

NIHR IS Programme – Progress Report January 2008

Introduction

The NIHR IS Programme was formally initiated early in 2007. This year has been spent building the Programme in terms of governance, people, projects and systems as well as refining and building upon the papers that we published last January. As I stated previously another key objective has been to unify the information systems work of UKCRN within the NIHR IS Programme where appropriate.

We have made great progress since my last report in June 2007 and there is a great deal of new information that I would like to make available before the end of the year. In this report I will describe what we have been doing over the autumn and our delivery plans for the forthcoming year.

Programme Board

The NIHR IS Programme Board has been established and four board meetings took place between May and November 2007.

The members of the Board are:

Dr Louise Wood	DH RDD - Chair of IS Programme Board
Steve Walker	Programme Director NIHR IS
Marc Taylor	DH RDD representative
Nicola Coe	North Bristol NHS Trust
Colin Bell	NIHR Health Technology Assessment Programme
Dr Mark Middleton	Oncologist, Oxford Radcliffe Hospitals NHS Trust
Dr Katie Petty-Saphon	University Management Representative
Heather Lawrence	Chelsea and Westminster Hospital NHS Foundation Trust – NHS Confederation Representative
Kevin Dean	Cisco Systems
Dr Nick Deaney	Merck Sharp and Dohme Ltd - Health Research Industry Representative
Dr Janet Wisely	National Research Ethics Service
Prof Janet Darbyshire	UKCRN

The Programme Brief and Mandate have been agreed and signed-off by the Board and will be published shortly.

Current Work Programme Priorities

In October 2007 the Programme Team conducted detailed planning workshops with colleagues in the Department of Health Research and Development Directorate and UKCRN. The outcome of these workshops was an agreed list of five urgent priorities for NIHR systems delivery which will be primary objectives for the Programme during 2008. They are:

1. Establishing a robust and fully functional national database of research projects as the first phase of the R&D Management Information System. This will meet the needs of a wide range of users across the whole of UKCRN as well as in the Department of Health and the NIHR. It will subsume the National Research Register (see below) and the current UKCRN Portfolio Database and will be integrated with "external" systems including those supported by NRES;
2. The NIHR CSP System (Coordinated System for gaining NHS Permission) - paying particular attention to integration with NRES Integrated Research Application System (IRAS) and the national database of research projects;
3. The NIHR Portal will be expanded and improved. We will increase the user base, adding innovation and useful functionality, linking to the current NIHR website, adding areas for key stakeholder groups e.g. BRCs, developing the public pages and bringing the Advice Services and Experimental Medicine sites into the portal. We will work with partner organizations including the British Library to create new functionality and ensure that systems are "joined up";
4. The NIHR IS team will work very closely with the National Research Ethics Service to ensure that existing and future developments (including IRAS) are fully integrated in order to achieve a key "busting bureaucracy" objective of "Best Research for Best Health";
5. Developing secure national applications to enable the management of information relating to people working in research. The first phase of this will be the creation of the NIHR Faculty database and this work has already been started by the NHS Service Delivery and Organisation Research and Development Programme. During 2008 this database will be migrated to new systems that will be implemented by the NIHR IS Programme. A clear objective will be to ensure that, from a user's point of view, logging in to systems is straightforward and ideally this is done once i.e. single sign-on. The NIHR Programme will be working closely with the National Programme for IT and the academic community on this project.

Further information about how these priorities will be addressed appears later in this report.

The Enterprise Architecture and Data Standards

On 01 October 2007 we published the first draft version of the NIHR Enterprise Architecture (EA) on the NIHR website¹. This document, which will continue to be refined during 2008, describes how the business requirements and information systems will be aligned so as to achieve the goals of NIHR as described in "Best Research for Best Health". It provides a blueprint for the design of information systems to support the management of health research in the NHS in England.

In parallel with the EA we are just completing the first iteration of the proposed NIHR IS Data Dictionary which we intend to publish shortly for consultation. The first iteration will focus on core UKCRN and NRES issues.

