



*National Institute for  
Health Research*

**NIHR Information Systems  
High-Level  
User Requirements Specification**

**Portal and National R&D  
Management System**

DRAFT FOR CONSULTATION

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## 2 Document Controls

### 2.1 Amendment History

Version	Date Issued	Brief Summary of Change	Owner's Name/Signature
0.1	03/07/06	Initial draft heading outline	W McTaggart
0.2	16/07/06	Combines mind maps and further non functional text	W McTaggart
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1.0	14/08/06	QA, review and re-write	S.N. Walker

### 2.2 Approvals - Content

Version	Name	Organisation	Signature	Date
1.0	S.N. Walker	NIHR/UKCRN		14/08/06

### 2.3 Approvals - Quality

Version	Name	Organisation	Signature	Date
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### 2.4 Approvals - Distribution

Version	Name	Organisation
1.0	Prof Sally Davies	Department of Health

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).

### 3 Introduction

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

BRfBH defines a number of specific goals:

- Establish the NHS as an internationally recognised centre of research excellence;
- Attract, develop and retain the best research professionals to conduct people-based research;
- Commission research focused on improving health and care;
- Strengthen and streamline systems for research management and governance;
- Act as sound custodians of public money for public good.

Section 4 of the strategy – “Goal 4: Manage our knowledge resources” relates to the development of the information systems and information management processes that are required to underpin the whole of the BRfBH programme. It contains the following objectives:

- Create a ***unified knowledge management system*** to meet the needs of stakeholders;
- Use ***information systems to harmonise and simplify research processes***;
- Ensure research knowledge is made readily available to professionals in the service, researchers and the public;
- Facilitate the application of research outcomes to improve health and delivery of services.

And the commitment to implement:

- A unified and coherent system will be in place to meet our strategic knowledge management requirement;
- A single IT system for researchers and NHS research management which will “unify and simplify the administrative procedures associated with regulation, governance, reporting and NHS research administration”.

Following the publication of “Best Research for Best Health” the Department of Health has issued a number of work plans describing how the various implementation work streams will be taken forward. Implementation plan 4.2 “Bureaucracy Busting: Research Information Systems” (v1 February 2006 and v2 June 2006 - <http://www.dh.gov.uk/assetRoot/04/13/17/65/04131765.pdf>.) explains the initial steps that will be taken to provide:

- A national portal to support the National Institute of Health Research;
- NHS R&D information management and systems infrastructure to reduce the administrative burden of R&D proposals, applications and reporting;
- Definition of data standards and data handling processes;

This work is being lead by the NIHR Information Systems team which will be working closely with:

- The other BRfBH work streams, in particular the development of the NIHR Faculty and also advice services (work stream 4.1);
- UKCRN to ensure that the emerging systems requirements of the NHS networks are addressed in a strategic and integrated manner;
- HTA, SDO and the NIHR CCF with regard to R&D commissioning data and systems.

## 4 Purpose of This Document

This document defines the outline requirements for the portal and portal based systems supporting the National Institute for Health Research. This specification contains only those high-level, common requirements that will apply to all aspects of the services provided through the portal.

Further documentation will be published in due course and this will include:

- Detailed user requirements for the NIHR portal services;
- Detailed user requirements for R&D Management Systems;
- Mapping of current organisations, systems and processes.

It is likely that new versions of this document will be issued from time to time as the detailed requirements are developed.

## 5 Definition of Terms

### 5.1 Portal

The secure, internet web-based NIHR portal will provide a single gateway to applications, information and knowledge bases for the broad community of NIHR stakeholders including researchers, R&D managers, Department of Health managers and the research networks.

The key features of the portal include:

- **Access/search:** To allow a user to get all the information needed (but no more) in the desired context;
- **Classification:** The portal will classify and describe all information so that it is delivered to the user within the context needed;
- **Collaboration:** to enable individuals to collaborate regardless of their geographical location.
- **Personalisation:** The information provided to individuals using the portal will be personalised to match that person's role, preferences, and habits.
- **Expertise and profiling:** Expertise and profiling is essential for the collaboration element of a portal. Individuals within an enterprise will be profiled according to their experience and competencies. The portal will provide the facilities to allow members of a project to collaborate with each other based on these profiles.
- **Application integration:** The portal will allow individuals to deliver, access, and share information regardless of applications used.
- **Security:** The portal will provide information to users based on security clearance. The user will log on and be given access only to information that the user is authorised to access.

