



**NIHR Information Systems Programme  
Contracting for Hosting Services**

Programme Board Meeting Date	N/A		
Agenda Item			
Submitted By	Andy Childerhouse (Programme Manager)		
Document Name	NIHR IS Programme Brief	Filename	20071130 NIHR IS Programme Brief v1.0.doc
Purpose of Document	The Programme Brief defines the Programme’s objectives and the required outcomes.		
Summary of Document	<p>The Programme Brief provides:</p> <ul style="list-style-type: none"> <li>▪ an outline description of the new capability to be delivered by the Programme;</li> <li>▪ a definition of Programme scope;</li> <li>▪ an estimation of Programme costs;</li> <li>▪ an overview of how benefits will be achieved;</li> <li>▪ an initial listing of candidate projects;</li> <li>▪ a summary of key risks;</li> <li>▪ an overview of the Programme governance arrangements and the relationship between the Programme documentation that will be produced.</li> </ul> <p>The Programme Brief will be updated to reflect significant changes to the Programme as and when they occur (e.g. changes to the Programme scope, costs and candidate projects). As such, the Brief is designed to be a “living document” that will provide a key and current point of reference for all involved in the Programme.</p>		
Board Action Required	For Information	For Approval	Other
	X		

# NIHR IS Programme

## Programme Brief

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## 1. Amendment History

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## 1 Approvals

### Content

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## 3 Management Summary

### 3.1 Introduction

#### 3.1.1 Origins of the Programme

The Department of Health's Best Research for Best Health – a new national health research strategy sets out the government's health research strategy for England covering the period to April 2010.

Implementation plans covering components of the strategy have been developed and published; the National Institute for Health Research (NIHR) has been tasked with delivering them.

This Programme Brief describes the plans and activities of the NIHR Information Systems Programme, which is intended to deliver Implementation Plan 4.2 Bureaucracy busting: Research information systems, as well as providing ICT support for the NIHR as a whole.

#### 3.1.2 Purpose of this document

This Programme Brief responds to the Programme Mandate.

It acts as the initial comprehensive statement of intent of the Programme: what it will do when, what benefits will be delivered and what risks it entails. It acts as a checkpoint for the Programme Board to confirm that the Programme should proceed, and then provides an ongoing guide for the Programme and its constituent Projects as they proceed.

## 3.2 Summary of Strategic Case

### 3.2.1 Vision for the Programme

The government's aim is to promote a regulatory and governance environment that both facilitates high-quality research and protects the rights, dignity and safety of those who agree to take part. The government is committed to promote research governance processes that are proportionate to risk, and to unify and streamline administrative procedures associated with regulation, governance, reporting, research administration and approvals, ensuring that procedures and data input are, wherever possible, undertaken once for multiple uses.

Its aim is to develop a unified IT system for researchers and NHS research management which will populate information systems for the many users and parties interested in health and social care research, and will make information supporting regulatory approvals and permissions available to those who need it.

Fragmented processes and disjointed IT present significant barriers to researchers and discourage inward health research investment in the UK. They also manifest themselves in:

- Duplication of data held across multiple systems;
- Inconsistent data standards being applied across different systems;
- Data integrity issues;
- An inability to present a “whole project” view to researchers;
- Inefficiency;
- Time consuming;
- The absence of clearly defined workflows;
- The lack of transparency and predictability in the approvals process.

The NIHR IS Programme will address these issues by delivering seamless, streamlined health research and management processes underpinned by a standardized and unified IT architecture. In so doing, the Programme will stimulate increased investment in health research in England by making the approval and management of health research projects more straightforward, streamlined and consistent.

This will be achieved through the provision of IS solutions to simplify the approvals process and to provide better management and reporting tools for research projects. This will be underpinned by standard data definitions/data dictionary and supported by the delivery of a unified IT architecture. The new architecture will be centred around a WEB Portal providing access to a unified Research and Development Management Information System (R&DMIS) capability that will access the disparate R&D systems to provide a single view of any given research project from approval through to project completion and publication.

