



*National Institute for
Health Research*

NIHR Information Systems Programme

National Research and Development Management Information System - Discussion Paper

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Amendment History

Version	Date Issued	Brief Summary of Change	Owner's Name/Signature
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Approvals

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Distribution

Version	Name	Organisation
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This is an NIHR controlled document. The procedures described in this document are a mandatory requirement and form part of the NIHR Quality System. Amendments are only permitted via the document change procedure defined in NIHR4.2.QP001. On receipt of a new version, please destroy all previous versions (unless a specified earlier version is in use throughout the project).

1 Executive Summary

The Government's "Best Research for Best Health" (BRfBH) initiative, launched in January 2006, describes the provision of information systems that will help 'bust bureaucracy' associated with the set up and governance of clinical research. This is described in more detail in the Department of Health's Implementation Plan 4.2¹.

The proposed "**R&D Management Information System**" (R&DMIS) that is described in this paper is a secure web-based application that will be delivered by the NIHR² Information Systems programme to act as a "one stop shop" for all those concerned with the commissioning, governance and management of clinical research in the NHS, academia and industry.

The R&DMIS will be a key application in a national systems architecture that is intended to help streamline processes, enable easy and secure access to information and contribute to the busting of bureaucracy. However it is recognised that more efficient management of the overall study life-cycle can only be achieved through fundamental changes in processes and behaviours rather than by new information systems alone.

The first phase of the R&DMIS is required to be in place in April 2008. However infrastructure will be established in 2007 and further developments will be introduced after phase one so that the application is enriched and refined as requirements evolve. It is intended that once all phases are complete, the R&DMIS will offer a world-class set of tools that will manage the entire lifecycle of research projects and will significantly contribute to making the UK an efficient and attractive place to conduct high quality clinical research. It will interact with a number of "external" applications including R&D commissioning systems, approvals systems and the UKCRN Portfolio Database as well as local systems.

When the UKCRN has developed the related operating procedures, the R&DMIS will support the coordinated operation of the research networks under the UKCRN. It will offer ready access to information about:

- local NHS resources available to support new research proposed for adoption by the UKCRN, so that the UKCRN networks can place them successfully;
- readiness of particular NHS sites to conduct specific studies, enabling the UKCRN networks to complete site assessments for ethics committee review;
- review, authorisation, and other types of approval or permission required before an individual study can receive the single sign-off by which the UKCRN will streamline local NHS permission for research; and
- individual researchers in the NIHR Faculty, to facilitate the operation of the Research Passport and other measures enabling collaboration among universities and the NHS members of the UKCRN networks.

The NIHR IS team will also deliver the **NIHR Portal**³, which will be launched before the R&DMIS, and provide a single gateway to applications (including the R&DMIS), information and knowledge bases for the broad community of NIHR stakeholders for example:

¹ <http://www.nihr.ac.uk/publications.aspx>

² <http://www.nihr.ac.uk>

³ http://www.nihr.ac.uk/systems_research_information_systems.aspx

- Researchers;
- People involved in the monitoring of adopted R&D projects especially those in UKCRN;
- Department of Health managers;
- The NIHR Faculty.

The NIHR portal is described in detail in documents that have been published at www.nihr.ac.uk

The national systems architecture that is described in this paper is totally dependent on agreed standards of data definition and exchange and will require key stakeholders to identify, agree and implement common data sets and data interchange formats. This work is currently being undertaken as part of a data standards project in the NIHR IS team and the R&DMIS will be based on these emerging data standards. The development of secure APIs to exchange data between different systems will also be an essential element of the R&DMIS.

The R&DMIS will have broad scope in terms of types of clinical research. It is intended that it will be used for any clinical research project involving human subjects, their tissues and/or data. This will include DH/UKCRN-funded studies as well as pharmaceutical company-sponsored research. It is being developed to meet specific requirements of research carried out in England however we intend that systems architectures will be generic to enable broader collaboration in due course. Discussions are taking place with representatives from the other UK countries.

Implementation of the R&DMIS will be undertaken in a phased manner over a period of years with Phase 1 delivering critical functionality in April 2008 in line with Department of Health targets.

2 Purpose of This Document

This document describes:

- The need for a national R&DMIS ;
- What we expect the R&DMIS to provide for a wide range of users;
- How and when the NIHR IS programme team is intending to deliver the R&DMIS.

It has been developed following an extended period of consultation with a large group of stakeholders from the NHS, Department of Health, academia and industry. It is likely that there will be further iterations of this document over the next few months and these will be published via www.nihr.ac.uk .

The intention of publishing this document is to encourage discussion and engage stakeholders in the definition of a detailed “user requirements specification”. At this stage there is significant scope for refining plans and priorities and the programme is keen to ensure that the ultimate users of the R&DMIS help to ensure that it:

- Is fit for purpose;
- Meets their requirements;
- Is easy to use;

- Has a community of users who are able and willing to use the system.

This is version 1.0 of the R&DMIS Discussion Paper. It is likely that there will be further versions of this paper as our understanding of the requirement evolves and that initially there might be quite rapid iterations. In due course an R&DMIS User Requirement Specification (URS) will be produced before final decisions are taken on implementation which must begin mid-2007. It is our intention to consult with a wide range of stakeholders during the early part of 2007 and to provide every opportunity for those stakeholders to contribute to the specification of the systems described in this document.

3 Introduction

In January 2006, the Government published 'Best Research for Best Health' (BRfBH), a paper that summarises how the Government intends to make the UK the best place in the world for health research, development and innovation.

Implementation of this strategy is described in a set of implementation plans, classified into six categories. Each implementation plan sets out the aim of the proposal, who will be involved, how it will be funded, and the timetable for implementation.

- 1. The National Institute for Health Research**
 - Implementation Plan 1.1 The National Institute for Health Research (NIHR)
- 2. Transition**
 - Implementation Plan 2.1 Funding transition
- 3. National Institute for Health Research Faculty**
 - Implementation Plan 3.1 National Institute for Health Research Faculty
- 4. Research Systems and Governance**
 - Implementation Plan 4.1 Bureaucracy busting: Governance, advice and ethics systems
 - Implementation Plan 4.2 Bureaucracy busting: Research information systems
 - NIHR Information Systems Portal User Requirements Specification
 - NIHR Information Systems High-Level User Requirements Specification
- 5. NHS Research Infrastructure**
 - Implementation Plan 5.1 Clinical Research Network for England
 - Implementation Plan 5.1a Comprehensive NHS Research Network
 - Implementation Plan 5.2 Clinical research facilities for experimental medicine
 - Implementation Plan 5.3 Technology platforms
 - Implementation Plan 5.4 NIHR School for Primary Care Research
- 6. NIHR Projects, Programmes, Units and Centres**
 - Implementation Plan 6.1 Overview of NIHR research projects, programmes, units and centres
 - Implementation Plan 6.2 Research for Patient Benefit (RfPB) and Research for Innovation, Speculation and Creativity (RISC) project schemes
 - Implementation Plan 6.3 Existing R&D programmes
 - Implementation Plan 6.4 Invention for Innovation Programme
 - Implementation Plan 6.5 Programme grants for applied research
 - Implementation Plan 6.6 Research units
 - Implementation Plan 6.7 Research Centres

The information systems developments discussed in this paper are being delivered as part of **implementation plan 4.2** which has the objective to create, with partners, an integrated set of national systems for health research and research management that will:

- Unify and simplify the administrative procedures associated with regulation, governance, reporting and research administration;
- Enable procedures and input of data to occur once and once only;
- Make information supporting regulatory approvals and permissions available via secure systems and processes to everyone who needs to act on it;

The NIHR IS Programme will:

- Develop an information management and systems infrastructure; the R&D Management Information System;
- Offer access to information services via a national portal
- Work with all the relevant bodies to define data standards and processes

The ultimate aim of the R&DMIS and portal is to provide a set of tools that will allow the efficient management of the whole life cycle of clinical research projects.

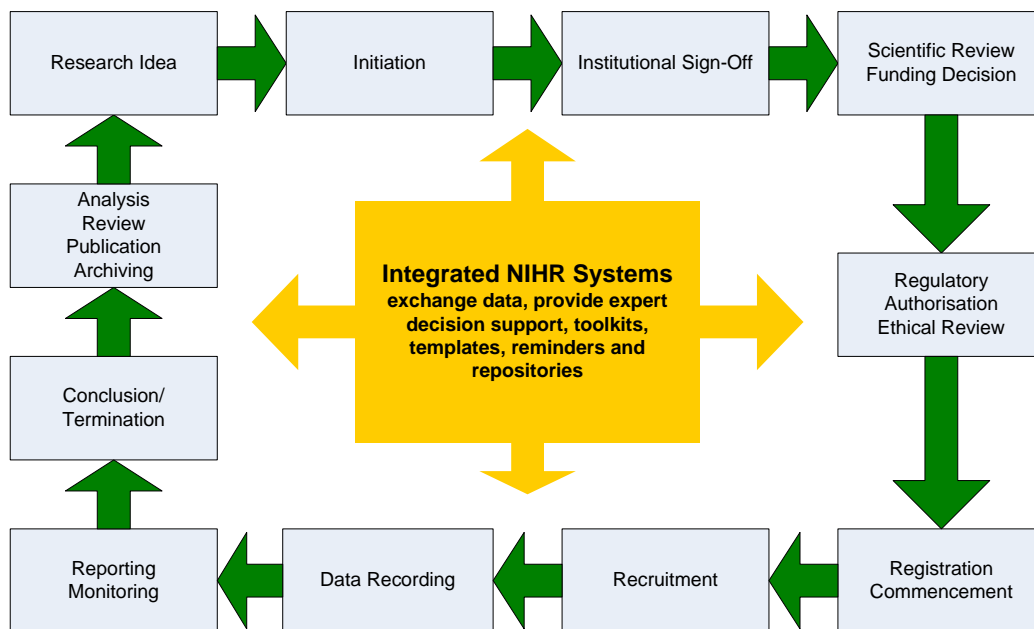


Figure 1 - R&D Life Cycle

The approvals processes for clinical research in the UK have grown up over a long period of time in a rather uncoordinated way. This has given rise to a proliferation of information systems that have been developed to meet specific national and local requirements but which:

- Have neither an overarching systems architecture nor an underpinning set of data standards. This means that systems cannot “talk to each other”;
- Force people involved in the various aspects of the life cycle to access and input information into multiple systems;
- Have resulted in poor quality information;

- Do not enable an easy or accurate view of the current state of research and research projects at either a national or local level;
- Do not enable an easy or accurate view of the NHS capacity available for new research projects at either a national or a local level, hindering the placement of high priority studies at the sites where they are most likely to succeed;
- Do not enable swift or reliable access to information about the contractual status of researchers or whether they have completed the checks appropriate to the type of research they conduct in the NHS;
- Mean that significant time and effort is consumed in the processes associated with approval, permission, monitoring and management rather than in research.

Recently-enacted legal obligations particularly the EU Clinical Trials Directive⁴ have made the situation more complex. There is widespread confusion amongst the research community about the approval and governance requirements for various types of clinical research.

For example: an inexperienced junior researcher wishes to give a group of healthy volunteers a food supplement, and another group a placebo. She wishes to take blood samples from the patients for genetic analysis and collect follow up data on the volunteers from their clinical notes.