### 5.2 NHS R&D Management System

The aim is to develop national web-based applications that will be used by people in NHS organisations, clinical networks, commissioning agencies, and the Department of Health to manage R&D funding, proposals and projects from conception to completion. These will be based on common, clearly defined, work flow processes and data standards. A key objective will be to ensure that minimum time and effort are involved in the preparation, submission and review of proposals.

Development of these applications will take into account the integration and standardisation of previous investments in NHS R&D management information systems.

## 6 System Objectives

### 6.1 NIHR Portal

In due course it is intended that this will provide:

- A single point of contact for all defined users to obtain information about NHS research;
- The method of access to a single nationwide application (the R&DMS) for the submission and management of research applications. The high level user requirements for the R&DMS are described elsewhere in this document;
- A single point of entry to a data repository containing reports from research projects, all research policy documentation and any other quality controlled research information;
- Access to guidance resources that will help researchers to submit better applications. In particular these are likely to be provided via the advice services that are being delivered via work stream 4.1;
- Tools and resources to help improve communications between research teams;
- Controlled access to all the data resources and applications that it contains.

### 6.2 Integrated R&D Management System

The R&DMS will embody most aspects of the 'bureaucracy busting' changes resulting from work stream 4.2. In particular the aim is to:

- Enable researchers and research managers to access and manage the information and guidance required to operate efficiently and participate in high quality R&D with proper governance;
- Reduce the administrative burden of proposals, applications and reporting, releasing effort to manage outcomes;
- Enable more effective monitoring and review.

The initial work that is being done to map current organisations, their systems and system suppliers will help to determine the initial and long term scope of the R&DMS. It will also help to define the relationship between the R&DMS and the R&D management systems that are currently used nationally and in individual NHS organisations and elsewhere. This work will focus on existing information flows and will lead to the definition of the streamlined processes and rationalised systems that are required to deliver some of the key objectives of "Best Research for Best Health". A specific focus of this work will be to consider the role of the various forms-based systems that are currently used in a number of organisations and to develop a more data driven approach which is not based upon the transfer of data between multiple disparate systems.

Specific objectives for the R&DMS include:

- Enabling the Department of Health to generate good quality statistics about the status of all NHS sponsored research projects as a by-product of the standardised information that is routinely input by researchers and R&D managers throughout the project lifecycle;
- Enabling single entry of information required for ethics review, NHS site-specific permissions and authorisation of clinical trials;
- Ensuring that consistent and common data standards and data management processes apply throughout the project life-cycle and that these are enforced within information systems;
- Ensuring that, where appropriate, researchers and research managers can collaborate on-line to complete proposals;
- Minimising the use of paper during the proposal process;
- Improving productivity for researchers and research managers;
- Developing a data resource of R&D projects that will support R&D commissioning and clinical networks;
- Ensuring that data is re-used wherever appropriate thereby avoiding the need for duplicate data entry;
- Ensuring that information about projects is easily retrieved by authorised users in a variety of forms;
- Providing authorised users with alerts regarding the status of projects and actions required;
- Supporting the exchange of standard, clearly defined datasets with external organisations and systems.

This list is not comprehensive and the full user requirement for the R&DMS will be developed in consultation with a wide range of stakeholders including system suppliers.

## 7 Relationship between the Portal and the R&DMS

The portal will provide the method of access to the R&DMS and to other resources (such as data repositories) which will be useful to researchers and other users.

The R&DMS will be functionally independent of the portal and other such applications may be added to the portal in the future.

The following diagram gives a simple illustration of how the portal will provide secure, managed access to specific applications as well as supporting more general access to particular types of information and services.