### 3.2.2 Scope and Objectives

The Programme will address functions and processes to deliver the following objectives:

- Improve predictability of timeframes for research approvals.
- Reduce approvals timescales.
- Provide effective overarching research management.
- Provide monitoring for research study recruitment levels.
- Provide monitoring for funding levels.
- Support the NIHR Faculty.
- Support management of the NIHR Portfolio and networks through UKCRN.
- Maintain appropriate security and confidentiality of data held and processed by those systems within the scope of the NIHR IS Programme.

The following is excluded from scope:

- Changes to systems owned by bodies such as MHRA and NRES , except where explicit agreement with these bodies has been reached.
- 
- Local research system data integrity.

The Programme will deliver its objectives for organisations and activities that take place in England. There is the potential for some of the activities undertaken and solutions delivered in England to be more widely applicable in Scotland, Wales and Northern Ireland. In such cases the Programme will endeavour to ensure there is no impediment to these countries subsequently taking what the Programme has delivered and applying it themselves, as part of their own Programmes of work at their cost.

In addition, the Programme is charged with some specific responsibilities with regard to UKCRN which are UK-wide. These include delivery of the UKCRN Portfolio Database and Portfolio Management System.

### 3.3 Summary of Economic Case

To deliver the Programme objectives, there are three main areas of business processes that the Programme will need to concern itself with:

- Research projects/studies/trials
- Human resources and client relationship management (CRM)
- Financial management

The key systems components and outputs to be delivered are:

- Information and Data Architecture
- Technology Architecture
- Data standards, data definitions, unique identifiers interoperability and security
- NIHR Portal
- Research and Development Management Information System (R&DMIS)
- Portfolio database, including subsuming within it the National Research Register
- Local Portfolio Management System (LPMS)
- Systems support for the Central Signoff Unit and National Advice Service
- Rollout of electronic data capture to support clinical trials.
- Systems support for CTU registration.
- Systems support for the NIHR Faculty and its members
- Systems support for the Research Passport and honorary research contracts

In delivering these outputs the Programme will provide the systems support to allow other Programmes of work to deliver the far-reaching objectives listed in section 1.2.2. As such, there are no directly measurable benefits of this Programme. Rather, the benefit measure in each area of output will be whether the output does indeed provide sufficient ICT support to allow others outside this Programme to deliver their objectives. This will require the Programme to remain in very close contact with the relevant stakeholders at all stages of the Programme's life.

The main strategic risks to the Programme's successful delivery are:

- As with any ICT infrastructure Programme, there is a risk that what is delivered by this Programme may not be in step with what is required by others outside the Programme to achieve the strategic benefits. In this situation, it would be possible for this Programme to deliver successfully a series of ICT solutions, but with no resulting strategic benefit.
- Failure to engage stakeholders effectively and efficiently, leading to a lack of support for the Programme and failure to meet the real needs of the R&D community.
- The Programme scope is not clearly defined and stable leading to scope creep, poorly defined requirements, delays, escalating cost and failure to deliver.
- The Programme is driven by short-term issue resolution and the delivery of tactical solutions, rather than meeting strategic need.

- The true cost of delivering the Programme may be significantly greater than current estimates leading to budgetary shortfall.
- Insufficient resource is available to the Programme, both in terms of numbers and skill set, leading to delays and poor quality delivery.

### 3.4 Summary of Financial Case

The Programme will be required to respond to new requirements as they emerge, and as the business requirements change. Consequently, the funding requirement for the IS Programme cannot be fully and accurately determined at this stage.

In response to this situation, the Programme has adopted a “bottom-up” approach to resource estimation. Based on this, the best estimate of the cost of known work is in the region of £6.5 - £8M over three years from April 2007, subject to detailed costing of individual projects.

However, recognising the uncertainties inherent in these estimates, and that not all the required work is yet known, the Programme has applied an Optimism Bias adjustment, in line with HM Treasury and DH guidance. This shows that the Programme is currently susceptible to substantial cost variation. Based on this, the projected actual resource requirement becomes £6.5M + 100% to £8M + 200% which equates to £13M - £24M from April 07.

The Optimism Bias adjustment will be refined as the Programme proceeds and gains greater clarity on options, issues and requirements, stakeholder buy-in, selection of contractors and interfaces with other systems and organisations. This is in line with HM Treasury and DH guidance.

