# DEVELOPING THE *COCHRANE REGISTER OF STUDIES*: STEERING GROUP REPORT FROM THE CRS PROJECT BOARD, KEYSTONE 2010

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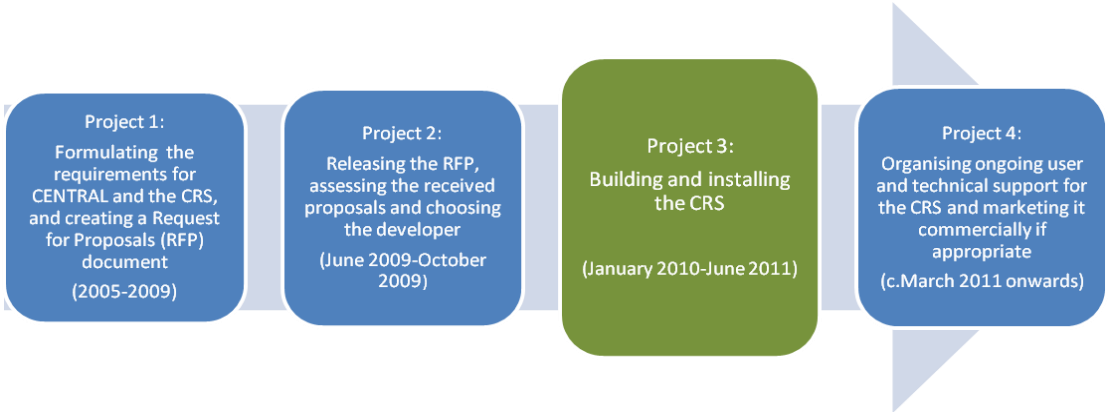
**Document prepared on:** 16th September 2010
**Purpose:** To update the Steering Group on the progress of developing the *Cochrane Register of Studies*. This paper is for information only: no decisions are required of the Steering Group at this meeting and no recommendations are made.




The CRS will contain the Collaboration's Specialised Registers (SRs) of healthcare studies and their reports, together with records identified by handsearching of journals and conference proceedings and records sourced from MEDLINE and EMBASE, to be published in the *Cochrane Central Register of Controlled Trials* (CENTRAL) in *The Cochrane Library.*

## 1) A reminder of the rationale for developing the *Cochrane Register of Studies* (CRS)

Core to the rationale for developing the CRS is the need to improve the 'build' process for the aggregation of the SRs, remove duplication and inconsistency, and implement a standard workflow and tracking system that all Cochrane entities can use.

**This should have three principal outcomes:**

1. The improvement of the quality and accessibility of the information in CENTRAL, which represents the essential infrastructure of the Collaboration, both for supporting the authors of SRs, and as a unique, marketable product.
2. The creation of the leading global register of clinical studies (particularly randomised controlled trials) and their reports, which may itself become a marketable product and/or be based on Collaboration-owned software that may be marketable.
3. The improvement of the experience of those who maintain SRs.

## 2) Membership of the Project Board

Since the last update submitted to the Steering Group for its mid-year meeting in March 2010, the Project Board has expanded to include Gail Higgins. Gail is, as you know, the TSC Representative on the Steering Group and a member of the TSCs' Executive. Although the Board had agreed to keep its

membership to a minimum – in line with the principles of PRINCE2 management, which it is broadly following – we also felt that Gail's expertise, experience with the Request for Proposals process and role on the Steering Group, make her an essential member.