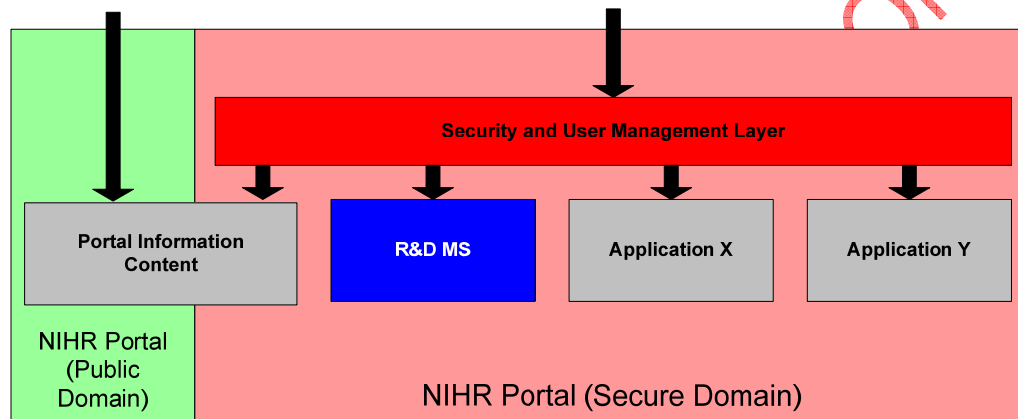


Figure 1

## 8 Users and Roles

A variety of users will be able to access the Portal and through it the R&DMS to undertake a number of activities. These will range from looking up information, submitting research approvals, viewing portfolios of activity and generating reports for various governing bodies. The table below summarises some typical user's roles.

User type	Portal Role	R&DMS Role
Sponsors of research including pharmaceutical companies and academic organisations, NHS.	'One stop' access (and potential contribution) to information about research	'One stop' entry for trial information and approval applications/responses.
Investigators, Research Nurses, Trial Project Managers	'One stop' access (and potential contribution) to information about research	'One stop' entry for trial information and approval applications/responses.
R&D managers, research governors, regulatory bodies. 'Approvers'	'One stop' access (and potential contribution) to information about research	Central location for overview of all research projects, their activity and approval status.
Funders of research	Contribution to portal content	Data interchange for funding applications.
Patients, public	Ability to openly access information about clinical research	Access to information about research and eventually data on their own participation in research projects

Not all of these user interactions will be possible from the launch date of the portal, but they will become available through 2007 and 2008.

## 9 User Interface Characteristics

The portal will provide a consistent look and feel throughout all the information resources, applications and other content.

- The portal will contain resources and systems that will be either:
  - Freely accessible to everybody or
  - Require controlled access.
- All users who need to access any of the controlled content or applications will be required to register with the portal, have their identity verified and subsequently log into the portal to access the controlled areas.
- The portal will provide a single sign-on for access to controlled areas. Following this single sign-on, users will not need to further identify or log-in to any resource or application during a session.
- The portal will be designed such that users who are not familiar with medical research will be able to find and use the resources that are provided and that are available to them.
- A comprehensive search capability will be provided allowing all documents in the data repository to be searched for key words.
- The portal and all its publicly accessible resources will be designed for accessibility by the disabled and will therefore be compliant with the Disability Discrimination Act.
- A limited number of role-based views will be provided so that users are presented with information in the most relevant way for their needs.
- The portal will include facilities to be “pushed” to users as required.

## 10 Main Business Processes

### 10.1 NIHR Portal

Few if any business processes will be provided directly by the portal. The portal will mainly provide access to a range of useful information and facilities including the R&DMS. The following diagram illustrates the type of functionality that may be provided:

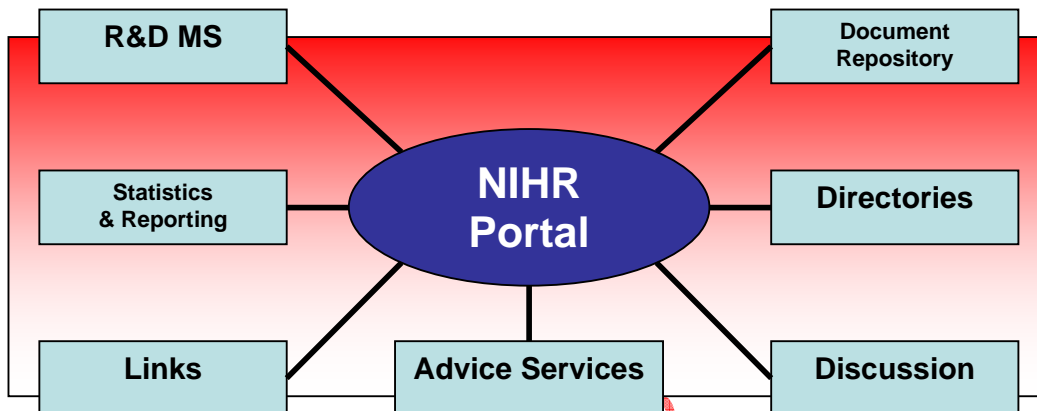


Figure 2

Following consultation with a wide range of stakeholders a long list of features that people would like to see in the NIHR portal has been developed. These include:

