DEVELOPING THE *COCHRANE REGISTER OF STUDIES*
CCSG REPORT, AUCKLAND 2010

At its last meeting in Singapore, in October 2009, the CCSG approved the recommendation to engage Metaxis Limited as its development partner for the new *Cochrane Register of Studies (CRS).* Immediately following the meeting the decision was communicated to the Collaboration at large and was received very positively.

Since then, a Project Board has been established to manage the development project, consisting of Nick Royle, David Tovey, Ruth Foxlee, Gordon Dooley (Director of Metaxis Limited), Steve Greenaway (independent technical advisor and former employee of Oakleigh Limited, who provided support during the RFP process) and Lucie Jones (ex-officio). The full management structure for the project is explained in the Terms of Reference document, below. This document is open access and will be distributed widely across the Collaboration.

The Project Board will meet every 4-6 weeks during the project and communicates regularly by email. Basecamp is being used to manage the Project Board's activities.

The services agreement

At the beginning of this year, a services agreement was signed between Metaxis and the Collaboration, which contracts Metaxis to design, build and install the CRS according to the Collaboration's specifications, and to provide technical support of the system for three years after that. Long term user and technical support will need to be considered separately from the development project and it is a likely that a proposal will be presented to the CCSG at the Keystone Colloquium.

The services agreement ensures that the Collaboration retains full intellectual property rights to the CRS: in the agreement it is defined as "*a bespoke, stand-alone, fully-functioning and marketable piece of software wholly owned by The Cochrane Collaboration".*

The agreement is dated from the 1st January 2010 for an eighteen month period, although completion of the project is dependent on the completion of all deliverables. The project Gantt Chart it attached as an annex; **note that it is not open access**. I am pleased to report that Metaxis is progressing well in meeting its first milestones: the database and interface functional designs.

Managing change

At the UK and Ireland Cochrane Contributors' meeting in Cardiff, 2-3 March, a number of events will be held, which will allow Collaboration members to find out how project is proceeding and put forward their ideas about how the new system will work, particularly relating to the database and interface functional designs.

For those not attending the meeting in person, a webcast will be made available on cochrane.org, and we are also planning a live web broadcast. Similar events are planned over the course of the development process, including at the Keystone Colloquium later in the year, to ensure that all the CRS's stakeholders, from all the Collaboration's contributing countries, have ample opportunity to provide input. We also plan to use cochrane.org to keep people updated and to contribute, and we may be one of the first groups to use the new cochrane.org intranet system for this purpose.

In addition, although members of CRS Advisory Group (see below) are not representing any of the Collaboration's constituencies per se, they are important links to these constituencies. Gail Higgins and Sonja Henderson are both members of this group.

Integration with other systems

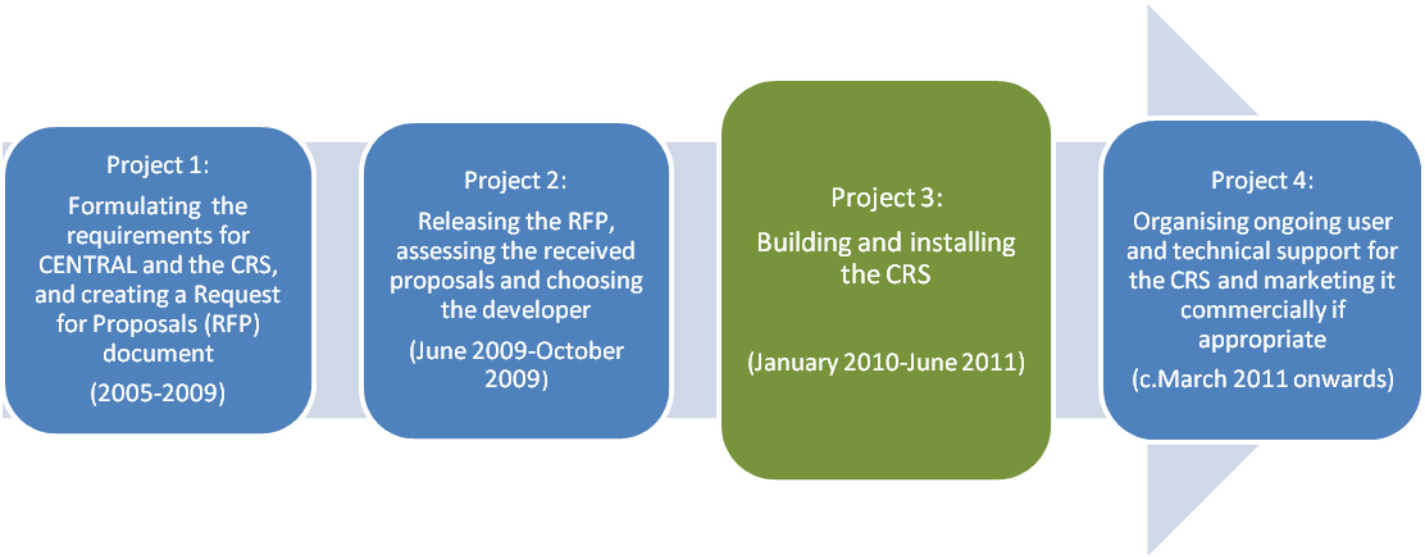
Monica Kjeldstrøm from the Collaboration's IMS Team, and Deborah Pentesco-Gilbert from Wiley-Blackwell, will be working with Project Board to ensure that the CRS is integrated with the Collaboration's existing systems.