### 3) Building the CRS: progress update

| DELIVERABLE | |
|---|---|
| **Phase 1 Design and consultation** | **COMPLETED?** |
| **1a Database functional design**<br>A document to define the structure, tables and referential integrity of the database. This will be the document from which the initial database is developed, though it is understood from the outset that the structure may change as development proceeds. | ✓ 04.03.10 |
| **1b Functional specification for preliminary designs**<br>A document outlining the functional requirements of the interfaces. This document will form the basis of the interface designs to implement the functionality. | ✓ 04.03.10 |
| **1c Preliminary Management interface design**<br>A document describing all the screens in the management interface, based on the functional specification. | ✓ 04.03.10 |
| **1d Preliminary Web interface design**<br>A document describing all the screens in the web interface, based on the functional specification. | ✓ 04.03.10 |
| **2a Consultation**<br>A series of consultations (for example email, face-to-face, telephone) and a document outlining the main findings. | ✓ 01.07.10 |
| **2b Final designs**<br>A document specifying the management interface and web final designs based on the preliminary designs and modified in light of the consultation. This will be the basis for starting programming the interfaces. | ✓ 01.07.10 |
| **Phase 2 Database implementation** | |
| **3 Database implementation**<br>A SQLServer 2005 database containing all tables with referential integrity as specified in the database design document. No live data at this stage, but test data to enable the database functionality to be tested. | ✓ 05.04.10 |
| **Phase 3 MeSH implementation** | |
| **4 MeSH tables and import routines**<br>The MeSH thesaurus SQLServer 2005 database populated with 2010 MeSH data. Routines to import future MeSH thesaurus data from NLM in the current NLM format. | ✓ 20.04.10 |
| **Phase 4 Management routines** | |
| **5a Import existing data**<br>Routines and programs to import existing specialised registers to populate the main database. | ✓ 09.06.10 |
| **5b PubMed lookup**<br>Routines to discover PubMed ID and other PubMed data from records in the System not loaded from MEDLINE. | ✓ 09.06.10 |
| **5c MeSH reload**<br>Routines and programs to perform the annual MeSH reload, MeSH thesaurus updated to 2010 version using these routines. | ✓ 09.06.10 |
| **Phase 5 Integration with Cochrane data** | |
| **6 Routines to access legacy Cochrane data**<br>Routines and programs to import existing RevMan data to populate the main database and studify the records. | ✓ 09.06.10 |
| **Phase 6 Management Interface** | |
| **7 Main program**<br>Program shell with auto update, look and feel, login and permissions. | ✓ 29.06.10 |
| **8 Upload module** | TO BE COMPLETED BY |

| | |
|---|---|
| Screens and routines for getting records into the System from specialised registers, MEDLINE and EMBASE or direct input. | KEYSTONE COLL. |
| **9 Export module**<br>Screens and routines for getting records out of the System as export files. | TO BE COMPLETED BY KEYSTONE COLL. |
| **10 Workflow module**<br>Screens and routines for managing workflow of users and records. | TO BE COMPLETED BY KEYSTONE COLL. |
| **11 User testing**<br>Beta version of the management interface made available for user testing. User testing report. | |
| **12 Finalising and delivery**<br>Release version of the management interface made available for acceptance testing. | |
| **Phase 7 Web interface** | |
| **13 Web interface**<br>Web interface based on the web interface specification document. | |
| **14 User testing**<br>Beta version of the web interface made available for user testing. User testing report. | |
| **15 Finalising and delivery**<br>Release version of the web interface made available for acceptance testing and initial rollout. | |
| **Phase 8 Documentation and training** | |
| **16 Program documentation**<br>Full documentation of all the modules in the project based on the specifications and modified to account for changes made over the development life cycle (database, management interface, web interface). | |
| **17 Training resources**<br>Help files for the management and web interfaces and an online tutorial on how to use the software. | |
| **18 Bug reporting interface**<br>Online interface for reporting and tracking software issues and bugs. | |
| **Phase 9 Rollout** | |
| **19 Initial rollout report**<br>Report on initial rollout and report of any bugs or issues at the acceptance testing stage prior to final rollout. | |
| **20 Final rollout report**<br>Report on the final rollout and report of any bugs or issues at the final rollout stage. Project acceptance and sign off. | |

**ESTIMATED COMPLETION OF PROJECT: JUNE 2011**

### The Deliverables

By the time of the Keystone Colloquium, Metaxis will have developed the majority of the CRS system's components. Although there have been some minor delivery delays, we are pleased to report that the Deliverables produced so far have been delivered as per their specification as set out in the Collaboration's Request for Proposals (RFP) document (and subsequently the services contract), to an acceptable standard, and on the whole, to time. We are on target to the finish the development project in June 2011, as per our initial project plan.