- Directories of researchers and research managers;
- Links to guidance and expert advice on methodology;
- Information for the public and healthcare professionals regarding trials and recruitment into trials;
- Enabling the sharing of information between the NHS and academic organisations;
- Frequently asked questions;
- A national document store accessible via the web;
- A webpage for researchers for access to COREC, R&D, PIAG, EuDRACT and other regulators;
- One portal for governance and ethics;
- A comprehensive portal service that meets the needs of managers, researchers and the Department of Health

#### 10.1.1 External Interfaces

The portal will contain information resources that are actually managed and produced by many different organisations. The portal will provide a consistent interface for the presentation of those resources so that the user sees a uniform collection of information. The portal will provide the technical infrastructure within which the information providing organisations will operate, so that they are relieved from the responsibility of providing these on a 24/7 operating basis.

Development of systems and processes that will enable researchers to access information derived from the Care Records Service is a longer term goal for the NIHR IS Programme.

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## 10.2 NIHR Research & Development Management System

Access to the R&DMS will be via the NIHR portal on the internet. Only secure access will be allowed. A mechanism for validating users and providing secure accounts will be established.

Key aspects of the system are described below:

### 10.2.1 Characteristics

**Secure** – The R&DMS will keep information securely, so that it is available only to individuals who have the right to use it. Security will be built into all aspects of the R&DMS design.

**Web-Based** – all users will be able to use the R&DMS from any internet connected computer using only a standard web browser. This simplifies the implementation of the system for both users and system administrators;

**Single Point of Entry** – The R&DMS will be accessible only through the portal. Once a registered user has logged into the portal they will be able to access all information and applications (including the R&DMS) that are available to them without needing to log in to each application individually. The R&DMS will provide a single point of entry for research approvals;

**Published Integration Standards** – the programme will publish open standard interface standards information to enable external systems to interact with the R&DMS;

**Standardised Approach** – the R&D MS will support and enforce a standard, common, data based approach to the submission, review, approval and reporting of R&D projects.

### 10.2.2 Users of the R&D MS

Authorisation of users and the functionality and data that users can access will be carefully controlled with full audit trails enforced with regard to changes in user information. In due course the system will support research passports.

Potential users could include:

- NHS staff including researchers, clinicians, R&D managers and other managers;
- University staff including academics, researchers, finance and contracting;
- Department of Health;
- UKCRN and clinical research networks;
- Ethics Committees;
- Commissioners/Funders including MRC, Wellcome, HTA, CCF, Charities;
- Regulators including MHRA;

- Commercial organisations including pharmaceutical companies, contract research organisations, systems suppliers;
- The public and NHS patients;

The specific functionality that the R&DMS is intended to provide include:

- Life Cycle Management – management of R&D projects from conception to completion including proposal development, proposal approvals, project management and reporting and outcomes monitoring;
- Reporting
  - Access to approval status by various agencies;
  - Reporting mechanisms for various agencies;
  - Generation of annual reports for national and local management purposes;
- Notifications and Alerts - The R&DMS will send messages to users when specific information is changed, or when defined events occur. These alerts will be sent by email or by SMS messages. The system may also support the escalation of actions contained in the workflow for example; if reviewer X does not complete required actions in the prescribed timescale this situation would be notified to a higher authority (as defined in the workflow);
- Data Store – the R&DMS will be based on a data view that will enable and enforce structured information to be derived from proposals and projects for management information and other purposes;
- Document Archive - a facility that will enable researchers and research managers to confidentially store all documents related to proposals and projects;
- Portfolio Management – the management of groups of projects
- Single Project Management
- A facility for researchers (including research nurses, project managers and trial sponsors) to enter, once only, the information required to support funding and ethics proposals. Workflows will be defined which will enable relevant information to be passed to and accessed by reviewers and authorising authorities in order to structure and streamline the project approvals process;
- An easy-to-follow (possibly wizard-based) on-line guide to the approvals process to allow less experienced researchers to navigate the logistics of setting up research projects more easily and rapidly;
- A “dashboard” view that would enable users to focus on their projects;
- Submission of applications to MHRA for CTAs;
- A mechanism to ‘sign’ such approval applications so that they can be submitted electronically;
- A method of electronic notification and feedback from ‘approvers’ of research with any comments/concerns for researchers to address;
- A transaction service for communications between applicants and approvers to address/resolve comments/concerns;
- Provide a method of approvers to confirm (or decline) and sign formal approvals;
- Provide ‘real time’ overview for research governors and other appropriate authorities to view status of approvals and communications relating to approvals;
- Allow reporting of safety events (SUSARS) to the Eudravigilance/MHRA competent authorities;