Market Research

In October and November 2007 we conducted an intensive period of consultancy with the systems supplier community including those involved in the development and support of open source software (OSS). To initiate this work we published a high level user requirement for NIHR systems on the NIHR website and issued an OJEU Prior Information Notice (PIN). A large number of "suppliers" responded and over 50 individual meetings took place. This was an intelligence gathering exercise not the start of a procurement process. The objectives of the meetings included:

- To explain and discuss the objectives of the NIHR IS Programme;
- To receive feedback from the supplier community about the strategy and requirements that we are developing for the Programme;
- To understand better the supplier market and the products that may be available.

Outcomes included the further revision of the user requirement and the enterprise architecture documents. A paper summarizing conclusions and general points is now being finalized and will be made available shortly.

The R&D Management Information System

Whilst we focus on the five immediate priorities that I have described above, we will not lose sight of need to implement national systems that will integrate the various processes and systems that are involved in the life cycle of R&D projects. We refer to this vision of integrated systems as the R&D Management Information System (R&DMIS) and it remains the highest medium/long term objective of this Programme. The development of the national database of research projects, the people database, the work with NRES and the NIHR Portal are all building blocks of the R&DMIS. The work that we are doing with the BRC's will also inform how the R&DMIS develops. It is unlikely that

¹ www.nihr.ac.uk/systems_research_information_systems_ent_arch.aspx

the R&DMIS will ever be a single system; rather it will consist of national infrastructure applications (and the standards that support them) which enable a number of systems to interoperate.

We are currently completing the next version of the R&DMIS User Requirement Specification (URS) which takes into account everything that we have learned since the last version and which has significantly greater functional scope and detail than previous versions. Following internal review we intend to publish the new URS for consultation shortly.

Business Analysis and Process Definition

Working initially with colleagues in the Department of Health and UKCRN we have now begun to develop detailed formal process maps which will describe the business activities that NIHR Information Systems are required to support. These will underpin the Enterprise Architecture and the R&DMIS URS. We intend to concentrate initially on describing the overall process at a high level before drilling down into specific functional areas. It is likely that the process maps and associated documents will be published for consultation when they have completed internal sign-off.

NIHR Coordinated System for gaining NHS Permission (NIHR CSP)

The Government's health research strategy, "Best Research for Best Health" (BRfBH), launched in January 2006, described the provision of information systems that will help 'bust bureaucracy' associated with the set up and governance of clinical research. One of the changes in business processes made in support of BRfBH is the introduction of a unit to coordinate the gaining of NHS permission (CSP) to undertake trials and other studies. This unit will ensure that trials requiring NHS service support will follow a single, uniform, sign-off process which will be accepted as definitive by all interested parties.

CSP will "Ensure that research projects are approved quickly through a streamlined process that introduces no additional checks but which addresses all the quality assurance and statutory requirements."

CSP will therefore be a critically important part of the lifecycle of most trials, and must be supported by appropriate information systems which integrated within the NIHR systems architecture. To this end the NIHR IS Programme, in partnership with the CSP team working in UKCRN, initiated a phased project as follows:

Phase 0 was intended to determine the information requirements and business processes of C SP as well as to develop actual systems. It was successfully delivered, on time and in budget, by 13th December 2007. It has produced a working system developed by NPNB Ltd to the specification of the CSP and NIHR IS teams. This system has now completed all testing and been signed-off. It

provides a platform for further development (including live use) and has been fundamental in understanding and documenting requirements.

Phase 1 will be initiated early in the New Year (2008) and should be completed by early April 2008. This phase will build on phase 0 further defining requirements and implementing the robust web-based systems that integrate the CSP work flow with other key developments including the NRES IRAS system.