Where delays have occurred, these have mostly been due to the need to gather more input from the user community and to make amendments to the system design based on this feedback. However, we have been careful to ensure that development of the CRS remains guided by the RFP: any requested deviation from the RFP requirements or any proposed new functionality –made mostly on the CRS Discussion Forum - has required an assessment of the financial and time implications before being considered and approved, or disregarded as appropriate. We have considered deviation from

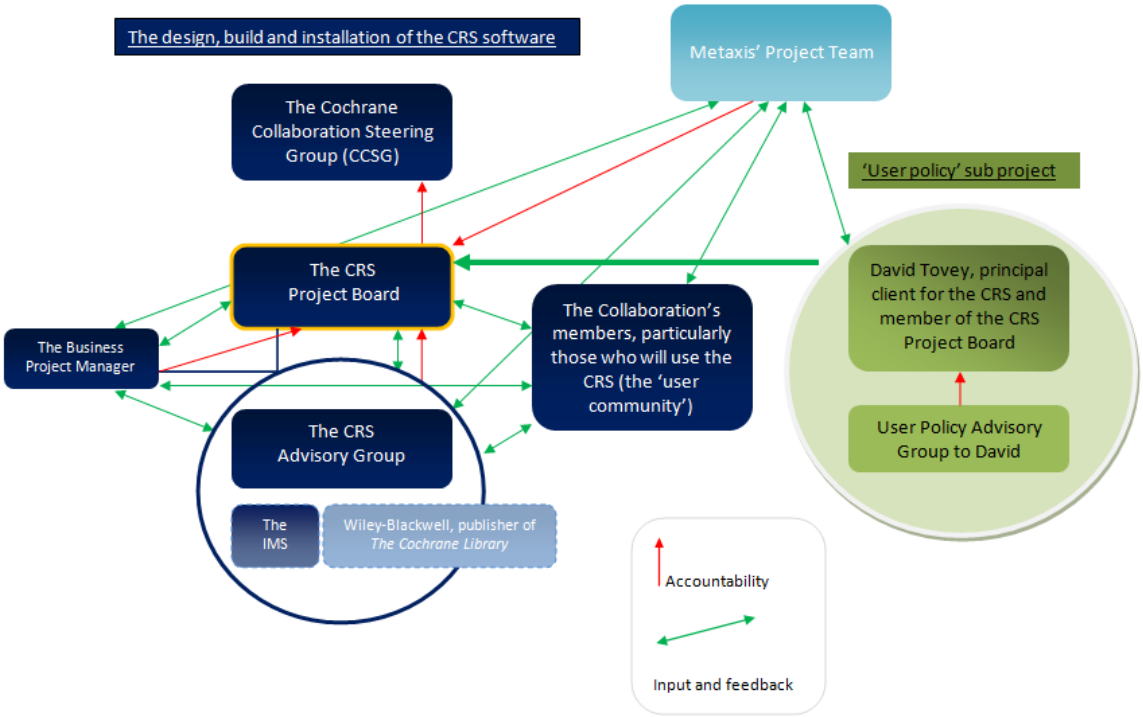
the RFP requirements as a potential risk to the project and are working from the perspective that they should not be permitted unless there is a strong case that they will result in a better product, which can still be delivered to time.

**Project management**

The Project Board meets every 4-6 weeks: some members attend in person and others by teleconference. At our meeting on July 1st 2010, we took the decision to create a sub-project to the development project that will address 'user policy' issues that affect the development. These are the issues that relate to how end-users want to use the system, and the creation of guidance, regulations, processes, procedures, 'can-do's', 'can't-do's', and best practices for using it. We felt that these issues were better dealt with in a separate forum to the Project Board meetings, so that we could maintain our focus on the build and installation threads of the development.

This sub-project will become more important over the coming months as we begin the programme of user testing and subsequent installation of the completed version of the CRS. We have created a 'User Policy Advisory Group', which is composed of the current CRS Advisory Group, the TSCs' Executive, and other members including Mike Clarke and Clive Adams. One of main 'user policy' decisions that will need to be taken in the coming weeks is deciding who the end-users of the system will be: should it only be those who maintain their entity's SRs, or should we promote wider access, to author teams for example? Are there other ways of accessing CRS data than by accessing it through the CRS, perhaps by integrating with other Collaboration systems (see section 4 below)?

More detail on the management of the project can be found in the Terms of Reference document, available on the CRS Discussion Forum on cochrane.org: http://www.cochrane.org/forums/cochrane-register-studies-crs




## 4) Work still to complete

In the remaining months of the project, the focus will switch from building the components of the CRS system to completing the population of the system with data, beginning a program of technical

and user testing, creating technical and user guidance, and 'rolling-out' the system across all entities. As described above, we will also be agreeing how we want to exploit and integrate the CRS with other systems and products – moving towards Project 4 in the series, as shown in the diagram at the top of the paper. For the next Steering Group meeting (not for this meeting, as initially projected), it is intended that we will submit a proposal for the ongoing technical and user support of the CRS.