Lucie Jones
Business Project Manager for the CRS development project
18th February 2010

Developing the *Cochrane Register of Studies* (CRS)

Building and installing the CRS

TERMS OF REFERENCE DOCUMENT



Rationale for developing the CRS

Following an open competition (Project 2), the Collaboration chose Metaxis Limited as its development partner for the new *Cochrane Register of Studies* (CRS). 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.*

The CRS will represent a change to the existing arrangements for the compilation, aggregation and publication of CENTRAL, which is currently an amalgamation of Cochrane entities' individual SRs and other records, developed and maintained by individual entities using a variety of different proprietary software packages. The CRS is envisaged as a 'meta-register' or central repository for SRs from all Cochrane entities, and will be a way of managing the SRs and other submissions that feed into CENTRAL, which will continue to be published by *The Cochrane Library's* publisher, Wiley-Blackwell.

Instead of being compiled by Wiley-Blackwell from individual files received from groups, CENTRAL will be derived from this meta-register. Within the meta-register, each entity will have access to its own specific record set, i.e. what each entity currently thinks of as its own SR. All Cochrane entities will be required to transfer their existing SRs to the CRS, which will in turn be used to create CENTRAL.

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. 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. 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. Improvement of the experience of those who maintain SRs.

Principal parties

- **Supplier: Metaxis Limited**

Based on its response to the Collaboration's Request for Proposals (RFP), Metaxis will build and install the CRS for the Collaboration, to the satisfaction of the Collaboration, and provide technical support for a period of three years after it has been delivered and accepted by the Collaboration.

- **Client: The Cochrane Collaboration**

The Cochrane Collaboration will purchase the CRS in instalments, based on successful completion of the development phases and associated deliverables. Final payment will be made to Metaxis on delivery and acceptance of the completed product and all component deliverables.

- **Independent technical consultancy: Steve Greenaway**

The Collaboration will obtain technical consultancy from Steve Greenaway as required. It is envisaged that Steve will be particularly involved in testing the 'back end' system deliverables, providing independent quality assurance for the Collaboration.

The product

The CRS will be a bespoke, stand-alone, fully-functioning and marketable piece of software wholly owned by The Cochrane Collaboration and defined in the following sections of the RFP:

Section 3: Summary of business needs
Section 4: Functional requirements
Section 5: Operational requirements

Section 6: Technological requirements

In its response to the RFP, Metaxis outlined how it would build and deliver the product to fulfil the Collaboration's requirements. Additional requirements may be added to the build if deemed necessary by the Project Board.

'Build' and delivery structure

The 'build' and delivery of the CRS will loosely follow the AGILE framework, which advocates a collaborative, phased development process. It will be split into *phases*, each with distinct *deliverables.* The completion and delivery by Metaxis of the phases and deliverables will be mostly, but not necessarily, in chronological order. Each phase and deliverable must be accepted and signed off by the Project Board, on behalf of the Collaboration (see below). Following sign-off, and with approval from the Project Board, deliverables may be amended by Metaxis if subsequent development phases make it necessary and/or sensible to do so: this will require re-approval from the Board. The final phase is the 'roll-out' of the product, that is, its implementation across the Collaboration.