NIHR Portal

The NIHR Portal was launched in 2007 with a private collaborative site for the Primary Care Research Network in June and public pages accessed via the current NIHR website available in November. Currently the Portal has over 200 active users with representatives in the majority of the Topic-specific Clinical Research Networks, the Departments of Health in England and Northern Ireland, the NIHR Programme and ACTRIS (Academic Clinical Trials Research Information Systems), using Portal sites tailored to their organisational and individual needs. The Portal is also trialling the support of clinical studies through collaborative sites and options for public/patient involvement and data capture.

The Portal is an installation of Microsoft Office SharePoint Server 2007 and is intended to be the primary gateway and platform for all appropriate NIHR systems and services in the future. It requires no software installation and needs only an Internet browser, a connection and logon credentials. It offers a unique way for geographically-spread and diversely employed teams to collaborate and communicate.

In 2008 the NIHR Portal will continue to build on the foundations laid down this year by:

- Supporting the Topic-specific Clinical Research Networks and their Local Research Networks
- Developing connectivity with other NIHR and UKCRN systems such as the Portfolio Management System
- Assisting with the creation and management of new initiatives such as the Comprehensive Clinical Research Networks, Faculty and the Biomedical Research Centres.
- Developing new and innovative functionality to support researchers and research managers and the NIHR Faculty

The public face of the Portal will also develop with links, content and resources for members of the public and researchers alike.

Biomedical Research Centres (BRCs)

The NIHR IS Programme is working closely with all the Biomedical Research Centres to document systems requirements and implement common electronic data capture and management systems. As part of this an evaluation project is planned for early 2008.

This will primarily evaluate three open source applications against the user requirements specification that was developed in the second half of 2007. Users in the BRCs will lead the evaluation of the applications and they will focus on functionality and usability. The NIHR IS Programme Team will lead on issues including scalability, technical platforms, standards compliance (including compliance with the NIHR Enterprise Architecture and Data Dictionary). As a secondary consideration the evaluation will look at other elements, such as study management, planning approvals and administration. The applications chosen have been selected following an extensive market research activity.

The evaluation will be undertaken by both the Comprehensive and Specialist Biomedical Research Centres. They will use a mock protocol and dummy data to replicate a real study. The evaluation will be based on agreed technical and user experience criteria and will take place during early 2008. The results and recommendations from the evaluation will be used to inform the future developments of information systems for both the Biomedical Research Units and the National Institute for Health Research.

Following the completion of the evaluation phase a formal project board will be established to oversee the implementation and long-term management of the successful application.

The National Research Register

I am pleased to report that on 21 December 2007 – on schedule – the NRR Archive went live on the NIHR Portal at <https://portal.nihr.ac.uk/Pages/NRRArchiveSearch.aspx> . This enables users to search records from the previous NRR database covering Regional and National Research Programmes and Research Centres.

In addition – and again on schedule – new functionality has been added to the UKCRN Portfolio to take into account the closure of the NRR. This is also viewable and searchable on the NIHR Portal at <https://portal.nihr.ac.uk/Pages/Portfolio.aspx>

Data Capture and Clinical Trials Units

During the latter part of 2007 my team and I have had various discussions with people asking if clinical data capture systems are in-scope for the NIHR IS Programme. Earlier in the year Professor Davies confirmed that in due course we should develop a high-level “business case” to assess if there would be benefit in taking action at a national level with respect to these systems.

While this has not been a priority for the Programme so far I have met with people from trials units and the ACTRIS² Group and the leader of the ECRIN³ project in order to understand the issues and priorities. It is clear that there is a range of opinion about the need for or benefits of a national approach with some strongly in favour and others not quite so enthusiastic. However there is general agreement that early work on data and integration standards would be useful. There is also a recognition that some of the management data required to populate the R&DMIS must originate from “clinical” systems and therefore making this interface simple, secure and common will be important.

We will be addressing some aspects of clinical data management as part of the work that we are doing with the BRCs (see above) and this will lead to more formal requirements definition. We will also ensure that the future iterations of the data dictionary cover these aspects. Finally we will work with the UKCRN Clinical Trials Unit team on the development of the business case.