While this might appear a straightforward example there is currently no single place that the researcher can go to on the web to access definitive guidance on the approvals that they need and how they go about getting them. This is having at least three direct effects:

- The process of setting up and conducting research is confusing, painfully slow and bureaucratic;
- There is less clinical research being pursued because it's 'too much hassle' to initiate, and too difficult to contact sources of help in doing it well;
- Some company-sponsored research has been leaving the UK because the NHS R&D "management" environment is perceived to be slow, inconsistent, and not cost effective compared with some other countries.

Addressing these issues is a primary aim of "Best Research for Best Health". Work Programme 4.1 is focussed on governance, advice and ethics systems and procedures. Work Programme 4.2 will deliver the integrated information systems – specifically the NIHR Portal and the national R&DMIS - that will underpin this activity.

⁴ http://www.wctn.org.uk/downloads/EU_Directive/Directive.pdf

4 Benefits

One of the goals of “Best Research for Best Health” is to manage our knowledge resources. A specific objective is to use information systems to harmonise and simplify the research process for the benefit of the people and organisations involved in that process. It sets out plans for a series of bureaucracy-busting measures. These include unifying and simplifying the administrative procedures associated with regulation, governance, reporting and NHS research administration, ensuring that procedures and data are, wherever possible undertaken once for multiple purposes.

For the long term, the test of successful investment in NIHR information systems and services will be measurable improvements in process and outcome across the work of the NIHR. There are many areas where high quality information services and integrated systems could enable benefits measurable in terms of quality, speed, transparency or efficiency.

Consultation with the R&D community earlier in 2006 resulted in a long list of benefits that they would expect to be delivered by NIHR Information Systems in general and the R&DMIS in particular. These include:

- Single point to access and input information;
- Transparent work flow processes managed and reported via a single application;
- Use of common languages and data standards to reduce local variability and enable sharing of data;
- Reduced timescales from initiation to approval;
- Lower process costs;
- Lower recruitment costs;
- Unfruitful ideas rejected earlier;
- More appropriate recruitment;
- Appropriate and consistent consent;
- Adverse events identified, recorded, analyzed;
- Better risk assessment;
- Better risk management;
- Access to:
 - expert advice;
 - decision support;
 - complete, relevant information;
 - evidence of robust process;
- Opportunities to people to volunteer to participate;
- Access to standard information on
 - study design;
 - research costs;
 - NHS costs;
 - Risks;
 - research team’s skills;
 - feasibility of recruitment;
 - funding decisions;
 - progress reporting;
 - performance;
 - outcomes of review;
 - Standardised costing improving consistency.

5 Overall Systems Architecture

The R&DMIS will be closely coupled with the NIHR Portal and may be developed as an integral part of the portal rather than as a single, separately identifiable application. The following diagram is intended to give a high-level illustration of one way in which this might be implemented:

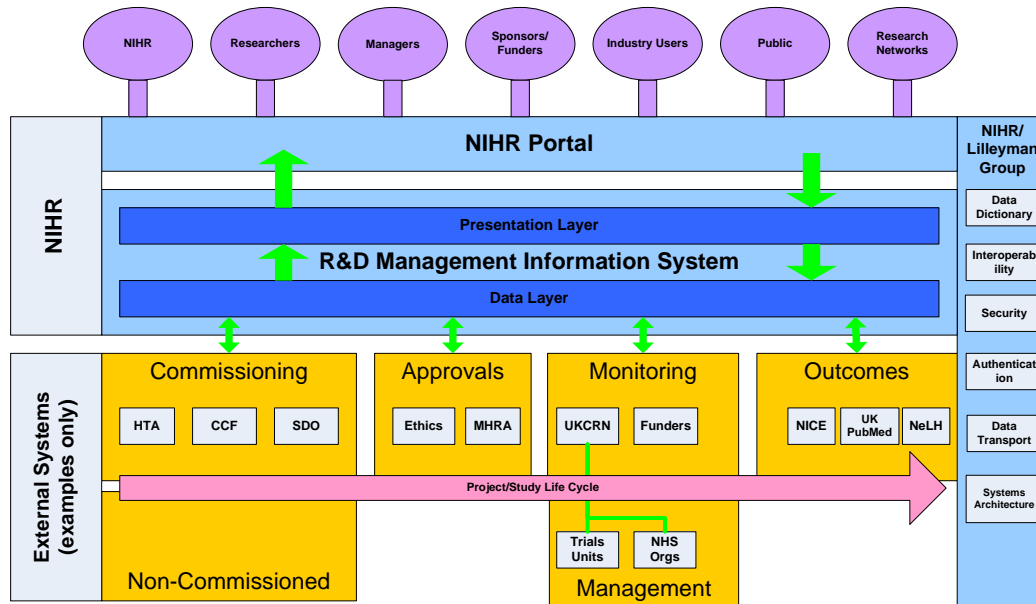


Figure 2 – High Level Systems Architecture

The diagram shows that there is a clear distinction between the systems that will be delivered and managed by the NIHR IS Programme and those that have been classified as “external”. The objective is not to replace existing systems where these are working efficiently and effectively but rather to implement national systems layers that:

- Provide secure access via a single portal;
- Provide new functionality that is required at a national level;
- Ensure that wherever possible data is input once and once only and used for other appropriate purposes in accordance with agreed protocols.
- Ensure that there are no barriers to the exchange of information with external systems, wherever the data controllers give permission for it.

Interfaces to “external” systems are described in Section 10 and will be the subject of more detailed papers which will be produced following discussions with the owners of those systems. There are a number of ways in which these interfaces can be achieved and critical issues that will be taken into consideration will include:

- Absolute need to preserve security and integrity of source and destination systems;

- Types of data involved and requirement to define and preserve confidentiality where appropriate;
- Frequency of data flows;
- Need for owners of source data to retain ownership of information provided from that source;
- Robust audit trails;
- Monitoring and management of data quality.

The R&DMIS will need to communicate at a minimum with a number of systems used by organisations responsible for the various kinds of review, authorisation or permission required before a research study can start.. Further definition of these is contained in Section 8.2.

Initially this communication is likely to take the form of the secure messaging of agreed data items/indicators/reports from the external systems to NIHR i.e. one way transmissions. Eventually it is intended that, following the development of detailed agreements on data and interface standards, this will be more interactive and, where appropriate, based on newly-developed, secure Application Programming Interfaces (APIs).

Figure 2 above shows the R&DMIS as consisting of a data (warehouse) layer and a presentation layer. Over time an application layer will be added to provide specific new functionality e.g. costing module. The objective will be to:

- Increase efficiency by providing access to standard tools to support the NIHR faculty;
- Standardise and improve access to expert advice, web-based tools and decision support; and
- Raise quality by embedding aspects of good practice through well-structured and well-signposted access to toolkits and templates.

Examples of information products and services provided could include:

- A costing module;
- A risk assessment tool kit;
- A risk management tool kit;
- A network of repositories for archiving research data and findings from completed studies.

6 Data Standards

The NIHR IS Programme has already begun a piece of work to understand areas where the development of core data standards is critical to the success of the integrated systems described in this paper. It has already confirmed that there is a wide divergence in approaches to structured coding and the use of free text and that this applies across all organisations and at all levels from project/study identifiers to organisational coding, identification of investigators and classification of research.

The NIHR IS Programme will publish the results of this work shortly and will then work through UKCRC, the Department of Health and a group currently chaired by Professor Sir John Lilleyman to develop core common data sets and implementation guidance.

The Programme will also work with existing system suppliers to confirm how these data standards will be implemented in systems. The intention will be to implement the standards within systems wherever possible rather than developing translation functionality within national systems.

Full account will be taken of the need to comply with appropriate international standards, including those yet to be generally adopted such as WHO standards for trial registration.

7 Implementation Approach - Priorities Driving Implementation

The first priority will be to deliver measurable benefits for NIHR faculty and those with whom they exchange information, through unified information services that harmonise and simplify research processes and deliver consistent, relevant, high-quality advice to NIHR faculty members.

The second priority will be to deliver a range of web-based tools and services that support NIHR faculty members in designing and conducting R&D to high standards, and in navigating ethical and regulatory processes confidently and securely.

The third priority will be to unify standard information systems and services that support NIHR faculty and partners throughout the health R&D cycle, delivering measurable improvements in knowledge management and in access to integrated, timely, relevant, quality-assured information to support decision-making.

In order to offer early benefits, the NIHR will not keep rigidly to these priorities. It may adopt standard data sets, applications and services in a different sequence if they are readily available, affordable and highly valued by NIHR faculty. Throughout this process, the development of NIHR systems will focus on the needs of the NIHR faculty while seeking opportunities to encourage convergence and integration between the systems of the NIHR and its partners.

8 User Requirements

This Section describes the functions that the R&DMIS is required to provide. These are based on an analysis of requirements gathered through meetings, workshops and discussions with a wide selection of different users.

The functionality is based mainly around the life-cycle of a clinical trial and how the management of such trials can be made more effective and efficient. Some more general requirements that are not directly trial related are covered at the end of this section.

8.1 Research Approval Wizard

8.1.1 Background

The wizard will perform the same type of function as a Microsoft Office 'wizard', which typically guide a user through a set of sequential processes, involving a number of key decisions. In this case the Research Application Wizard will guide an applicant who is seeking approval(s) for research projects through a series of questions and, based on answers to those questions, will:

- Indicate to the user which approvals are required;
- Present the user with the appropriate data fields to be completed.

To illustrate the type of functionality required, the following might form part of the wizard dialogue:

- | | |
|--|--------|
| • Does your research involve healthy volunteers? | Yes/No |
| • Does the project involve human tissues? | Yes/No |
| • Does the research involve data that could directly identify a patient? | Yes/No |
| • Is a therapeutic intervention involved? | Yes/No |
| • Is a medical device involved? | Yes/No |

On completing the wizard dialogue, the user might be presented with an output such as:

From the answers you have provided, your research project requires the following approvals:

- A Clinical Trial Authorisation (CTA) from the MHRA. More...
- An application to an ethics committee. More...
- NHS permission through your local R&D office More...
- You do **not** need approvals from the following organisations:
- Patient Information Advisory Group (PIAG) More...
- Human Tissue Authority More...

*If you have any queries please call the NIHR advice line on 08123 456 7890
Proceed to application forms? Go...*

The above content is for illustration only and is not intended to be comprehensive. A summary of the current legislative requirements for various research approvals is provided in Section 19.

During the life span of the R&DMIS these approval methods, and the underpinning data sets, are likely to be revised and the Research Approval Wizard must be designed so that it is possible to change the logic of the dialogue displayed to match the current legislation and approval process.

A useful guide on current processes for clinical research is available on the MRC Clinical Trials Toolkit website⁵ and this will be the starting point for the processes to be developed for the R&DMIS. The figure below is taken from the guide and illustrates the scope that the wizard will cover.