The Programme Board will manage this uncertainty by taking an incremental approach. It will review financial progress regularly and by reporting whether changes in the cost of the Programme’s components call for a reassessment of priorities or overall budget or both.

### 3.5 Summary of Management Case

The Programme represents a substantial and complex undertaking which requires a robust project management approach. The Management Case describes the related techniques and outputs, which include:

- Programme Mandate
- Vision statement
- Blueprint
- Project portfolio
- Stakeholder management strategy
- Communications plan
- Resource management strategy
- Programme plan
- Risk management strategy
- Issue resolution strategy
- Quality management strategy
- Project business cases

The scope and scale of the Programme’s work requires many people to be involved, including stakeholders, internal specialist staff, external specialist advisers, technical contractors, ICT service providers and others. The appropriate and timely sourcing of all these individuals is critical to the success of the Programme.

### 3.6 Summary of Commercial Case

The Programme will undertake a series of procurements, some large and complex and others small and simple. In each case the procurement route will be selected to match the items being procured.

In all cases, procurements will comply with EU law on public procurement, and will follow a set of key principles, drawn from published OGC best practice.

- Ensuring competition
- Ensuring value for money
- Demonstrating transparency
- Stimulating market creation
- Underpinned by business cases

## 4 Strategic Case

### 4.1 Drivers and Context

The Department of Health document, Best Research for Best Health – a new national health research strategy sets out the NHS Research and Development strategy in England, with the objective of delivering the following goals over the 5 years up to April 2010:

- 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 focussed on improving health care.
- Strengthen and streamline systems for research management and governance.
- Act as sound custodians of public money for public good.

Implementation plans covering each component of the strategy have been developed and the NIHR has been tasked with delivering them.

The plans relate to six broad areas, as follows:

- Establishing the National Institute for Health Research (NIHR)
- NIHR funding transition
- NIHR Faculty and research capacity development
- NIHR research systems and governance
- NIHR research infrastructure
- NIHR projects, programmes, units and centres

This Programme Brief describes the plans and activities of the NIHR Information Systems Programme, which is intended to deliver Implementation Plan 4.2 Bureaucracy busting: Research information systems.

## 4.2 Programme Scope and Objectives

The scope and objectives of the Programme are documented under the following headings:

- Function and process coverage.
- Geographical coverage.
- Organisational coverage.

### 4.2.1 Function and process coverage

The Programme will work with NRES, MHRA and other approvals bodies to:

- Make research approvals and permissions more predictable. The Programme will provide the IS infrastructure to help ensure that research approvals take a more predictable amount of time and that the approvals process is transparent.
- Make approvals quicker. The Programme will provide the IS infrastructure to support researchers by reducing/compressing approvals timescales.
- Enable joined-up research management. The Programme will provide IS facilities to give a clear view of the type, volume and value of people and project-based research being conducted in England, so that researchers (e.g. in universities and Trusts), NIHR research networks, research managers and others can manage more effectively the approval and conduct of research projects.
- Enable monitoring of research study recruitment levels. The Programme will provide IS facilities to monitor research study recruitment of participants to well-designed studies and subsequent follow-up, improving assurance and control over the recruitment process.
- Enable monitoring of funding. The Programme will provide IS capability to help plan and monitor expenditure of NIHR and NIHR partners' funds.
- Support the NIHR Faculty. The Programme will provide IS capability to support the NIHR Faculty to manage and maintain Faculty membership and to support the Faculty members, themselves. Additional requirements are likely to arise from the Faculty workstream and from those bodies (e.g. universities) that will have a direct interest in Faculty management. These requirements will be evaluated in light of the stated Programme scope.
- Support UKCRN. The Programme will provide the IS capability to support the UK Clinical Research Network in creating a world-class environment for clinical research.
- Process modelling and design.

The following is excluded from scope:

- Local Research Project Efficiency. The IS Programme will not deliver enhancements to research systems owned by external organizations in order to make research projects more efficient. It is judged that the resources and complexity involved in such an undertaking, together with the associated risk, would be too great when set against the potential benefits.

The one exception to this is those systems provided by UKCRN, as described above.

