery will constitute Project Completion.

6. System Improvements and Change Requests

Clearly once a system is delivered and being used across multiple sites, users will request additions (typically reporting) and additional functionality. We also recognise that even with the most extensive of system testing, problems may appear that impact on the operation of the system as specified in the systems specification documentation even after it has been delivered.

The following schema illustrates how we plan to deal with change requests following the delivery of a system.

System failures should be reported to the CIDMU Project Manager immediately and will be dealt with as soon as possible by the systems development team

All change requests are to be collected through the Study Project Manager.

- After 1 week post-delivery, all requests will be reviewed at a Team Meeting and categorised as Group 1 or Group 2 changes (see below)
- Group 1 change requests will be implemented 4 weeks following system delivery at a cost of \$80 per hour to a maximum of 4 hours
- All other change requests will be collated until 8 weeks following system delivery
- A Project Team meeting will be held in Week 8 to discuss, prioritise and rank changes according to the MOSCOW (must have / should have / could have / won't have) criteria.
- Group 2 changes will be considered as a new project and will follow the same Development Cycle as outlined above i.e. Project Brief, Systems Specification Document, Project Board Sign Off, Agreed Budget and Time lines, UAT and Delivery.

7. Systems Maintenance

All web-based systems require maintenance above and beyond change requests and systems development. Maintenance includes;

- Server Maintenance and where required Migration planning
- Domain and user management
- Security systems and backup maintenance

All systems will have a minimum maintenance requirement of 1 hour per week and will be costed at \$4,200 for each year the project is required to have a live functioning system available. Studies continuing beyond their original expected timelines will continue to be billed while this requirement exists and amendments to contracts / MOUs will be sought.

SYSTEM CHANGE REQUESTS

Group 1

Most of these requests (not all) can be done with pre-approval and can be finished within a day or few days.

1. Adding some option(s) to drop down list without changing the logic of the application (e.g. dropdown list with no dependent field/s)
 - 1.1 Code No/Name/description of the option should be provided.
2. New login request including unlocking the account, deactivating account, changing site access. For the VTE system, this task can be done by an admin user (e.g. Louise Phillips). Request for a new admin user must be requested to CIDMU via jobdesk.
 - 2.1 Full name, email, site(s) access details should be provided
3. Report bug/error to be fixed
 - 3.1 Patient ID, User's last action to the system, Captured screenshot(s) for the error should be provided for quick response
4. Changing/correcting typo/label/wording for each page
5. Minor data cleaning from user's human error (if that function is not provided on the application)
6. Data cut having the previous scripts (ready to run without changing)
 - 6.1 previous email request subject/date or previous Monash job desk reference # should be provided for quick response
7. Other requests without changing the current logics/procedures/programming codes of the application/page/tab/field

Group 2

For the following requests, our change controls and procedures are formally applied. The approval is also required from CIDMU supervisor before working on these requests. As a result, an expected complete date/time may be longer than the requests above (e.g. a week, few weeks, etc.) or may be on hold if not approved

1. Any request with adding to/changing the current logics/procedures/programming codes of the application/page/tab/field
 - 1.1 Finalised new/changed logic and procedure should be clearly explained in writing, sample forms/reports (if any) should be provided
2. New function(s) to be added to the system
 - 2.1 written requirements, supporting documents, sample forms/reports (if any) should be provided
3. Data cut with complex script required including a request for new format/pattern of data
4. Other requests requiring a lot of programming work.

Project Title

Week

		01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30		
1	Receipt of Project Brief	x																															
2	Response to Project Brief		x																														
3	Workshop 1			x																													
4	Workshop 2				x																												
5	Contract Sign Off - SRS					x																											
6	Iteration 1						x																										
7	Review Meeting 1							x																									
8	Iteration 2								x																								
9	Review Meeting 2									x																							
10	Iteration 3										x																						
11	Review Meeting 3											x																					
12	Internal System Testing												x																				
13	UAT													x																			
14	Post UAT Review														x																		
15	UAT Sign Off															x																	
16	Delivery																x																
17	Group 1 Changes																	x															
18	Group 2 Changes Meeting																			x													
	Planned time-line	x																															
	Actual Time-line	x																															