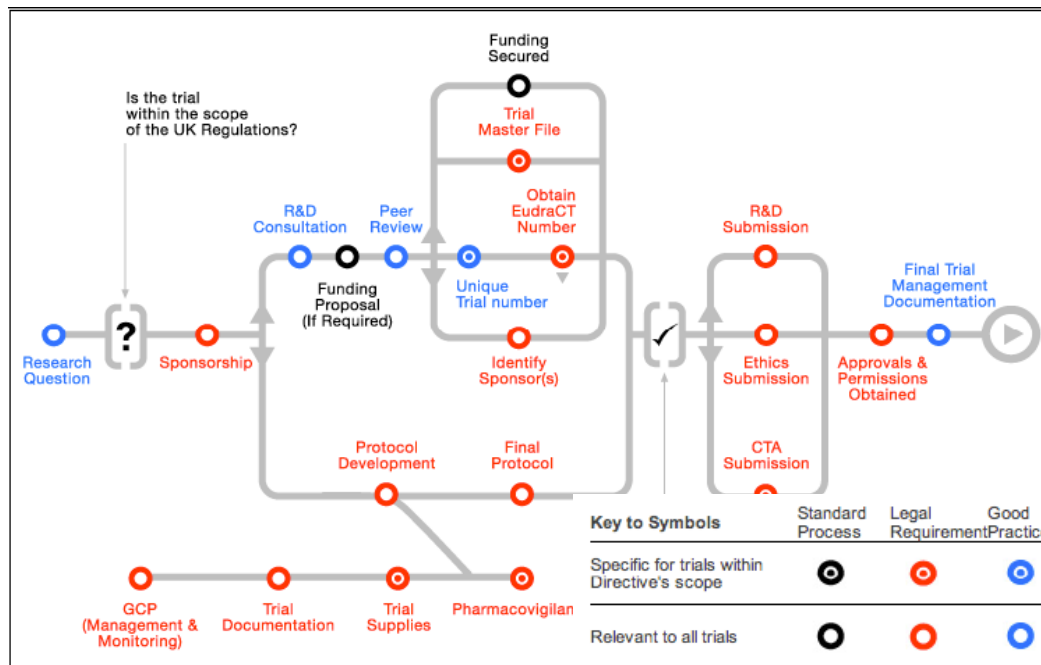


Figure 3 – MRC - Planning a new trial

8.1.2 Detailed Requirements

The Research Approval Wizard will:

- Provide a user-friendly introduction for the non-technical user and explain how the wizard works.
- Provide a button in the portal to take the user into the wizard.
- Present a series of questions, asking the user about the type of project they are planning.
- Based on answers to these questions, and the new harmonised processes being developed, inform the user which elements of approval are required. The logic that underpins this function must be easily changed to match the current regulatory framework.
- Provide links to the regulatory organisation's web sites and a 'more...' link to explain why a particular regulatory review, authorisation or permission is or is not required. These 'more' links will provide an intelligent and reasoned answer to the user's project intentions. These explanatory links

⁵<http://www.ct-toolkit.ac.uk>

must be updateable in the same way as the underlying logic, so that they reflect current practice.

- Store data from user enquiries so that reports on what types of projects people are enquiring about and the guidance provided by the system can be generated. A unique identifier should be associated with each completed wizard episode so that when the same user comes back into the system during a new session they do not have to re-answer all the questions.
- Allow partially completed wizard enquiries to be saved. This will allow users to partially complete the wizard, realise that they need more information to complete the next question and return to that precise position in the dialogue at a later time when they have the required information.
- Provide a listing of the user's previous enquiries so that they can pick up any previous query where they left off, or edit a stored query to correct an error.
- Lead the user, if he/she wishes at this stage, through to the data fields identified during the wizard process for completion of the required questions in the relevant approval forms.
- Point users to the National Advice Service⁶ for further guidance on regulatory issues if necessary.
- At the end of the wizard process, present the user with a summary of the data that they have put into the system and ask them to check its accuracy.
- Following completion of all the questions, and the accuracy check, indicate to the user which authorisations, approvals and permissions from which organisations are required.
- Ask the user if they wish to proceed to start the relevant set of applications. If so, lead them into the next area of functionality (the application process).
- Keep an audit trail. The Research Approval Wizard must store each completed wizard session together with the version number of the underlying logic that was in place at the time of completion, so that it is possible to demonstrate that the wizard gave the correct advice to the user at the time the wizard was used. This record will form part of the trial audit trail.

⁶ http://www.ukcrn.org.uk/index/clinical/regulatory/advice_service.html

8.2 Research Approval Data Entry

8.2.1 Background

The Research Approval Data Entry function will provide a single point of entry for NIHR faculty members to make research regulatory applications (and amendments). It will eventually provide a unified interface with the information systems of all the bodies concerned with health research regulation and ethics. In the first instance, it will provide an interface with the bodies which have harmonised their information requirements in collaboration with the Central Office for Research Ethics Committees.

The authorisations and approvals that will be covered by this function include:

- MHRA
- PIAG
- GTAC
- ARSAC
- RATE
- Ethics

as well as any other similar such approval bodies that may be added during the life-time of the R&DMIS application. It will also provide the information to facilitate local site assessments and rapid NHS R&D 'sign off' at the national, network and local levels.

The objective of this function is to allow users to come to one location to complete all the required applications for any clinical research review, authorisation, approval or permission.

Section 19 indicates the current regulations and organisations responsible for approvals.

As well as the initial entry of approval data, the system should allow for queries to be raised and resolved and subsequent amendments submitted for approval.

The contact details for each of these approval bodies are shown in the table below.

Abbreviation	Organisation/systems	Web site
Ethics committee	Central Office for Research Ethics Committees operates a central application system for research ethics committees.	http://www.corec.org.uk
NHS Organisations, sites	Currently, 3 rd party commercial systems. (In future, NHS organisations will be members of local research networks under the UKCRN, and will collaborate to deliver a single sign-off, supported by the R&DMIS.)	e.g. http://www.epsresearch.com/ http://www.infonetica.net/ [add UKCRN, CRN etc]
MHRA	Medicines and Healthcare products Regulatory Agency. TWO separate systems: drugs and devices. The EudraCT number would be obtained through this route.	http://www.mhra.gov.uk
PIAG	Patient Information Advisory Group	http://www.advisorybodies.doh.gov.uk/piag/
GTAC	Gene Therapy Advisory Committee	http://www.advisorybodies.doh.gov.uk/genetics/gtac/
ARSAC	The Administration of Radioactive Substances	http://www.arsac.org.uk/

	Advisory Committee (ARSAC)	
RATE	Regulatory Authority for Tissues and Embryos. This authority has yet to be established. In 2007 it is intended that RATE will replace the current Human Fertilisation and Embryology Authority (HFEA) and Human Tissue Authority (HTA).	http://www.hfea.gov.uk http://www.hta.gov.uk

Table 1 - User Classes and Roles

8.2.2 Detailed Requirements

For the applicant, the R&DMIS will:

- Provide, via the Portal, a secure space in which lead researchers and their assistants can assemble structured information relevant to regulatory authorisation, ethics committee review and other types of permission required before a study can start. This set of information will be the core of the documentation required to manage the study.
- Provide the detailed web forms and data fields required to collect all necessary data for applications to the organisations relevant to a specific study. The R&DMIS will provide a view of the organisation's own forms that will have a coherent flow and consistent non-redundant data entry irrespective of the underlying complexity of the approval organisation's forms.
- Collect the information required before the UKCRN will adopt a study, and by NHS sites whose permission is required. The information will facilitate the single national sign-off by which the UKCRN aims to streamline local NHS permission.
- Ensure that the data the user provides is transferred correctly to the forms or applications used by the relevant organisations so that no information is lost and the forms are correctly completed according to the rules of each approval organisation.
- Present the appropriate data fields/forms, as suggested by the approval wizard, to the user for completion. The 'expert' user should be able to bypass the wizard if so desired.
- Allow the user to complete the required data entry in stages during separate sessions, saving previously-entered data.
- Provide the ability to create a 'trial/project space' where various data and documents/data required for approvals can be collected.
- Allow the uploading of documents required for approvals in a variety of file formats including Microsoft Word.doc and Adobe.PDF files.
- Automatically append the users electronic CV, where required, to an application.
- Remind the applicant to check their on line CV and update if necessary before submission of application (see Section 8.11.6).
- Allow the submission of these documents and data via appropriate secure APIs to the 'approving organisations', electronically/digitally signed.
- As part of the application process, provide a tool to register the project with any recommended additional clinical research registries such as ISRCTN.
- Allow the sponsor or sponsor's agent (typically CI or Trial Project Manager) to begin the set up of additional sites in multi centre studies.
- Allow the NHS bodies in the R&D networks under the UKCRN to provide ethics committees with the assurances required for site assessment.
- Allow additional sites to complete the required data for an SSA and submit to the ethics committee for approval via their local R&D network.

- Once the project is established, offer the facility to seek approvals for protocol amendments. This should use a similar process to the original application in terms of queries and query resolution.

For approvers, the R&DMIS will:

- Provide a work list of approvals that have arrived in the approver's 'in tray' and links to begin to manage the application.
- Allow the review of an application and associated documents by approvers and provide the facility for generating queries about any aspect of the application. All of these communications to be through secure messaging.
- Provide a communication facility to indicate the creation of approver queries to the original applicant which allows the applicant to reply to that query and for the approver to either accept or reply to the applicant's response.
- Provide a warning email for the user to log in when a message has arrived in the R&DMIS for them.
- Following reconciliation of any approver queries, provide a facility for approvers to confirm their satisfaction with the application and indicate on the system that a project is approved.
- Ability to 'approve' must only be enabled for approving organisations so that all users viewing such approvals will know that they are the definitive status of approval.
- Provide the ability for any approvers to withdraw/suspend approval at any stage and notify CI/sponsor of such.

For all users the R&DMIS will:

- Allow for 'asynchronous' approval processes e.g. the applicant could apply for ethics committee review at a different time to MHRA authorisation and vice versa. Applications could be made, and approvals given, at different times. There should not be a 'rate limiting step' that obliges applicants to have their entire approval package finished before any single application can be processed.
- Provide a mechanism of 'passing the baton' between applicant and approver so that at any given time it is clear in whose 'in tray' a particular query or application sits.
- Provide a mechanism of 'stopping the clock' for the approver when they have done their application processing and passed it back to the applicant. The elapsed time the application has spent with either applicant or approver should be tracked.

8.3 Project Status Dashboard

8.3.1 Background

The R&DMIS will provide an overview of research projects and their current status in the form of a 'dashboard'. This overview will be available only to those users who have the appropriate access rights to those projects. The dashboard will provide a detailed view of user approval/sign off status and the staff associated with the project.

8.3.2 Detailed Requirements

The R&DMIS will:

- Provide an overview 'dashboard' of studies pending attention for various users. This would include, for example a CI with 2 projects in application phase as well as say PIAG who have received 6 applications plus an amendment that day for action.
- Allow the current user to see which other users are associated with a particular project.
- Provide a 'browse view' of unfiltered project related data.
- Provide sort function on all elements of the dashboard view.
- Provide filters on all elements of the dashboard view in order to narrow selection.
- Provide search facility to look for a given project by:
 - Key word in title or abstract;
 - Key project identifiers (nature of identifiers yet to be defined: to include international unique identifiers such as ISRCTN number, EuDRACT number, with links to related records in public registers and databases);
 - Investigator identifier;
 - R&DMIS user id;
 - Research site identifier;
 - Disease topic.
- Provide the facility to add to and customise the dashboard views.
- Provide a graphical, real time, 'clock' or 'progress bar' to indicate the progress of applications and who currently has the responsibility to take action on the application. The graphics should indicate how many days are left until a reply can be expected.
- Provide an easy-to-read indication that a project has been approved, such as a traffic light or tick and cross. This would be externally populated by the approving organisation and should NOT be editable by users outside of approving organisations.
- Provide a full audit trail of all approval activities including when, and by whom, data has been entered; when a project was submitted for approval; who generated which queries and when; when was final approval given.