- Local Research System Data Integrity. The IS Programme will not be responsible for data integrity in local research systems. However, it will specify data standards for those systems within the scope of the Programme and these standards will apply to data received from local systems. As such, the Programme reserves the right to validate and reject data that does not conform to the appropriate standards.

#### 4.2.2 Geographical coverage

While recognising the difference between the four countries of the UK, the aim of the UK Health Departments is to maintain compatible systems and processes so as to remove barriers to UK-wide research. The primary focus of the Programme is to deliver its objectives for organisations and activities within the remit of the NIHR in England. There is the potential for some of the activities undertaken and solutions delivered in England to be more widely applicable in Scotland, Wales and Northern Ireland. The Programme will endeavour to ensure there is no impediment to these countries subsequently taking what the Programme has delivered and applying it themselves, as part of their own Programmes of work and at their own cost. The definition and implementation of data and interface standards and a common data dictionary will help facilitate this.

In addition, the Programme is charged with some specific responsibilities with regard to UKCRN which are UK-wide. These include delivery and extension of the capability currently provided by the UKCRN Portfolio Database and Portfolio Management System. This objective may be achieved through the extension of these systems or by their replacement with a procured solution. A preferred approach will be determined following a full evaluation of the available options.

#### 4.2.3 Organisational coverage

The Programme scope encompasses all research in England that could fall within the remit of the NIHR. Consequently, any organisation that is engaged in research that is funded by the NIHR or which could use NIHR resources or infrastructure could potentially fall within the remit of the Programme.

## 5 Economic Case

This section contains material that is relevant to the economic case of various Programme business cases. Each business case will draw on this section as it is developed. See section 5.1.15 for more details of the business case development process.

## 5.1 Key Processes within Scope

The NIHR IS Programme will work with stakeholder organisations (SDO, HTA, etc.) to deliver IS solutions for those business processes that are within scope. This may entail changes to existing business processes being proposed. However, as noted earlier, it is outside the scope of the Programme to initiate the re-design of existing processes.

The business processes that are within scope and for which the Programme will deliver IS solutions are:

### 5.1.1 Research projects/studies/trials

1. Funding application
2. Commissioning
3. Bid management
4. Contract award
5. Contract management (including approvals, sign-off, reporting and payment authorisations)
6. Trials registration
7. Study conduct, including data capture (eDC) and database deposit
8. Interfaces with mechanisms for access to outputs, and for publication and dissemination of study results.

### 5.1.2 Human Resources and Client Relationship Management (CRM)

1. Stakeholder Relationship management (ranging from simple contacts lists, through committee management, through to relationship management)
2. Faculty Management
3. Research passport
4. Services to individual researchers
5. Increasing the speed of recruitment and numbers recruited to clinical trials
6. Collaboration and networking
7. Peer review

### 5.1.3 Financial Management

1. Programme Budget setting and allocation
2. Payment scheduling and authorisation
3. Infrastructure and other non-project based support (i.e. hosting and maintenance costs, etc.)

## 5.2 Key Systems Components within Scope

### 5.2.1 Information and Data Architecture

There is currently no set of data standards or supporting data dictionary common to all of the systems that support the Health Research process. The absence of a standard data set has resulted in local rules being applied to the storage of data

relating to people, funding, infrastructure and projects. This has led to inconsistency, disjointed IT, duplication of data and data integrity issues.

The business processes, together with the systems that automate and support them, need to be underpinned by a consistent and unified data architecture. Without such architecture, it will not be possible to deliver applications and services that are seamless and unified.

The four fundamental information objects to be defined by the Programme are:

Studies – any time limited research study which utilises NIHR resources.

People – any person involved in undertaking or managing research adopted (or intended to be adopted) by the NIHR; any person involved in the lifecycle of such research, including research subjects or users

Money – any financial resources committed directly or indirectly by the NIHR and its partners to supporting studies, people or facilities

Facilities – any organisation or group of organisations (networks) funded by the NIHR to support research

### 5.2.2 Technology Architecture

The technology architecture describes the computational resources deployed to support the information and business architectures.

A complete technology architecture may include descriptions of data centres, networks, operating systems, databases and other software platforms, systems management as well as specific applications.