It should be noted that completion and acceptance of all phases and deliverables does not necessarily constitute the completion of the CRS as a whole: the Collaboration will make a final sign-off at the end of the final phase to ensure the product is fully functioning according to its specified requirements and is 'equal to the sum of its parts'.

DELIVERABLE
Phase 1 Design and consultation
1a Database functional design 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.
1b Functional specification for preliminary designs A document outlining the functional requirements of the interfaces. This document will form the basis of the interface designs to implement the functionality.
1c Preliminary Management interface design A document describing all the screens in the management interface, based on the functional specification.
1d Preliminary Web interface design A document describing all the screens in the web interface, based on the functional specification.
2a Consultation A series of consultations (for example email, face-to-face, telephone) and a document outlining the main findings.
2b Final designs 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.
Phase 2 Database implementation
3 Database implementation 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.

Phase 3 MeSH implementation
4 MeSH tables and import routines The MeSH thesaurus SQLServer 2005 database populated with 2009 MeSH data. Routines to import future MeSH thesaurus data from NLM in the current NLM format.
Phase 4 Management routines
5a Import existing data Routines and programs to import existing specialised registers to populate the main database.
5b PubMed lookup Routines to discover PubMed ID and other PubMed data from records in the System not loaded from MEDLINE.
5c MeSH reload Routines and programs to perform the annual MeSH reload, MeSH thesaurus updated to 2010 version using these routines.
Phase 5 Integration with Cochrane data
6 Routines to access legacy Cochrane data Routines and programs to import existing RevMan data to populate the main database and studify the records.
Phase 6 Management Interface
7 Main program Program shell with auto update, look and feel, login and permissions.
8 Upload module Screens and routines for getting records into the System from specialised registers, MEDLINE and EMBASE or direct input.
9 Export module Screens and routines for getting records out of the System as export files.
10 Workflow module Screens and routines for managing workflow of users and records.
11 User testing Beta version of the management interface made available for user testing. User testing report.
12 Finalising and delivery Release version of the management interface made available for acceptance testing.
Phase 7 Web interface
13 Web interface Web interface based on the web interface specification document.
14 User testing Beta version of the web interface made available for user testing. User testing report.
15 Finalising and delivery Release version of the web interface made available for acceptance testing and initial rollout.