We have already begun negotiations with the IMS Team about how the CRS can access IMS data, and potentially, how CRS data could be integrated with the IMS , specifically Archie and RevMan. The technical and resource implications of these proposals are currently being considered by the IMS Team, and a budget request will be brought to the Steering Group by the end of 2010.

From the Collaboration's perspective, the last months of the development project may be the most complex as we roll-out the CRS, which will inevitably change working practices and lead to a period of adjustment for those who maintain SRs. The biggest risk we face in terms of meeting timelines and fulfilling expectations is a scenario where the CRS exists as a functioning product, built according to the specifications of the RFP, but which re-ignites discussions as to what it should be and do: i.e. it creates a confusion between how the CRS can be used (the user policy sub-project) and what the CRS is (Project 1 in diagram at the top of the page). The aim of the Project Board – and one which is needs to communicate regularly – has always been to create the CRS based on the agreed specifications in the RFP. However, should changes be proposed and agreed in future, it will be possible to make them due to the flexible system Metaxis is building: it is fully expected that the CRS, like any software, will have different versions.

### 5) A vision for the CRS

Once the CRS has been rolled-out across the Collaboration, it will sit within the new governance structure of the Collaboration's information systems, to be proposed by David Tovey in his report to the Steering Group as Editor in Chief. In this way, we hope to ensure that the CRS is considered as part of the 'big picture' of the Collaboration's information needs. We are aware of the desire in the Collaboration to improve both the efficiency and quality of CENTRAL and Cochrane Review production, and it is part of the core rationale for developing the CRS that it can contribute to these improvements.

At our meeting on 29th September we will be considering a process of 'cleaning' CENTRAL data, and at the Keystone Colloquium, we will be meeting with members of the Collaboration to discuss linking the CRS with prospective trial registries, and how this might happen. Towards the end of the development project, in 2011, we intend to run a conference to examine how we can maximise the benefits of the CRS and resolve questions that may shape its use, e.g. "how will people find trials in five years?"; "how we can ensure standards development and implementation?"; "who are the potential markets for the CRS?". The CRS is being built as an editorial process tool, designed with sufficient flexibility that it will be capable of being used in many different ways now, and capable of being changed to accommodate working practices as we want them to be in the future.

### 6) Maintaining a transparent project

The aim of the Project Board is to conduct the development project according to the principles of the Collaboration: with relevance, accessibility and wide participation. We have made use of the discussion forum functionality on cochrane.org, using it post questions and request feedback from

the Collaboration's contributors at any time throughout the project. The CRS Forum is also the place to download all relevant CRS documents, including the CRS Project Board Bulletin, which summarises the main proceedings from each Project Board meeting: http://www.cochrane.org/forums/cochrane-register-studies-crs.

We held an open session on the CRS at the UK and Ireland Cochrane Contributors' meeting in March 2010, which we broadcast live online, and have made a recorded version available for anyone to download. At the Keystone Colloquium we have planned a range of activities. We will be running two sessions: the first, an open-access presentation by the Board on the progress of the development project so far, including a presentation by Gordon Dooley demonstrating a 'live' version of the CRS. The second, an invited session where participants, representing a range of SR management approaches, will be introduced to the user testing process and will generate the formal testing schedules. We have added the CRS to the agenda for the joint meeting of the Co-Eds, MEs and TSCs, and Gordon Dooley and his team from Metaxis, who will be attending the Colloquium, will be available at the Collaboration's exhibition stand (the *Cochrane Exchange*) at various times throughout the week. The first session and the joint meeting will be broadcast live over the web.

7) **Comment from Gordon Dooley, on behalf of Metaxis:**

*"The development team at Metaxis is very excited about this project. Not only does the CRS help make the management of studies and study-based registers easier but it also facilitates data cleaning and offers a fresh way to look at study data: an important step in paving the way for future developments of CENTRAL. Some of the functionality Metaxis is building into CRS is ground-breaking (linking directly to trials registers for example), and as such it offers the potential to be a marketable product that may well offer the Collaboration a way to offset some of the costs of development, as well as challenging the current reference-based paradigm of bibliographic databases. The version available at the Colloquium will give Collaboration members the opportunity to see the software and to explore its possibilities, and Metaxis will have a strong presence there to help ensure the right information is available."*