UKCRN Information Systems Developments

The UKCRN IS team has delivered a number of new application developments in 2007 as well as continuing to support the Portfolio Database. These include:

- Industry Tracking System
- Advice Services Website
- Experimental Medicine Website – to be released early in 2008
- The NIHR Portal
- The NRR Archive

In the forthcoming year the UKCRN IS team will be strengthened and expanded to provide the “in-house” development capability that is required by the NIHR IS Programme. This will enable us to work more closely and effectively with the Research Networks, to develop rapid prototypes/proofs of concept and to build robust infrastructure that will meet the needs of the diverse and distributed research management community. New governance arrangements will be established to oversee this programme of activity. The existing team, which has been focused mainly on system development, will be complemented with new teams dealing with service and user support, infrastructure, quality management and information management.

The NIHR IS Programme Team

² Academic Clinical Trials Research Information Systems Group

³ European Clinical Research Infrastructures Network

The following table describes the current members of the combined NIHR and UKCRN IS teams and their roles:

Name	Role	Work Area	Base
Bates, John	Web Developer	UKCRN Systems	UKCRN, Leeds
Charvill, Jim	Database Manager	UKCRN Systems	UKCRN, Leeds
Childerhouse, Andy	NIHR IS Programme Manager		NIHR, Macclesfield
Davies, Adam	Database Developer	UKCRN Systems	UKCRN, Leeds
Eary, John	Business Analyst	Portfolio Management	NIHR, Macclesfield
Farr, Richard	Project Manager	Biomedical Research Centres and Communications	UKCRN, Leeds
Grogan, Duncan	Systems Administrator	UKCRN Systems	UKCRN, Leeds
Hannan, Noel	Project Manager	NIHR Portal	NIHR, Macclesfield
Hobbs, Jonathan	Web Developer	UKCRN Systems	UKCRN, Leeds
Johnston, Carl	Systems Administrator	UKCRN Systems	UKCRN, Leeds
Lord, Alastair (p/t)	Procurement		NIHR, Macclesfield
Massey, Jacqueline	PA and Programme Administrator		NIHR, Macclesfield
Matthews, Peter	Web Developer	UKCRN Systems	UKCRN, Leeds
McTaggart, Bill	Business Analyst	R&DMIS	NIHR, Macclesfield
Offless, Laura	Office Support (temp)		NIHR, Macclesfield
Rajander, Anna	Business Analyst	Requirements Analysis	UKCRN, Leeds
Rana, Sarwar	Web Developer	UKCRN Systems	UKCRN, Leeds
Schlaepfer, Ben (p/t)	Sharepoint Support	NIHR Portal	London
Smith, Janis	UKCRN Assistant Director (IS)		UKCRN, Leeds
Squire, Jenni	Business Analyst	Process definition and market research	UKCRN, Leeds
Thompson, Michael	Business Analyst	UKCRN Systems	UKCRN, Leeds
Toth, Ben	Enterprise Architect		NIHR, Macclesfield
Trout, Catherine	Project Manager	Portfolio Management	UKCRN, Leeds
Truman, Laurence	Development Team Leader	Portfolio Database	UKCRN, Leeds
Walker, Steve	NIHR IS Programme Director UKCRN Deputy Director (IS)		NIHR, Macclesfield

Welsh, Ben	Project Manager	People Project	NIHR, Macclesfield
Zammit, Mike	Project Manager	CSP	NIHR, Macclesfield

Programme Offices

The NIHR/UKCRN IS Programme currently operates from two bases; the UKCRN Coordinating Centre, 15-19 Hyde Terrace, Leeds, LS2 9LT (01133 432314) and Beechfield House, Winterton Way, Macclesfield, Cheshire, SK11 0LP (01625 509126).

Steve Walker
NIHR - IS Programme Director
UKCRN - Deputy Director (Information Systems)
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