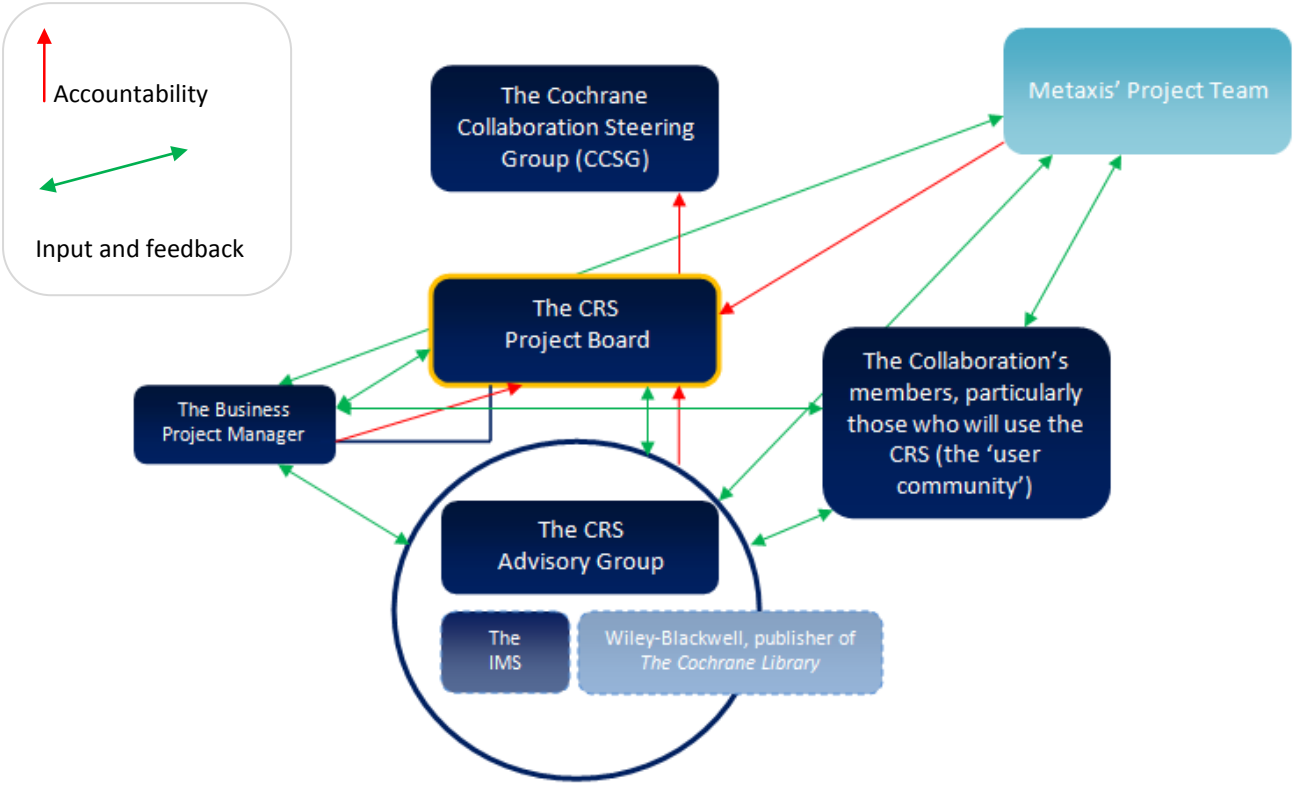
Phase 8 Documentation and training
16 Program documentation Full documentation of all the modules in the project based on the specifications and modified to account for changes made over the development life cycle (database, management interface, web interface).
17 Training resources Help files for the management and web interfaces and an online tutorial on how to use the software.
18 Bug reporting interface Online interface for reporting and tracking software issues and bugs.
Phase 9 Rollout
19 Initial rollout report Report on initial rollout and report of any bugs or issues at the acceptance testing stage prior to final rollout.
20 Final rollout report Report on the final rollout and report of any bugs or issues at the final rollout stage. Project acceptance and sign off.

Product acceptance and quality assurance

Successful completion of phases and associated deliverables will be determined by the CRS Project Board, with support from the CRS Advisory Group (see below) according to the requirements set out in the RFP, and any agreed with Metaxis during the 'build' process. The Collaboration will give formal acceptance with sign-off of each phase, which will require the signature of the Collaboration's CEO (Nick Royle) and *The Cochrane Library's* Editor in Chief (David Tovey) on behalf of the Collaboration, to be countersigned by the Director of Metaxis (Gordon Dooley) as 'read and understood'.
The Collaboration expects the CRS to be delivered to the standard it set out in its RFP.
On completion of the delivery and 'build', and on the basis of continuous operation of 24 hours per day, seven days per week, the CRS must have availability to the end user of at least 99% when averaged over a calendar month period.

The Collaboration's management structure for the 'build' and installation of the CRS*

***Metaxis' project team has its own management structure**



Scope and jurisdiction of the project groups

- **The Collaboration's Steering Group (CCSG)**

The CCSG provides policy and strategy leadership for the Collaboration and has overall responsibility for the development of the CRS. The CCSG will provide no management input to the project, but the Project Board will keep it informed of progress and updates may be requested at any stage.

- **The Project Board**

The Project Board will have day-to-day responsibility for managing the project and will:

- Take all project decisions
- Assess acceptable risk to the Collaboration
- Monitor progress, quality and expenditure
- Accept the deliverables on behalf of the Collaboration
- Control communication to the Collaboration and all other CRS management groups

Membership

- **David Tovey,** Editor in Chief of *The Cochrane Library* and principal client. Has primary responsibility for ensuring the product meets the Collaboration's requirements.