- A search and filter facility to allow easy retrieval of information relating to particular projects and investigators;
- Reporting tools for users such that regular mandatory reports (possibly a unified, integrated report for various regulators) can be semi-automatically produced;
- Integration with and population of various national databases of research activity;
- The R&DMS will develop, provide and maintain data standards (a data 'spine') that will allow the system to 'talk' to other Information Systems;
- Additional functionality and integration will be established as the system is further developed from 2006 to 2011.

It should be noted that the workflows and approvals processes that will be supported by the R&D MS are dependant on agreement being reached by the various parties associated with these activities. Professor Sir John Lilleyman is currently chairing a group which is addressing the standardisation of datasets and processes.

### **10.2.3 External Interfaces**

Public and secure APIs are required for portals and other applications to interact programmatically with the system without using the native web user interface. All APIs will adhere to conventional SOAP and WSDL standards and will have documented open standards to allow users/suppliers to the NIHR R&D Management System appropriate access.

### **10.2.4 Electronic Data Interchange and Reporting**

The R&D management system will have the capacity to import and export data in predefined XML schemas, and to generate reports in formats such as Word, Excel, CSV and PDF.

The R&D management system will also provide activity logging to enable tracking of report production so that it is possible to see which users have produced which reports. It will also automate alerts to provide critical information to end users in the event of significant changes or immediate needs for response.

## 11 Outline Performance Requirements

The system will deliver the following performance characteristics given these sizing requirements:

The system must simultaneously support:

- A throughput of 2,000 new research applications per month;
- 200 concurrent users for the R&DMS system;
- 1,000 concurrent users for the rest of the portal services.

The system must respond to requests for any static data download within 2 seconds, i.e. the download must start within 2 seconds of completing the request.

The system must respond to any search request within 10 seconds of completing the request.

The system must be designed to allow scalability to enable:

- Throughput of 4,000 new research applications per month;
- 500 concurrent users for the R&DMS;
- 1,500 concurrent users for the rest of the portal services.

within the proposed design architecture, by the addition of hardware and software at a cost proportionate to the increase in performance.

## 12 Design Constraints and Standards

All data delivered by the portal, whether from static resources or from application systems must comply with HTML 4.01 or XHTML 1 or PDF Version 1.4 or later

All data and applications delivered through the portal must be fully usable with all common web browsers, to include Microsoft Internet Explorer, 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 data or applications delivered through the website. In particular client software that requires a separate commercial license to use is not acceptable.

All data and applications delivered through the portal must comply with the usability standards defined by:

- Web Content Accessibility Guidelines 1.0 (w3.org) *and/or*
- E-Government website guidelines (including Quality standards).

Where there is any difference between these standards, the option providing wider accessibility will be used.

## 13 Reliability, Availability and Maintainability

The portal and all associated application systems must be designed to allow for continuous operation on a 24 hour, 365 day per year basis.

The portal and all associated systems 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.

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 so that the failure of any one server or other component cannot cause interruption of service.

It must be possible to upload new material to be viewed through the portal without interruption to normal use.

Essential maintenance to applications must be capable of performance without interruption to service.

If downtime is experienced for any application delivered through the portal, a notice must be displayed on the portal stating the expected time to repair.

## 14 Security/Confidentiality

These security requirements are the common, minimum requirements that will apply to the portal and all associated application systems. Individual data resources and applications will have significantly more complex and restrictive security requirements which will take precedence for the use of those resources and systems.