The proposed technology architecture will be described via a schematic and supporting text. It will encompass the computational style, standards and key system components of NIHR information systems, differentiating between systems to be provided by the NIHR IS programme and those provided by others with which it will interface.

The proposed technology architecture will have the following features:

- Loose-coupling – a base assumption is that the overall system will be composed from a series of semi-independent software applications which nonetheless have the capability of appearing to the user to be a single system
- Service orientation – the fundamental way in which loose-coupling will happen is through the exposure and consumption of services
- Internet enabled – it follows that the underlying network architecture will be the Internet, or if not the Internet use TCP/IP
- Software as a Service – defined as a software application delivery model where a software vendor develops a web-native software application and hosts and operates (either independently or through a third-party) the application for use by its customers over the Internet.

### 5.2.3 Standards

Data - In keeping with the above, the standard way for representing data should be XML, the primary purpose of which is to facilitate the sharing of data across information systems.

Data definitions – data definitions will be developed in response to need.

Unique identifiers. Key system objects will be identified by URLs. This is not intended to be a hard and fast rule but should be applied where it makes sense to do so. For example, each research project should have a URL; each person in the NIHR system should have a URL, to serve as the basis for personalisation and identity management.

Interoperability – defined as the ability of two or more systems or components to exchange information and to use the information that has been exchanged. The NIHR architecture includes at least two methods for achieving interoperability, both of which rely on common standards:

- Web-services – the provision of a service by one system component to another. For example a ‘research project’ service running on one NIHR system might return the details of a research project to a requesting programme that submitted a unique identifier. RSS is an XML based service with very wide usage and applicability and could be quickly and easily adopted as a standard web service for sharing information across NIHR
- Data exchange in the form of datasets. For example, the CCF (Central Commissioning Facility) systems may transfer data to NRR (National Research Register) as a dataset.

Security – security standards underlie a range of services which ensure the integrity, confidentiality and appropriate use of information. Services include event monitoring, virus checking, encryption, firewalls, and access control.

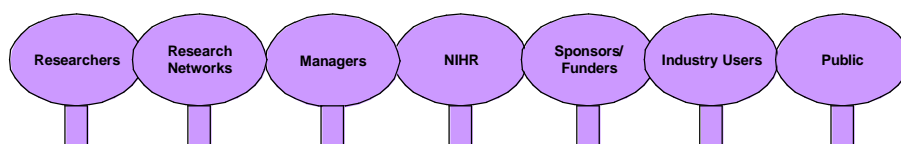
The first area where standards are being developed is identity management, where a proposal to adopt the OpenID standard is being developed.

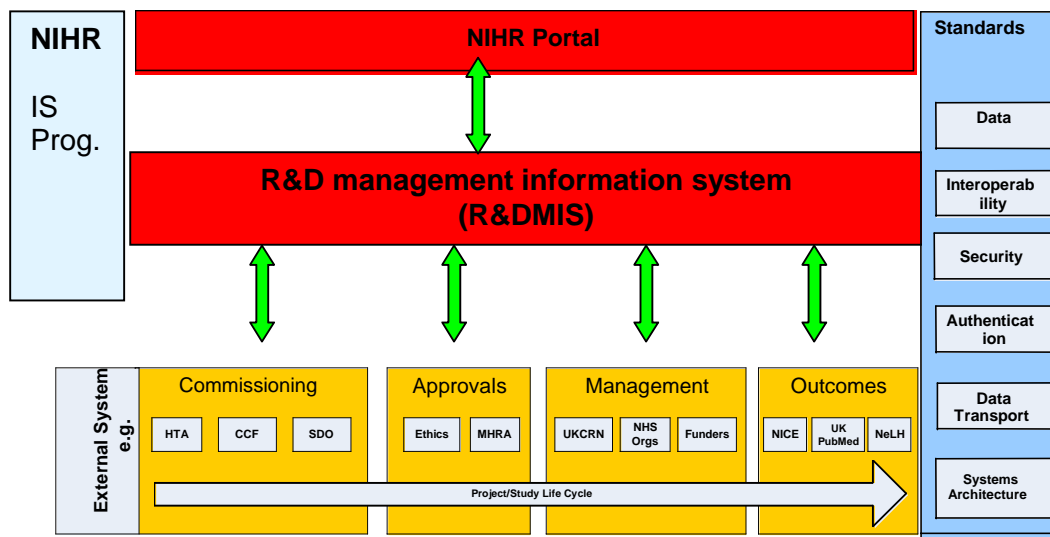
Human Computer Interfaces - these will be largely web based, and should meet accessibility standards, with intuitive and elegant user interfaces.