8.4 Performance Metrics Presentation

8.4.1 Background

The R&DMIS will provide a generally accessible, transparent presentation of process performance metrics associated with applications. This function will allow anyone interested in clinical research to see how the UK systems of NHS R&D management and regulatory approval are performing. This is a simple, but very important, element of the R&DMIS as it will, in part, provide the metrics by which the R&DMIS and the BRfBH initiative is judged.

8.4.2 Detailed Requirements

The R&DMIS will provide a dynamically updated display on the home page of the portal (i.e. visible to the general public without needing to log in to the non-secure area) showing real time performance metrics such as the:

- total number of projects in the system;
- total number of registered users;
- number of users currently logged in;
- number of studies approved in the last week, month and year.
- average time (and range) from the first approval submission to the first patient on a study;
- average time from application submission to approval for each of the approver organisations;
- range of times from application submission to approval for each of the approver's organisations;
- percentage of approvals from different organisations that have been processed 'on time' in a similar way to the publication of train company punctual arrival metrics;
- present R&DMIS system performance metrics such as downtime, response times etc;
- enable feedback to users and organisations associated with apparent delay.

8.5 Customised Reporting

8.5.1 Background

The R&DMIS will provide *ad hoc* reporting facilities to generate standard and customised reports on various data in the system. This function is to give users with the appropriate permissions, flexibility to access data in the R&DMIS that may not be easily available from the 'dashboard' views. These facilities would allow users to generate and schedule their own custom reports.

8.5.2 Detailed Requirements

The R&DMIS will provide:

- Ad hoc reporting tools to allow a user to generate any type of report they wish from the data they have permission to access in the R&DMIS;
- Tabular, textual and graphical outputs must be supported;
- A number of standard template reports will be made available to users but these templates should also be customisable. These templates will be defined as part of the development of the R&DMIS;
- The reports will be downloadable by the user in any of the following file formats:
 - Microsoft Word (DOC);
 - Adobe Portable Document Format (PDF);
 - Microsoft Excel (XLS);
 - Comma Separated Values (CSV);
 - Extensible Markup Language (XML).
- Allow the scheduling of ad hoc reports that can be automatically sent to defined users by email.

8.6 NIHR Funding Application Wizard

8.6.1 Background

This area of functionality would cover the very beginning of a research project – seeking funding for a new study. At present, numerous different systems are used by different funding bodies, even those within the NIHR. The wizard will support a consistent approach towards funding applications and help users find funding for their project. The wizard will communicate with the IT systems of the NIHR programmes and of NIHR partner funding agencies, and may replace certain systems as they become obsolete.

Part of this work would be the development of standard national listings and tariffs which would allow transparent costing of research at different sites.

This function is intended to be similar to the Research Approvals Wizard. It will guide an applicant who is seeking funding for research through a series of questions and, based on answers to those questions:

- indicate to the user which bodies may be able to fund the project and then;
- present the user with the appropriate data fields to be completed.

To illustrate the type of functionality required, the following might form part of the wizard dialogue:

- | | |
|---|--------|
| • Does your research involve human subjects? | Yes/No |
| • Does the project involve human tissues? | Yes/No |
| • Have you applied for funding for this project previously? | Yes/No |
| • Does your project involve patients with cancer? | Yes/No |
| • Is a medical device involved? | Yes/No |

On completing the wizard dialogue, the user might be presented with an output such as:

“Thank you. From the answers you have provided, your research project may qualify for funding from the following NIHR programmes and funding partners:

- ’
- HTA,
- MRC.

*If you have any queries please call the NIHR advice line on 08123 456 7890
Proceed to application forms? Go... ”*

The above content is for illustration only and is not intended to be comprehensive. During the lifespan of the R&DMIS project, funding opportunities/mechanisms and the underpinning data sets are likely to be revised and the Funding Application Wizard must support all future variants of these funding mechanisms, not simply the current processes. In this context the R&DMIS may be less relevant to industry-

sponsored studies where funding will already have been established although industry may wish to influence and adopt the standard costing elements.

8.6.2 Detailed Requirements

The R&DMIS will:

- Provide a user-friendly introduction for the non-technical user and explain how the wizard works.
- Provide a button in the portal to take the user into the wizard.
- Present a series of questions, asking the user about the type of project they are planning; and
- Compare the answers with the criteria used by NIHR programmes and external funding partners.
- Based on answers to these questions, inform users which funding possibilities are open to them. The logic that underpins this function must be easily changed to match the changes in funding criteria.
- Provide links to funding organisations web sites and a 'more...' link to provide more detail about the criteria and the type of commissioning process. These 'more' links will provide an intelligent and reasoned answer to the user's project intentions. These explanatory links must be updateable in the same way as the underlying logic, so that they reflect current practice.
- Store data from user enquiries so that reports on what types of projects people are enquiring about and the funding guidance provided by the system can be generated. A unique identifier should be associated with each completed wizard episode so that when the same user comes back into the system during a new session they do not have to re-answer all the questions.
- Allow partially completed wizard enquiries to be saved. This will allow users to partially complete the wizard, realise that they need more information to complete the next question and return to that precise position in the dialogue at a later time when they have the required information.
- Provide a listing of the user's previous enquiries so that they can pick up any previous query where they left off previously, or edit a stored query to correct an error.
- Lead the user, if he/she wishes at this stage, through to the data fields (identified during the 'wizard process') for completion of the required questions for a funding application to the selected organisation. Users must be obliged to declare whether they are seeking funding from more than one of the NIHR partner organisations at a time.
- Point users to RD Info ⁷ for further guidance if necessary.
- At the end of the wizard process, present the user with a summary of the data that they have put into the system and ask them to check accuracy:
- Following completion of all the questions, and the accuracy check, indicate to the user which funding possibilities are open to them and from which organisations.
- Ask the user if they wish to proceed to start a funding application. If so, lead them into the funding application process.

⁷ http://www.ukcrn.org.uk/index/clinical/regulatory/advice_service.html

8.7 Research Funding Data Entry

8.7.1 Background

The R&DMIS will provide a single point of data entry for research funding applications. This will include the following funding sources:

NIHR programmes

- Health Technology Assessment (HTA);
- Central Commissioning Facility (CCF);
- Service Delivery and Organisation (SDO);
- Health Devices Programme;
- Invention for Innovation;
- Research for Patient Benefit;
- Research for Innovation, Speculation and Creativity;
- Programme Grants for Applied Research;
- Research Units;
- Research Centres.

NIHR funding partners

- Medical Research Council;
- Wellcome Trust;
- Other Research Councils and charitable funders who wish to participate.

The function will provide a clear and consistent funding application route for all clinical research proposals. There are a number of existing systems used by funding/commissioning bodies that would need access to the system via secure APIs. Guidance on funding applications already exists on the RD Info website and this guidance should be incorporated into the R&DMIS⁸.

The contact details for each of these NIHR programmes and partner funding organisations are shown in the table below.

Abbreviation	Organisation/system	Web site
HTA	The NHS Health Technology Assessment Programme	http://www.hta.nhsweb.nhs.uk/
CCF	NIHR Central Commissioning Facility	http://www.nihr-ccf.org.uk/site/default.cfm
SDO	The NIHR Service Delivery and Organisation (SDO) Research and Development Programme	http://www.sdo.lshtm.ac.uk/
MRC	Medical Research Council	http://www.mrc.ac.uk
Wellcome	Gene Therapy Advisory Committee	http://www.wellcome.ac.uk/
Other research councils and charitable funders	e.g. Research Councils and Association of Medical Research Charities members.	http://www.rcuk.ac.uk/default.htm http://www.amrc.org.uk/

Table 2 – Funding Organisations

⁸ <http://www.rdinfo.org.uk/>

8.7.2 Detailed Requirements

For the applicant, the R&DMIS will:

- Present the appropriate data fields/forms, as suggested by the funding application wizard, to the user for completion. The 'expert' user should be able to bypass the wizard if so desired.
- Provide a costing⁹ template to the user to assist in the construction of a budget.
- Allow the user to complete the required data entry in stages during separate sessions, saving previously-entered data.
- Provide the detailed web forms and data fields required to collect all necessary data for funding applications to any of the funding organisations. The R&DMIS will provide a view of the approval organisations own forms that will have a coherent flow and consistent non-redundant data entry irrespective of the underlying complexity of the approval organisation's forms. Wherever possible, project data previously entered using other data entry functions should automatically populate data fields so that user does not have to enter and given data element more than once.
- Allow the uploading of any additional documents required for funding applications in a variety of file formats including Microsoft Word .doc and Adobe. PDF files.
- Automatically append the users electronic CV, where required, to an application.
- Remind the applicant to check their on line CV and update if necessary before submission of application;
- Allow the submission of these data and documents, via appropriate secure APIs, to the funding organisations, electronically/digitally signed.

For the funder(s), the R&DMIS should:

- Provide a work list of funding applications that have arrived in the funder's 'in tray' and links to begin to manage the application.
- Provide a simple tool to check that a funding application is 'complete' i.e. has all the necessary data submitted.
- Allow the review of a funding application and associated documents and provide the facility for generating queries about any aspect of the application. All of these communications to be through secure messaging.
- Provide a communication facility to indicate to the applicants the existence of any funder queries and allow the applicant to reply to that query and for the funder to either accept or reply to the applicant's response. A warning email will be sent to the user, reminding them to log in when a message has arrived in the R&DMIS for them.

⁹ Note that the UKCRN Coordinating Centre have begun work in this area and the NIHR IS team will be working closely with UKCRN

- Provide the facility for the funder to send the application out electronically for peer review and to capture the comments of peer reviewers and pass on to applicant (anonymously if necessary).
- Following reconciliation of any funder queries, provide a facility for funders to confirm their satisfaction with the application and indicate on the system that a project has been funded and communicate this electronically.

For all users the R&DMIS will:

- Provide a mechanism of 'passing the baton' between applicant and funder so that at any given time it is clear in whose in tray a particular query or funding application sits.
- Provide a mechanism of 'stopping the clock' for the funder when they have done their application processing and passed back to applicant. The elapsed time the application has spent with either applicant or funder should be tracked.

8.8 Integrated Clinical Research Progress Reporting

8.8.1 Background

The purpose of this function is to:

- Establish an efficient, standardised method for research teams and their sponsors to comply with statutory and other reporting requirements;
- Provide much more efficient information gathering about clinical research in all sectors across the country.

Work is underway to harmonise the statutory and non-statutory reporting requirements for clinical research but currently this work is not complete. Agreement on the content, format, frequency and appropriate distribution/access to such reports has yet to be agreed amongst the various organisations concerned but there is willingness in principle to move to this model. The following requirements represent a 'wish list' of functionality that the R&DMIS will be expected to deliver in due course.