The portal and all applications associated with it will comply with all UK legal requirements, including, in particular Data Protection.

The portal and its accompanying R&DMS system is **not** suitable for direct interfacing with Connecting for Health in its initial releases, at least until the end of 2008. A full security study will be required before this is possible.

All data accessible through the portal will be flagged at the lowest level of granularity available to indicate the classification of access that is to be provided to it.

All applications that may access data associated with the portal or any external data will provide access to those resources only through a valid sign-on using a standard authentication method.

All users seeking to access any resources other than those that are flagged for public non-controlled use must log in to the portal using a standard secure authentication method. This must then allow them access only to those resources that their identification and classification permits.

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 any other resource or application through the portal.

All user access to the portal that involves access to non-public data should be logged, so that a record of the user identity, time in, time out resources and applications visited and data changed, is kept.

Audit trails will be developed and enforced with regard to all the changes made to data accessible through the portal, (including the non-controlled data).

Inactive logged-in users must be logged off after a period of 10 minutes.

The portal 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 portal and its application for other purposes and any other such exploit. The strength of the portal design and implementation will be tested by periodic penetration testing as well as other audit and validation processes.

An intrusion detection system will form part of the portal design. This system is intended to alert system management that an attack on the portal may be under way and allow them to take appropriate countermeasures.

All data accessible through the portal, all application code, all application associated data and all portal 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 portal or the entire portal state from scratch.

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

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## 15 Implementation Timeline

ID	Task Name	2007												2008											
		Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul		Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
1	<b>NIHR Portal</b>																								
2	First Draft User Requirements and Options Appraisal Published																								
3	Confirm Approach for Portal Procurement and Implementation																								
4	Implementation and Testing NIHR Portal v1																								
5	Version 1 NIHR Portal Launched																								
6	<b>R&amp;DMS</b>																								
7	Draft User Requirement Published																								
8	Proof of Concept Trials ???																								
9	Confirm Approach for R&DMS Procurement and Implementation																								
10	Piloting Phase																								
11	R&DMS Available for Full Use																								

The portal will be launched in March 2007, with a limited number of portal resources and without the R&DMS. The programme will work with a range of users to identify priorities for early implementation. Further resources will be added to the portal throughout 2007 and 2008 using a phased approach. For example:

**Phase 1** - Portal service for researchers and research managers applying for funding, linking to existing sources of forms, data and reports. **Benefit** - consistent applications under current processes and formats; increased speed to application;

**Phase 2** - Advanced Portal service for researchers and research managers applying for funding using a revised process and tools facilitated through the portal. **Benefit** - even greater consistency of applications, reduced effort and time to application, reduced time to decision;

**Phase 3** - Advanced Portal services plus R&D process management (the R&DMS), for researchers and research managers. In addition to Phase 2, the provision of additional tools accessed via the portal to monitor and report on financial and milestone progress of all funded projects. **Benefit** - as Phase 2 plus continuous performance management capability on funded projects;

**Phase 4** - Add to Phase 3 a national research results repository, with indexing and meta-data tags to applications and in-life monitoring reports on each project, for researchers and research funders; and for general NHS staff via the National Knowledge Service/National Library for Health. **Benefit** - greater access and use of research results;

**Phase 5** - Add to Phase 4 a tool for research portfolio planning, for research funders. **Benefit** - avoid unintentional duplication of research; support research plugging gaps in knowledge

The R&DMS will be piloted in September 2007 and will become fully available in April 2008.

## 16 Glossary of Terms

API	Application Program Interface – the method by which one program can work with another
CCF	Central Commissioning Facility - manages and administers the NHS National Research and Development Programme
CfH	Connecting for Health – previously known as the National Programme for IT (NPfIT) – see <a href="http://www.connectingforhealth.nhs.uk">www.connectingforhealth.nhs.uk</a>
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
CTA	Clinical Trial Authorisation - issued by MHRA and necessary to launch a clinical trial
DH	Department of Health
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
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.
NPfIT	The NHS National Programme for Information Technology
PDF	Adobe Portable Document Format - a standardised platform independent format for documents
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
UKCRN	UK Clinical Research Network - provides support for clinical research and facilitates the conduct of randomised prospective trials and other well-designed studies.
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.
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