In consultation with industry, the Programme will ensure that relevant NIHR IS are compatible with FDA standards for IT systems and data capture.

### 5.2.4 Description of systems components

The key system components are shown in the diagram below. The systems to be provided by the NIHR IS Programme are shown in red. Other NIHR systems are shown in yellow. This diagram is intended to provide an overview; it does not comprehensively depict all systems and bodies within the NIHR space.





#### 5.2.4.1 Portal

The Programme will deliver a single WEB Portal to streamline the health research regulatory and approval process. Key features of the Portal will include:

- Secure log-on with publicly accessible and private pages
- Collaborative working capability
- Personalisation
- Access/search capability
- Document repository
- Events calendar
- H&R Information dissemination/news service
- NIHR Faculty document delivery services
- Workflow to support R&D process

Portal benefits will accrue from standardised access to and management of Health Research information for the participating networks. Full realisation of benefits will occur following delivery of and integration with the R&DMIS components, some of which will be delivered via the Portal.

#### 5.2.4.2 Research and Development Management Information System (R&DMIS)

The Programme will deliver a unified R&DMIS capability to automate streamlined processes for the approval, management and results publication/dissemination of Health Research projects/studies.

The R&DMIS is required to provide a single longitudinal data record of every participating health research project. In so doing, it will facilitate the following:

- More rapid feasibility, set-up and delivery of new research projects
- Clearly defined workflows
- Researchers' assistance (e.g. answering questions such as "what approvals do I need, now?")

- A single point of entry for Approvals with supporting workflows to guide users through the appropriate approvals process
- e-Approvals capability
- Monitoring, governance and control
- Unified and configurable reporting capability
- Secure, personalised access
- Availability and performance in accordance with published Service Level Agreements (SLAs)

R&DMIS is not envisaged as a single system, in its own right. Instead, the R&DMIS capability will be delivered via a series of separate, modular components. These will consist of the following:

1. Research Approval Wizard. It is envisaged that this will be achieved through a context-specific, process workflow that will be used to indicate to the user which approvals are required and which data fields need to be completed on an approvals form. This would support the aims of the Central Sign off Unit (CSU).
2. Research Approval Data Entry. This function will provide a single point of entry, via the Portal, for research applications and amendments. The authorisation and approvals process that would be covered by this function include:
  - NRES
  - PIAG
  - GTAC
  - ARSAC
  - RATE
  - Ethics

The formal agreement of these organisations will be required. The Programme team will prepare a technical proposal to which the Department of Health will seek agreement.

3. Customised Reporting. The requirement for reporting has not yet been well-defined but it is envisaged that this would form a function within the Local Portfolio Management System, which is to be developed as integrated function of the Portfolio Database, and would be accessed via the Portal. Additional reporting capabilities may be required outside of the LPMS but these have yet to be defined.
4. NIHR Funding Application Wizard. At present, numerous different systems are used by different funding bodies, even within the NIHR. The wizard (or context-specific, process workflow) would support a consistent approach towards funding applications and help users find funding for their project. It is envisaged that this would be a function provided via the Portal and would support the CSOU.
5. Research Funding Data Entry. It is envisaged that the R&DMIS would provide a single point of data entry (SPOE) for research funding applications from a wide range of funding sources/organisations. This SPOE could be provided via the Portal.