The MRC Clinical Trials tool kit provides a summary of the current statutory and recommended reporting requirements¹⁰. The current requirements are shown in the figure below. Note that, as with many of the processes that the R&DMIS will support, it is inevitable that regulations and requirements will change and the R&DMIS needs to be flexible in catering for these changes with minimal recoding.

A broad intention is to move to a **unified annual research project report** that all governing and commissioning bodies could refer to and which would contain all the data they required.

¹⁰ http://www.ct-toolkit.ac.uk/route_maps/map_landing.cfm?cit_id=248

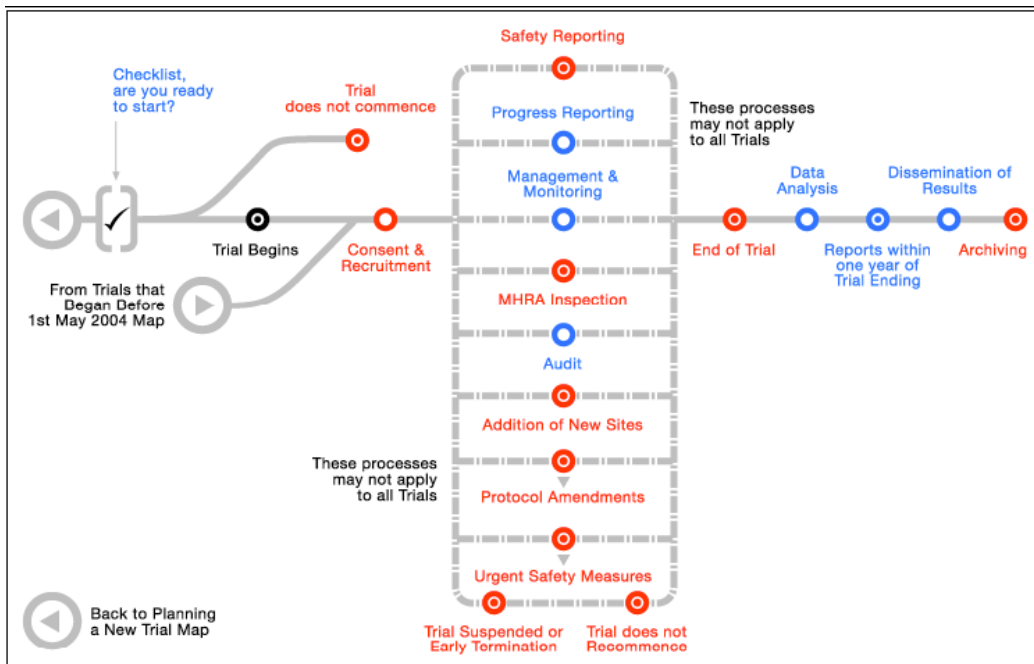


Figure 4 – MRC Recommended Reporting Requirements

Key to Symbols	Standard Process	Legal Requirement	Good Practice
Specific for trials within Directive's scope	⦿	⦿	⦿
Relevant to all trials	⦿	⦿	⦿

8.8.2 Detailed Requirements

For 'reporters', the R&DMIS will:

- Allow the semi-automated creation of a unified annual research project report, bringing together data from the R&DMIS in a standard format and allowing the CI/sponsor to add appropriate commentary. The format of this report is to be agreed.
- Prompt a sponsor and study project team when a unified report is due for submission.
- Provide functionality that will allow the CI/sponsor to digitally sign their report and submit to regulatory/funding bodies.
- Notify CI/sponsor when annual report has been successfully received by the intended recipient(s).

For recipients of reports, the R&DMIS will:

- Notify the user, through a 'for review' list, that a report has been received;
- Provide the ability to acknowledge receipt of annual reports;
- Provide the facility for sending or allocating a received report to another user for peer review and provide a method to capture, and feed back to CI/sponsor where appropriate, reviewer comments;
- Provide the regulator/original approver the ability to renew or withdraw ongoing research approval(s) based on review of the annual report;
- Provide a listing of late/outstanding reports due and the ability to remind CI/sponsor to submit;
- Allow an auditor/inspector to examine the route taken to research set up and approval and check on current status of approval of a study or studies.

8.9 Integration of SUSAR Reporting to EudraVigilance

8.9.1 Background

There is an EU-wide legal requirement for sponsors to report Suspected Unexpected Serious Adverse Reactions (SUSARs). The reports have to go both to EU regulators and to the relevant ethics committee. At present there is much confusion about SUSAR reporting. The R&DMIS will provide functionality that will help to clarify what exactly a SUSAR is, and provide a simple mechanism for a CI/sponsor to submit to Eudravigilance and to the relevant ethics committee.

There are international legal requirements to report SAEs in a mandatory timeframe and in the required format, such as the FDA's MedWatch Form 3500A or the Council for International Organizations of Medical Sciences (CIOMS) I form.

The EMEA has implemented an electronic regulatory submission environment, the EudraVigilance Gateway, which follows the ICH M2 Gateway Recommendation for the Electronic Transfer of Regulatory Information (ESTRI-Gateway). The EMEA require SUSAR reports to be submitted electronically in a standard XML file schema called E2BM11.

The purpose of the EudraVigilance Gateway is to operate a single, common, European Economic Area (EEA)-wide Gateway for receiving regulatory submissions in a fully automated and secure way including all aspects of privacy, authentication, integrity and non-repudiation of all transactions in pharmacovigilance.

8.9.2 Detailed Requirements

The R&DMIS will:

- Provide functionality, in the form of a small wizard that will guide the user through what constitutes an SAE and a SUSAR and remind the user of the regulatory requirements for submission.
- If the SAE is defined as a SUSAR, provide an electronic version of the CIOMS I form for CI/sponsor to complete with as much pre-population from the R&DMIS as possible e.g. sponsor name and address, CI, project title.
- Provide a SUSAR notification form to complete which complies with the E2BM19 XML data standards.
- Upon submission by CI/sponsor, provide the facility to seamlessly submit an E2BM19-formatted XML file to the Eudravigilance gateway¹²; and to the relevant ethics committee.
- Capture and present to the user an acknowledgement from Eudravigilance that SUSAR has been successfully received and validated.
- Use a flexible method to maintain the logic behind the SUSAR and SAE definitions so that these can be changed as the international regulations are updated.

¹¹ <http://eudravigilance.emea.europa.eu/human/evGateway01.asp>

¹² <http://eudravigilance.emea.europa.eu/human/evGateway03.asp>

- Record the version of the regulations that were used in any guidance given to the user so that it is possible to establish an audit trail for the results.

8.10 Integration with Connecting for Health

8.10.1 Background

Section 4.2 of Best Research for Best Health describes the goal of ensuring that the data collected via the NHS Care Record Service and supporting infrastructure meet the needs of researchers and public health practitioners. In the long term there are likely to be large benefits to the research community from linking the NIHR Information Systems to Connecting for Health (CfH), with robust arrangements to protect patient confidentiality. An expert group under the UK Clinical Research collaboration is overseeing a series of simulations to define the capability that the NHS National IT system could provide. The main focus is on the recruitment of patients to clinical trials and the gathering of data to support work on the health of the population and the effectiveness of health interventions. At the present time it is difficult to project when the NHS Care Record Service (CRS) will be available for clinical research. The NIHR IS will pilot elements of communication and potential integration with CfH in due course.

8.11 Other General Requirements

These requirements are not as closely associated with the life-cycle of a trial but are important aids in making the management of a trial more effective and efficient.

8.11.1 Audit

The R&DMIS will:

- Have an audit trail for data entries in compliance with FDA 21 CFR part 11/GCP regulations on electronic signatures.
- Allow electronic/digital 'signature' of all actions undertaken whilst in the R&DMIS.

8.11.2 Data Export

The R&DMIS will:

- Have the ability to export data in a variety of formats: to include Word, Excel, PDF, CSV, and XML.

8.11.3 Flexibility and Scalability

The R&DMIS will:

- Provide a flexible platform for future development.
- Be scaleable to take account of changing business needs and increase in volumes of trials.
- Offer an 'away/holiday' feature that allows a user to hand over their role to another appropriately qualified/authorised user whilst unavailable and claim that role back after they return. Effectively the ability to delegate their responsibilities. This delegation should be fully audit trailed.

8.11.4 Adaptability

The R&DMIS will:

- Have a feedback/comments facility for users to contribute improvement suggestions.

8.11.5 Help

The R&DMIS will:

- Provide comprehensive help facilities so that a user with no prior experience of similar systems will be able to use the facilities effectively. Help facilities should include a help menu, and help buttons on all pages of the R&DMIS.

8.11.6 On line Curriculum Vitae

Curriculum Vitae (CV) are a very important part of an application for project approval and need to be kept up to date. The R&DMIS will provide functionality to help researchers with this process. The types of data that could be covered by this include:

- personal details;
- qualifications;
- previous employment;
- type of professional (e.g. nurse, physiotherapist, doctor);
- current employment;
- professional body registration number (e.g. GMC and possibly research passport no. in future);
- previous experience in clinical research;
- training undertaken;
- publications;
- personal references.

The Online CV function would:

- Provide a 'myProfile' function for researchers which will include an online short CV.
- Provide a choice of how CV data is provided: either document upload or entry of data fields: the latter preferred.
- Allow the facility for user to upload CV document in Microsoft Word .doc or Adobe. PDF format.
- Provide a reminder to the user at the time that they start a new trial application to check their CV and update as appropriate.
- Remind users that their CV will be visible to a number of individuals and ask them to check a box if they agree to its distribution in this way.
- Make the CV of any given user visible/downloadable to various 'approvers', funders and/or research governance managers for review.
- Provide the facility for the user to add a digital signature to validate their current CV.

9 Users and Roles

The portal will offer facilities to twenty-eight user types, grouped within sixteen classes. Not all of these users and roles are relevant to the R&DMIS. The table below shows the users that will have an interaction with the R&DMIS.

The missing user class numbers belong to users that have no role within the R&DMIS. Refer to NIHR4.2 URS002 for details.

User Class	User Type	Examples	Roles ¹³
Researcher¹⁴			
2	Chief Investigator (CI)	In charge of whole project and is agent of sponsor	Review and contribute information to specific projects. Create research applications. Contribute research papers Can access everything to do with the project
3	Principal investigator (PI)	Specific to a site, reporting to the CI	Access to data on their site only.
4	Research Nurse	Specific to a site	Work on specific trials, assist with recruitment
5	Trial Project manager	Project management	Manages the detail of a single trial
6	Non-clinical Researcher	Research fellow, PhD or MSc Research student	Interest in medical research projects
R&D Manager			
7	R&D Manager	R&D Manager in NHS Trust. Manages a portfolio of trials	Review research applications, Manage applications and projects for a specific organisation
Faculty Member			
9	Faculty Investigator ¹⁵	Researchers and collaborators, whose salary is funded at least in part by the NIHR	Similar to researcher roles 2 and 3, but with access to additional Faculty based content
10	Senior Faculty Investigator ³	Research leaders, across diverse areas of patient focussed research	Will lead faculty development and be active in research
Network Manager			
12	Topic Specific Network manager	Cancer network, Comprehensive network	Manage activities in a topic specific network
13	Local network manager	Network manager for one of the thirty three regional cancer networks	Manage activities in a local network

¹³ Members of professional bodies will have access rights associated with the role they undertake.