- **Gordon Dooley,** Director of Metaxis and principal supplier. Has primary responsibility for building the product and delivering it to the Collaboration.
- **Nick Royle,** CEO of the Collaboration. Has primary responsibility for managing the business, contractual and budgetary requirements of the project.
- **Ruth Foxlee,** Trials Search Coordinator of the Cochrane Wounds Group and senior end-user for the project. Has oversight responsibility for ensuring the product meets the needs of the Collaboration's end-users.
- **Steve Greenaway,** has responsibility for providing independent technical support to the Collaboration.

The Project Board's management of the project will be loosely based on PRINCE2 methodology.

- **Business Project Manager**
  - **Lucie Jones:** Responsible for managing the project on a day-to-day basis and organising communication between the management groups and the Collaboration. Is directly accountable to the Project Board and is an 'ex officio' member.

- **The Advisory Group**

The Advisory Group will be composed of members of the Collaboration who have the expertise to carry out user acceptance testing of the software delivered and to recommend acceptance of all the deliverables produced during the phases of the project. This will be the primary responsibility of the Advisory Group. Other responsibilities will include:

- Helping the Project Board to manage the expectations of the Collaboration's members – particularly as existing working practices are subjected to change - by collecting feedback and reporting progress to the Collaboration's stakeholders in partnership with the Business Project Manager.
- Helping the Business Project Manager to organise information and training sessions for the Collaboration's members.
- Other responsibilities identified during the course of the project.

Limitations of scope

- The Advisory Group will not be involved in the management of the project.
- Advisory Group members will be representative of the various stakeholders of the CRS and CENTRAL, but will not be representing any constituencies (so, for example, a TSC is not expected to represent the interests of all TSCs).
- Although meetings of the whole Advisory Group may be required at some point during the project, it is more likely that the Project Board and the Business Project Manager will consult members individually to provide expertise on particular aspects of the project.
- Members should not initiate communication on behalf of the Advisory Group, although individuals may collect feedback and report progress to the Collaboration's various stakeholders (see above). The Business Project Manager should be copied into all communication.

Relationship to the Project Board

Members of the Advisory Group will provide advice to the Project Board on request. The Business Project Manager, on behalf of the Project Board, will keep the Group as a whole updated on the progress of the project, who may at times be privy to confidential information, which will be clearly marked as such. The Group will not be expected to attend regular meetings or teleconferences.

Membership

Chair of the Group: David Tovey (Editor in Chief of *The Cochrane Library* and principal client).

- **Carol Lefebvre:** Information Specialist for the UK Cochrane Centre; Convenor of the Cochrane Information Retrieval Methods Group; and significantly involved in drafting the RFP (Project 1).
- **Gail Higgins:** Trials Search Co-ordinator (TSC) representative on the CCSG; TSC for the Cochrane Renal Group; member of the CENTRAL Vision Group (CVG) who prepared a strategic plan for CENTRAL; member of the project team for Project 2; co-ordinator of the CENTRAL production 'interim measures'; and member of the TSC Executive who were significantly involved in drafting the RFP.
- **Roberta 'Bobbi' Scherer:** Associate Director and TSC of the US Cochrane Center (USCC); Methodological Editor and Associate Director of the US satellite of the Cochrane Eyes and Vision Group; assumed responsibility for the Master List of Journals Being Handsearched in 2006, originally developed by the USCC in 1998.
- **Sonja Henderson:** Managing Editor (ME) representative on the CCSG and ME for the Pregnancy and Childbirth Group.
- **Toby Lasserson:** ME of the Cochrane Airways Group and seconded Scientific Editor of *The Cochrane Library*.

Others may be asked to join the Advisory Group during the development project if the Project Board so requires. A member of the Editorial Management Advisory Group (EMAG) will be nominated to join the Group in the near future.

- **Gordon Dooley:** Principal supplier and member of the Project Board.

Gordon will not be involved in recommending acceptance of the deliverables. His role on the Group will be in helping to coordinate user testing and collecting input from the other members of the Group to inform the development process.

- **Other Advisors**
  - **Deborah Pentesco-Gilbert:** Associate Editorial Director of *The Cochrane Library*, Wiley-Blackwell.
  - **Members of the Collaboration's IMS Team:** in particular, Monica Kjeldstrøm, Director of the IMS.