6. Integrated Clinical Research Progress Reporting. The purpose of this function would be to establish an efficient, standardised method for research teams and their sponsors to comply with statutory and other reporting requirements and to provide more efficient information gathering about clinical research in all sectors across the country
7. Integration of SUSAR (Suspected Unexpected Serious Adverse Reaction) Reporting to EudraVigilance. The IS Programme will deliver a simple secure mechanism for a CI/sponsor to submit to EudraVigilance via their electronic Gateway, supported by a process workflow to guide users through the process and to decide what report(s) if any need to be submitted. It is envisaged that the process and supporting process workflow would be functions within the Portal.
8. Integration with NHS Connecting for Health. BRfBH describes the goal of linking NIHR with NHS Connecting for Health's (NHS CfH). National Programme for IT This would be dependent on developments in the NHS Care Record Service. The programmes related to those deliverables are the responsibility of NHS CfH.

This is a long term aspiration that cannot currently be planned with confidence. It is not expected that the Programme will be able to deliver this before 2010.

#### 5.2.4.3 Portfolio Database

The provision of a Portfolio database and management capability is central to the R&DMIS architecture. However, it is not yet clear whether the Programme's objectives can best be met through building and extending the current UKCRN Portfolio database and Portfolio Management system or by replacing them with a procured solution. An options appraisal will be taken to determine the optimal approach. The selected option will be presented to the Programme Board for approval.

The UKCRN Portfolio Database is a database of approved, UK research studies. It will form a key component of the NIHR IS Programme as it will provide a single database of all approved research studies in England that fall within the scope of the Programme (i.e. all research studies that are NHS funded or that utilise NHS resources). The Portfolio Database has the following capability:

- Study Definition – new studies are initialised in the Portfolio Database using a simple web form. Once initialised, additional study details can be added online. Changes are controlled, audited and validated through a simple Approvals workflow, which includes an automated mechanism for checking that a minimum data set is specified and publishing approved changes to the "live" searchable Portfolio database. Individual permissions control who can initialise a new study, amend an existing study definition and approve study amendments.
- Accrual Upload – users upload their accrual data directly into the Portfolio Database accruals' database using a simple web form. Firstly, the structure of

the uploaded file is automatically validated to check that it conforms to the UKCRN standard. Secondly, the data uploaded is automatically checked for consistency and quality. Finally, a managed approval workflow passes the uploaded data for manual coding, checking and release. Release allows the approved data to be copied from a holding tank of accrual data into the "live" reporting platform.

- Portfolio Search – The portfolio search tool provides users with access to approved details of studies within the Portfolio database. Users can search the portfolio in a variety of ways for example by Topic, Disease or by simple text search. For each study, a "Study Summary" page is available, which provides details such as current phase of development, inclusion criteria, estimated timeframes, recruitment rates (if appropriate) and contact details for the study. The storage and transmission of this data requires appropriate security with access only permitted to those users who have appropriate pre-defined access-rights. The reason for this is that some study recruitment rates are commercially sensitive and subject to legal and regulatory considerations.

Planned extensions to the portfolio system include:

- Study Weighting – this includes the weighting of types of studies to allow accrual and portfolio reports to reflect the level of activity and resource required for different types of studies.
- Web Services – this will provide an interface layer into the Portfolio Database, allowing data to be supplied remotely to partners and collaborators through web services.

#### 5.2.4.4 Portfolio Management System

The existing UKCRN Portfolio Management System provides a basic tool for Local Research Networks (LRNs) to manage their own study portfolios - in particular, tracking key dates and milestones throughout a study's natural lifecycle. This application will either be replaced by a procured solution or developed and extended to meet user requirements.

#### 5.2.4.5 Central Sign-off Unit

The Central Sign-off Unit facilitates a new part of the lifecycle of those studies eligible for and requiring NHS support. The intention of Central Sign-off is to help ensure that projects are approved quickly through a streamlined process that ensures predictability and transparency and to provide a mechanism through which clinical research projects enter the Portfolio.

The Programme will deliver IS capability in support of the CSU. The initial delivery of the R&DMIS will be in October 07 in support of the Central Sign-off unit. This is likely to take the form of a tactical delivery with limited functionality and integration. It will be followed by a strategic delivery in April 08.

#### 5.2.4.6 Advice Service

The function of the Advice Service aligns closely with that of the CSU, with the Advice Service providing advice on regulatory issues. The Advice Service will link front-line advisers in the NIHR networks with a network of national regulatory experts. It will generate reliable responses to regulatory questions. These written responses will also be available through the NIHR Portal.