¹⁴ "Researchers" include researchers who have a project in development, as well as approved

¹⁵ Honorary Investigator or Honorary Senior Investigator status will be available to individuals carrying out people-based research who are employed by a partner organisation (a University or research institution, or pharmaceutical industry body) and whose salary does not necessarily derive from NIHR funding.

Regulator/Approver			
15	MHRA drug trials approver	N/A	Drug trials approver.
16	MHRA devices approver	N/A	Device trials approver
17	PIAG	N/A	Patient Information approver
18	GTAC	N/A	Gene Therapy approver
19	RATE	N/A	To be defined
20	COREC	N/A	Ethics approval
Policy and oversight			
23	Policy and oversight	DH	Overview of all NHS projects, Extraction of statistics, Overview of all information resources and tools
Systems Administrator			
25	Systems Administrator	Members of Portal and R&DMIS management Team	Access to all Portal and R&DMIS facilities
Sponsor			
26	Sponsor	NHS Trust, University, pharmaceutical company and other institutions	Make applications., review approval status, recruitment figures, trial documents etc.

Table 3 - User Classes and Roles

10 Interfaces

This Section describes the interfaces that the R&DMIS must provide with other NIHR components, the user, and external systems via Application Programme Interfaces. The location of these interfaces can be seen on the architecture diagram below as vertical (up and down) arrows.

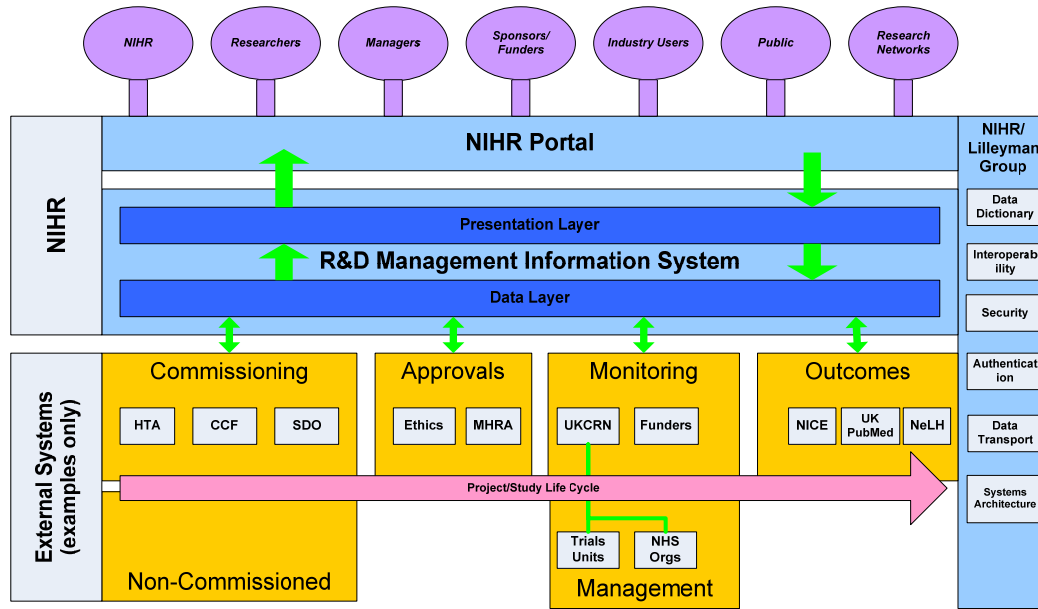


Figure 5 – High Level Systems Architecture

10.1 Portal Interface

The R&DMIS will have no direct interface with the user. All interaction of the R&DMIS with the user will be via the portal. The actual interfaces are highlighted on the architecture diagram below. The requirements for the portal are provided in the portal requirements specification NIHR4.2 URS 002.

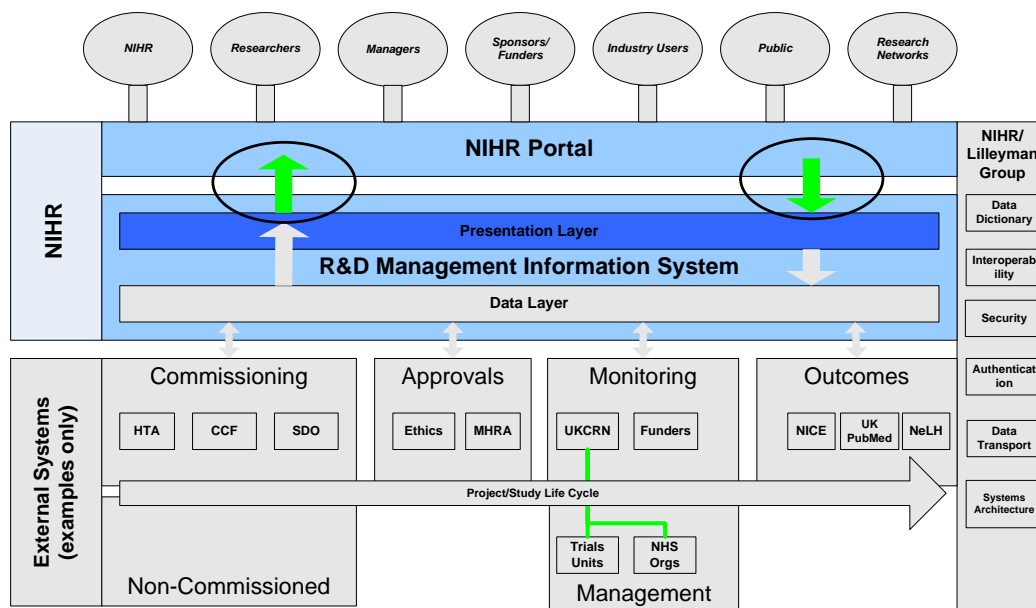


Figure 6 – Portal Interface

This indirection has four main objectives:

- The portal will carry out all authentication and identification processes in one place for all system components.
- A single channel of communication with the user is easier to secure;
- The portal can apply a standard look and feel on the communication with the user, thus ensuring a consistent appearance regardless of the diversity of the underlying applications.
- The user interface for the R&DMIS should be easier to design and implement.

The interface with the portal will be two-way:

1. Input from the user will be received by the portal and passed through to the R&DMIS. The R&DMIS will know that the input comes from an authenticated user and that the class of the user is known.
2. The R&DMIS will compose output to be sent to the user in its presentation layer. This output will be passed to the portal for despatch to the user.

Apart from the reference technical architecture diagram above, this User Requirements Specification does not place any other constraints on the methods used to implement this interface between the R&DMIS, except for the following:

- The communication channel between the portal and the R&DMIS must be secure. If the implementation is based on separately hosted systems, an appropriately secure channel between the two systems must be used.
- Given that the reliability of the entire R&DMIS will depend on this channel, it must be implemented in such a way that the required level of availability can be achieved. See Section 15.

10.2 Internal Interfaces

These are interfaces that are needed with the applications that form a fundamental part of the R&DMIS. The systems which will require such two-way interfaces are shown in the table below:

Organisation	System Type	Organisation/system	Web site
HTA	Commissioning	The NHS Health Technology Assessment Programme	www.hta.nhsweb.nhs.uk/
CCF	Commissioning	National Institute for Health Research Central Commissioning Facility	www.nihr-ccf.org.uk/
SDO	Commissioning	The Service Delivery and Organisation (SDO) Research and Development Programme	www.sdo.lshtm.ac.uk
COREC	Approvals	Central Office for Research Ethics Committees	www.corec.org.uk
MHRA	Approvals	Medicines and Healthcare products Regulatory Agency. TWO separate systems: drugs and devices ¹⁶ .	www.mhra.gov.uk
PIAG	Approvals	Patient Information Advisory Group	www.advisorybodies.doh.gov.uk/piag/
GTAC	Approvals	Gene Therapy Advisory Committee	www.advisorybodies.doh.gov.uk/genetics/gtac/
ARSAC	Approvals	The Administration of Radioactive Substances Advisory Committee (ARSAC)	www.arsac.org.uk/
RATE	Approvals	Regulatory Authority for Tissues and Embryos	www.hfea.gov.uk http://www.hta.gov.uk
UKCRN	Monitoring	UK Clinical Research Network	www.ukcrn.org.uk
Funders	Monitoring	Organisations that provide funding	N/A
NICE	Outcomes	National Institute for Health and Clinical Excellence	www.nice.org.uk
UK PMC	Outcomes	UK PubMed Central - free-to-access full-text digital archive	www.ukpmc.org
NeLH	Outcomes	National electronic Library for Health (becoming the National Library for Health)	www.library.nhs.uk

Table 4 – Organisations requiring an internal interface

¹⁶ We acknowledge that the processes that apply to devices is not one of approval of a study but rather one by which the MHRA has a 60 day window in which to raise objections to a study being taken forward.

The location of these interfaces is shown highlighted on the architecture diagram below:

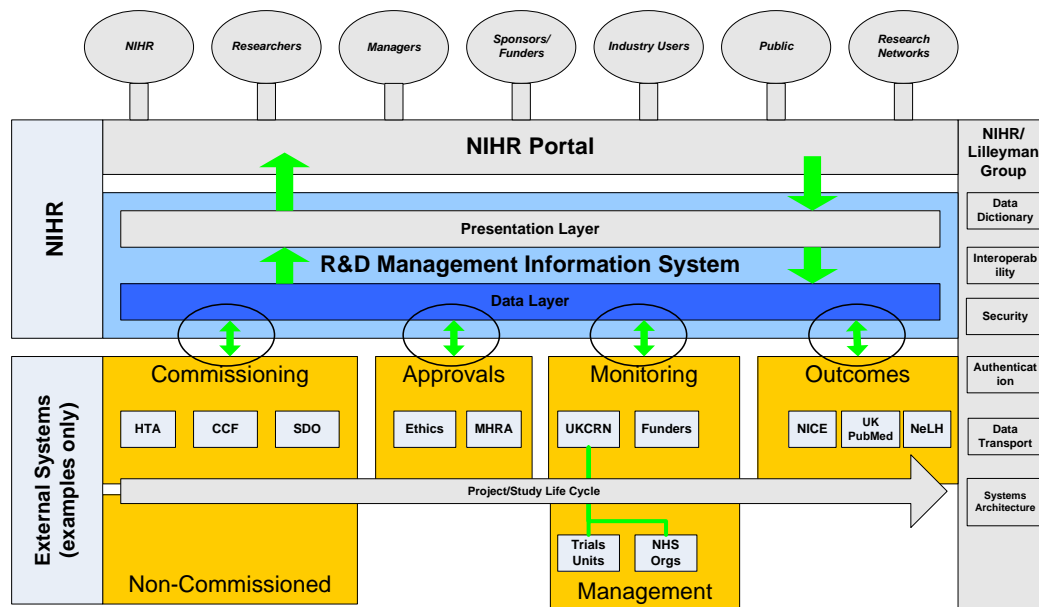


Figure 7 – Internal Interface

The design and implementation of these interfaces will need to be decided on a case by case basis, however the methods chosen must be:

- Stable and robust so that the applications at both ends of the interface can interoperate reliably;
- Committed to an agreed by the organisations at each end of the interface so that any future changes of individual application will not disrupt the interface;
- Secure so that it is not possible to subvert or to eavesdrop on the interface;
- Documented thoroughly.

The methods chosen should also, preferably:

- Use a standard messaging scheme;
- Be based on a standard 'language' such as XML.

These interfaces will require strong authentication to ensure that they are secure. The method of authentication between the R&DMIS and the application systems is to be defined. The portal will provide pass-through authentication of the user to the R&DMIS, so this information will be available in the R&DMIS if this would prove useful.

10.3 External Interfaces

External interfaces are those with other R&D Management systems for example those currently used in NHS Trusts.

NIHR policy with respect to this type of system is to:

- Offer a smooth migration path for users that wish to continue to use the commercial applications whilst still being able to obtain some of the benefits of the new NIHR R&DMIS system.
- Provide opportunities for commercial suppliers to interface with the R&DMIS so that they are able to add value to the core functionality.

In addition to this type of system, interfaces will be offered for the following type of external systems:

- portfolio management systems;
- electronic remote data capture;
- individual trial management systems;
- finance/accounting systems.

In each of these cases the interfaces must be able to operate in both directions.

In order to support the policy, this Application Programming Interface must be:

- Fully documented and published so that knowledge of the interface alone is sufficient to allow any supplier to produce code that exercise the functions defined in the interface.
- Be designed for security so that the interface can be used safely.

10.4 NHS Connecting for Health Interface

In order to meet the long term goals established in BRfBH, in due course an interface with NPfIT will be required. This would allow for the use of patient data in conjunction with the R&DMIS. An interface of this type will require very careful design and possibly changes to the R&DMIS and the portal systems. A full security study and audit will be needed before such a link is implemented and released. This interface is therefore an aspiration for the R&DMIS not an immediate priority for early implementation.

11 Documentation

Documentation is required to support use and management of the R&DMIS. The following minimum set of documentation will be provided.

Document Name	Type	Purpose
R&DMIS User Guide	User	Describes the functions that a user can perform in the R&DMIS.
R&DMIS Systems Manual	System	Describes the operation of the R&DMIS systems from the perspective of a system manager, Describing all the functions needed to keep the R&DMIS operating correctly.
R&DMIS Business Continuity Plans	System	Describe how the R&DMIS can be recovered from a disaster. This should contain Crisis Management plans and the method of invoking a recovery site or facility.

Table 5 – Documentation Types

User documents must be made available through the portal and for download in Portable Document Format (PDF). System Documentation is intended primarily for internal R&DMIS management team use and will not be made available through the portal or R&DMIS.

Documentation must be under configuration management and document control information will be provided at the start of the document in the same way as this document.

12 R&DMIS System Management

The R&DMIS will be a transactional system with a dynamic set of users and research projects. It will require active System Management and a set of tools to help make that process effective.

The tools required include:

- Statistical tools that will allow the extraction of data and production of reports about all aspects of the usage of the R&DMIS;
- Data administration facilities that can manage the R&DMIS as a whole and control all data associated with it;
- Facilities to help system managers to respond appropriately to Freedom of Information enquiries.

Most of the management activities associated with users and their registration will be handled by the portal. The system management functions associated with this are covered in document NIHR4.2 URS002.

The R&DMIS will log all user activity associated with projects. Tools are required to manage those logs and to extract useful information from them. This will include:

- Information about trials
 - New trails registered
 - The stage of all trials
 - Trails completed
 - Trends
- Information about usage trends
 - The profile of user activity across a specific date range;
 - The profile of user activity associated with specific types and ranges of trials
 - And any other such information.

The R&DMIS will provide tools that will help System Administrators manage project associated data. System resilience and reliability is covered in section 15, but it is essential that the R&DMIS has a comprehensive set of data management facilities that can provide at least the following:

- Full data backup and restore on a flexible basis, using a maximum of a one day cycle (i.e.) it should always be possible to retrieve data from the previous day.
- Full transactional log of all changes that occur in all projects under management of the R&DMIS, so that it is possible to roll back/roll forward changes on a selective basis to permit recovery from a system failure or error.
- Data archival on a selective basis for all project associated data and the means for rapid retrieval on demand from the archive. The use of SAN technology may make it less important (or un-necessary) to archive material off-line.

These facilities should be available using the typical combination of a RDBMS and SAN infrastructure to underpin the R&DMIS.

13 Performance Requirements

13.1 Anticipated Use

Initially the system must simultaneously support:

- A throughput of 2000 new research applications per month;
- 1000 concurrent users for the R&DMIS services.

The system must be designed to allow scalability to:

- A throughput of 4000 new research applications per month;
- 1500 concurrent user for the R&DMIS services.

The performance requirements above are for sustained average loading, measured over a period of 4 hours. In addition, the R&DMIS must be capable of sustaining a peak loading of 30% in excess of these performance levels for a period of 30 minutes maximum.

The proposed design architecture should be incremental and enable the increase in the users to be met by the addition of hardware and software at a cost proportionate to the increase in performance.

13.2 Project Volumes

The R&DMIS must provide facilities to manage the following minimum numbers of active projects. Active projects are those that are not permanently archived. The active projects include those that would be carried forward from existing projects at the time the R&DMIS is launched.

End Year 1	End Year 2	End Year 3	Growth Year4 onwards
100,000	150,000	200,000	15% p.a.

Table 6 – Project Volumes

13.3 Performance

The R&DMIS will deliver the performance characteristics shown in the table below. The system must respond to requests as indicated in the following table e.g. in a database search the download must start within 5 seconds of completing the request. Note these are the minimum requirements and are for the transmission of fully encrypted data.

Function	Performance Requirement
Any user transaction in which data input by the user updates the state of the project trial record	1.5 seconds
A search which successfully finds a set of records that match a project search criteria	5 seconds
Any transaction in which an external system pulls data from the R&DMIS from API-linked external system	10 seconds

Table 7 – Performance Requirements

Measurement will be made from the completion of the string or key stroke that sends the request from the client/system to the receipt of the first byte of the response back from the R&DMIS by the client/system.

Performance is to be measured so that the bandwidth and latency of the network between the R&DMIS and the user's machine does not contribute to the response time, i.e. performance will be measured with a direct connection to the web server, not through the Internet.

The R&DMIS will undergo appropriate load, stress and performance tests to ensure that it responds within the required parameters for initial use and future transactional volumes i.e. all current users, and expected numbers of future customers.

14 Design Constraints and Standards

All data delivered by the R&DMIS, whether from static resources or from application systems must comply with:

- HTML 4.01 or HIM 1 or;
- PDF Version 1.4 or later.

Documents may be stored in the R&DMIS document repository (e.g. CVs – see Section 8.11.6) using many other formats, e.g. Microsoft Word, etc. However, the R&DMIS is required to deliver all documents irrespective of their internal native format in one of the standard formats listed above. The R&DMIS must maintain the capability to read all the formats of all the documents that it manages, or has links to, irrespective of the age and version of the original native format of the document. The R&DMIS Managers may choose to convert documents from their original format to PDF where this would reduce the difficulty of maintaining the ability to convert from old formats.

All data and applications delivered through the R&DMIS must be fully usable with all common web browsers, to include Microsoft Internet Explorer, Netscape Browser, Mac OS Safari, Mozilla, and Firefox. In each case the version of the browsers is the latest available for full release.

No special client software should be required to use any aspect of the R&DMIS. In particular client software that requires a separate commercial licence to use is not acceptable.

No specific client Operating System (OS) will be required to use the R&DMIS. Any OS that is able to support a standard web browser should be able to use the system. The R&DMIS should not therefore use any proprietary controls or code that the client must execute in order to make full use of the portal.

All applications will need to be compliant with the current government Interoperability Framework (e-GIF).

The portal will handle the final formatting of all data that is sent to the user. The accessibility standards that will be met by the portal (and hence the R&DMIS) are defined in document NIHR4.2 URS002.

15 Reliability, Availability, Maintainability and Integrity

The R&DMIS must be designed for an anticipated life span of at least five to ten years and be future-proofed to manage technology changes over this period.

A change control process is required for all changes to the R&DMIS system.

All enhancements to the R&DMIS will be subject to testing, including User Acceptance Testing.

15.1 Reliability

All LAN and WAN infrastructure must be fully resilient so that the failure of any single component or link cannot cause interruption of service.

All computer hardware (particularly all servers) and associated equipment including power supply, network interfaces, air conditioning etc must offer full fail over capability so that the failure of any one server or other component cannot cause interruption of service.

15.2 Availability

The R&DMIS must be designed to allow for continuous operation on a 24 hour, 365 day per year basis.

The R&DMIS must deliver an overall availability of 99.95% with the maximum length of a single downtime incident in any one calendar (January-January) year being 4 hours.

15.3 Maintainability

Essential maintenance to the R&DMIS and all associated applications must be capable of performance without interruption to service.

If downtime is experienced, a notice must be displayed on the portal stating the expected time to repair.

Within one hour of any malfunction, the problem will be logged, analysed to gauge the severity of the problem and a course of remedial action identified with appropriate persons notified.

15.4 Integrity

The R&DMIS must be shown to be capable of maintaining the integrity of all the data which it controls and makes available. Integrity testing must form part of the system acquisition and acceptance process.

Effectively no data should ever be deleted by the R&DMIS. Even if a project is 'deleted' by a user, it should still be retained on the system but marked as 'deleted by user' and hidden from that users view.

16 Security/Confidentiality

While it is not intended as a repository of identifiable personal information, the R&DMIS will manage, deliver and receive information which could include identifiable private, personal, confidential and sensitive data under the control of users who have a duty to comply with data protection and other legislation. Security is a prime requirement of the R&DMIS. Many of the security requirements for the use of the R&DMIS through the portal are defined in the portal specification (NIHR4.2 URS002) and this should be consulted for full details.

16.1 General Requirements

The portal will provide transparent and automated security management of digital IDs, security policy enforcement and automated password resets. These features should significantly reduce the ongoing administration and management costs associated with web portal security. (Without transparent and automated security management processes, the burden of administration for both end users and administrators would quickly become unmanageable and the portal will not scale.)

The R&DMIS will comply with all UK legal requirements, including Data Protection Act 1998, Caldicott guidelines and the Freedom of Information Act 2000 and Copyright, Designs and Patents Act 1988.

A range of web transactions will need to be secured in order that users' personal details are not exposed to inappropriate view. Where personal data is collected there should be appropriate data protection notices provided to raise awareness on how that personal data will be processed. This should be reinforced with an accessible Data Protection policy statement. The terms and conditions of the use of such personal data should be provided including details of the sanctions that will be invoked if these conditions are not observed. The R&DMIS should facilitate the swift retrieval of data in line with requests under this legislation.

The R&DMIS system is **not** suitable for direct interfacing with Connecting for Health in its initial releases. A full security study will be required before this is possible. It may never be appropriate for users to query the NHS care record directly from the R&DMIS. Any such facility will depend on robust arrangements to protect confidentiality or ensure appropriate anonymisation.

The system should meet Information Security Management requirements as detailed in ISO 27001 (BS7799). This will require a full risk assessment of the system implementation and the identification of suitable counter-measures where indicated.

The system's security and measures will be independently evaluated and audited by a third-party.

There must be full and current anti-virus provision, including an anti-virus filter for all incoming and outgoing data.

The R&DMIS must be designed and coded so that SQL poisoning and injection is not possible.

16.2 API Security

The R&DMIS is totally dependent on several APIs in order to function. The security of these APIs is of crucial importance.

To ensure the security of data transferred between the R&DMIS and external systems full a transport layer security scheme must be used, capable of protecting against at least the following:

- eavesdropping;
- message tampering;
- message forgery.

This will require a cryptographic approach.

Both server and client authentication is necessary for such APIs, so a mutual authentication scheme using PKI (Public Key Infrastructure) is required

Each individual function call made to or by the R&DMIS will be authenticated. And each such call will be tested for access the access permissions that are granted to that particular system or user.

As there are many different systems involved, a separate specification document providing the detailed API design will be produced and this will be published. The security of the APIs will not depend in any respect on the secrecy of the specification or design.

The design of the APIs as well as the overall design of the portal and the R&DMIS will be subject to a full security audit before any of the NIHR systems are implemented.

16.3 Access and Authentication

Any authorised user of the R&DMIS must have been registered through the process of Portal user registration i.e. the same chain of trust validation must have been followed.

All data accessible through the R&DMIS will be flagged at the lowest level of granularity available to indicate the classification of access that is to be provided to it. Private data must be encrypted for transfer so that it cannot practically be intercepted by another party.

Inactive users must be automatically logged off after a default period of time set by the R&DMIS System Administrator or a Registration Approver. This period should be configurable by the R&DMIS management by class of user. Users will be informed that they will be logged off within a defined time limit if they continue to remain inactive.

The process of user authentication (sign-on) should be required only once for any user's single session through the portal. No further user sign-on should be required to access the R&DMIS.

16.4 Audit Trail

All user and system access to the R&DMIS should be centrally logged and tracked, so that a record of the user identity, time in, time out resources/applications visited and data changed is kept.

An audit trail showing all the changes made to data accessible through the R&DMIS will be kept. For avoidance of doubt, this is not intended to be the same as the transaction logs that will be maintained for the R&DMIS and used to roll back/forward the state of a trial/project. The audit trail will be maintained independently of any such log and must have essentially write-only access for systems and users.

16.5 Prevention of Malicious Actions

The R&DMIS and all associated applications must use best practice in design for security, specifically to avoid access to and unauthorised updating of content, stealing of personal data, subversion of the R&DMIS for other purposes and any other such exploit.

The strength of the R&DMIS design and implementation will be tested by periodic penetration testing as well as other audit and validation processes.

The system should support robust intrusion detection and a notification system to alert system management that an attack on the R&DMIS may be under way and allow them to take appropriate and timely countermeasures.

16.6 Business Continuity

All data accessible through the R&DMIS, all application code, all application associated data and all R&DMIS configuration data will be backed up on a daily basis to a geographically remote secure location so that it is possible to restore any individual part of the R&DMIS or the entire R&DMIS state from scratch.

Continuity plans, to include a complete IT Disaster Recovery plan will be produced to cover the entire state of the R&DMIS and all associated applications. This will be updated six monthly, and audited and tested yearly.

The continuity plans must be part of a full Business Continuity Management (BCM) environment, based on a full analysis of the Mission Critical Activities, Risks, Recovery Strategies and Provisioning. The BCM should be based on a recognised standard or specification such as PAS56.

17 Stakeholder Engagement

Since May 2006 the NIHR IS programme team have held a number of workshops with specific audiences including NHS Managers, system suppliers and industry. In addition we have had many individual meetings with a wide range of stakeholders including people from academic organisations, approving bodies, commissioning agencies, research networks, funders etc.

As the programme moves from the initial requirements gathering phase into the implementation phase, robust governance arrangements will be put in place to ensure that users of NIHR systems are appropriately represented and have a practical role in determining how these systems develop and are supported.

We expect to hold workshop sessions in the early months of 2007 to explain in more detail how the R&DMIS will be implemented.

We will publish all relevant documentation on the NIHR website (www.nihr.ac.uk) and provide an opportunity for people to submit comments about that documentation. In areas that require detailed discussions e.g. data standards we will establish on-line facilities to support those discussions.

18 Glossary of Terms

API	Application Program Interface – the method by which one program can work with another
CCF	Central Commissioning Facility - manages and administers NHS National Research and Development Programmes
CfH	Connecting for Health – previously known as the National Programme for IT (NPfIT) – see www.connectingforhealth.nhs.uk
COREC	Central Office of Research Ethics Committees - COREC is part of the National Patient Safety Agency and provides help and leadership for Research Ethics Committees (RECs) and the REC system by coordinating the development of operational and infrastructure arrangements in support of their work
CRS	
CSS	Cascading Style Sheets - a computer language used to describe the presentation of a document or a website
CTA	Clinical Trial Authorisation - issued by MHRA and required, along with a positive opinion from a recognised ethics committee, before it is legal to start a clinical trial of a medicine
DH	Department of Health
e-GIF	The (electronic) Government Interoperability Framework aims to improve public services by interlinking them and making these services, including the NHS, more accessible to the public
EMA	European Medicines Agency
ESTRI	Electronic Standards for the Transfer of Regulatory Information
EudraVigilance	A data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA)
FDA	Food and Drug Administration – US consumer protection agency
HTA	Health Technology Assessment Program - provides all those who make decisions in the NHS with high-quality information on the costs, effectiveness and broader impact of health care treatments and tests
HTML	Hypertext Markup Language is a language designed for the creation of web pages with hypertext for display in a web browser
ISRCTN	The ISRCTN is a simple numeric system for the unique identification of trials. ISRCTN is also the name of the independent not-for-profit company that owns the ISRCTN numbering system.
Metadata	Data that describes other data -usually a set of metadata describes a single set of data, called a resource
MHRA	Medicines and Healthcare products Regulatory Agency - the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.
MRC	Medical Research Council - a publicly-funded organisation dedicated to improving human health support ingresearch across the entire spectrum of medical sciences
NLH	National Library for Health
NNTP	Network News Transfer Protocol, the Internet protocol used to post, distribute, and retrieve USENET (discussion group) messages
NPfIT	The NHS National Programme for Information Technology
NRR	National Research Register - a database of ongoing and recently completed research projects funded by, or of interest to, the NHS
OS	Operating System – software that that manages the hardware and software resources of a computer. Microsoft Windows is an example of an OS
PAS56	Publicly Available Specification 56 - describes the objectives of business continuity management and makes recommendations for good practice.
PDF	Adobe Portable Document Format - a standardised platform independent format for documents
SAE	Serious Adverse Event – (in a trial)
SAN	Storage Area Network – a way of organising data storage devices and networks to deliver large scale, easy to administer data storage
SDO	Service Delivery and Organisation - the Service Delivery and Organisation (SDO), Research and Development Programme aims to produce research evidence directed at improving the organisation and delivery of health services, and to promote the uptake and application of that evidence in policy and practice
SUSAR	Suspected Unexpected Serious Adverse Reaction - a reaction which is not expected

	from current knowledge of a drug's toxicity profile.
UKCRC	UK Clinical Research Collaboration.
UKCRN	UK Clinical Research Network - provides support for clinical research and facilitates the conduct of randomised prospective trials and other well-designed studies.
URL	Uniform Resource Locator which identifies a resource and provides a means of locating it
URN	Uniform Resource Names -intended to serve as persistent, location-independent resource identifier
URS	User Requirement Specification – this document is an example of this type of specification, which defines what a system should do from a user's perspective.
Web Service	Web services - provide a standard means of interoperating between different software applications, running on a variety of platforms and/or frameworks.
WHO	World Health Organisation
XML	Extensible Markup Language – a language developed specially for Web documents. It allows designers to create their own customized tags, enabling the definition, transmission, validation, and interpretation of data between applications and between organisations

19 Matrix of Research Relevant Regulations and Governance Requirements

MATRIX OF RESEARCH RELEVANT REGULATIONS AND GOVERNANCE REQUIREMENTS: ORGANISATIONS RESPONSIBLE FOR REVIEW AND APPROVAL

Matrix indicating the organisations where specific, formal approval processes exists to review various statutory and governance requirements at the beginning of research.

- Key**
- Regulatory / Governance Organisation with responsibility for review / approval
 - Regulatory Organisation with statutory responsibility for approval

Title	Organisations																
	ARSAAC	GTAC	Human Genetics Commission	Home Office	HFEA	HTA	MHRA	PIAG	UK Stem Cell Bank	UKXIRA	Ethics Committee	Funder	Local Authorities	NHS Organisation	Sponsor	Social Services Organisation / ADSS ¹	Universities
Statutory																	
Abortion Act 1967																	
Adults with incapacity (Scotland) Act 2000 ²																	
Age of Legal Capacity (Scotland) Act 1991																	
Age of Majority (Ireland) 1969																	
Blood Directive 2002/98/EC																	
Caldicot Committee - 1997 (Caldicot Guardians)																	
Children Act (Northern Ireland) 1995																	
Children Act 1989																	
Clinical Trial Regulations 2004																	
Common Law Duty of Confidentiality																	
Consumer Protection Act 1987/88																	
Convention for the Protection of Human Rights 1997																	
COSHH 2002																	
Data Protection Act 1998																	
Declaration of Helsinki																	
Environment Act 1995																	
Environmental Information Regulations 2004																	
Environmental Protection Act 1990 (Waste disposal)																	
EU Directive on the legal protection of biotechnological inventions 1988																	
Freedom of Information Act 2000																	
Genetically Modified Organisms (Contained Use) Regulations 1992/1996																	
Health and Social Care Act 2001 – Section 60																	
Human Fertilisation and Embryology Acts 1990 and 2001 ³																	
Human Rights Act 2001																	
Human Tissue Act 2004																	
Medical Devices Regulations 2002 and (Amendment) Regulations 2003																	
Medicinal Products Directive (2001/83/EC)																	
Mental Capacity Act 2005																	
Mental Health Act 1983																	
Patents Act 1977/2005																	
Sponsorship (Investigational Medicinal Products)																	
The Health Service (Control of Patient Information) Regulations 2002																	
The Ionising Radiation (Medical Exposure) Regulations 2000																	
The TSE Regulations 2002 (England; Scotland)																	
"Tissue and Cells Directive" 2004/23/EC																	
Traditional Herbal Medicines Directive (2004/24/EC)																	
Use of animals (Scientific Procedures) Act 1986																	
Xenotransplantation ⁴																	
Governance																	
Contracts and Agreements																	
Genetic Testing																	
Honorary Contracts																	
Indemnity																	
Peer Review																	
Research Ethics																	
Research Governance Framework																	
Research Monitoring and Audit																	
Sponsorship																	
Student Research																	

¹ Association of Directors of Social Services Research Group
² In Scotland, Adults with Incapacity (AWI) Specialist Committee carries out ethical review
³ Includes HFE Act (Research Purposes) 2001, the 1990 Act , HFE Act 2001 and Human Reproductive Cloning Act 2001
⁴ a bibliography of law and ethics of xenotransplantation is available @ <http://www.advisorybodies.doh.gov.uk/ukxira/law-ethics-biblio.pdf> (accessed 02/09/2005)