A web based system has been developed to deliver NIHR support to the Advice Service. This system allows for the capture of advice requests into a central repository and control over the full lifecycle of request resolution, using managed workflows including formal approval processes.

#### 5.2.4.7 Biomedical Research Centres

The proposal is for the procurement/development of a research information management system that will support Comprehensive and Specialist Biomedical Research Centre (CBRC) activities including planning, review, approvals, execution and management. The proposal comprises of 4 modules which will be constructed from pre-existing resources, where this approach proves cost effective. The four modules are:

- Planning and submissions
- Documentation and version control
- Study logistics and finance management
- Research Database and e-data capture system

It is expected that these requirements will largely be met by the R&DMIS capability. However, there may be requirements that fall outside the scope of the R&DMIS and the IS Programme; these include the storage and management of patient data.

The Programme will work with the BRCs to support them in procuring/delivering a solution to those requirements that fall outside of the IS Programme scope.

#### 5.2.4.8 Electronic Data Capture (eRDC)

A Pilot study has been conducted to assess the viability of introducing Electronic Data Capture (eRDC) to support clinical trials. The Pilot successfully demonstrated that eRDC could be employed for the collection and storage of patient information for an academic, multi-centre, Phase III clinical trial.

The eRDC requirement will be delivered, in the first instance, as one of the four BRC modules described above.

#### 5.2.4.9 National Research Register

The National Research Register (NRR) is an historical, UK-wide database of all research studies conducted in the NHS. In January 2007, the decision was taken to re-provide the NRR within the UKCRN Portfolio Database. The NRR project is concerned with the phased migration of selected datasets from NRR to the Portfolio

Database and the archiving of the NRR (therefore enabling future search and interrogation of historical data that is not transferred to the Portfolio Database).

#### 5.2.4.10 CTU Registration

The CTU Registration application will provide a mechanism for CTUs to apply for the registration process with the UKCRN by submitting an on-line form. This data will then be managed through workflow mechanisms to ensure data integrity and efficient decision making processes.

### 5.3 Programme Benefits

In delivering the outputs described above, the Programme will provide the necessary systems support to allow other Programmes of work to deliver the far-reaching objectives listed in section 2.2. The IS Programme will enable, support and monitor delivery of these benefits by ensuring effective change and transition management and through the introduction of measures that will facilitate the monitoring of benefits realisation. However, the Programme cannot ensure benefits realisation and the responsibility for this resides with the other NIHR workstreams and initiatives.

### 5.4 Programme Risks

High-level Risk	Impact	Risk mitigation
What is delivered by this Programme may not be in step with what is required by others outside the Programme to achieve the strategic benefits. In this situation, it would be possible for this Programme to deliver successfully a series of ICT solutions, but with no resulting strategic benefit.	Potentially severe: it would be possible to expend the entire budget on ICT solutions, and commit to ongoing support and development costs, but without any significant strategic benefit being attained.	<p>Clarity on which other Programmes of work will use what is developed by this Programme to deliver the strategic benefit.</p> <p>Clarity on the scope, boundaries and benefits directly attributable to this Programme, and communication of this to the stakeholders identified above.</p> <p>Continued engagement with the identified stakeholders as the Programme proceeds to ensure that expectations will be met, and that any changes in strategic direction will be fed into this Programme in a timely manner.</p>

High-level Risk	Impact	Risk mitigation
Failure to engage Stakeholders effectively and efficiently.	Lack of support for the Programme. Continued focus on tactical initiatives, rather than strategic requirements. Failure to meet real needs of R&D community.	Establish clear Communications and stakeholder engagement strategy. Programme Board to proactively support creation of Benefit Forum as a means of engaging stakeholders. Appropriate focus on Comms to raise Programme's profile and to win hearts and minds.
Programme focuses on short-term issue resolution and the delivery of tactical requirements.	Funding and energy diverted to solve short-term issues and long term solutions never put in place.	Programme formed quickly. Target architecture and programme road-map designed, documented and agreed.
Programme Scope not clearly defined and stable.	Scope creep and failure to define requirements may lead to delays, escalating cost and failure to deliver.	Programme Scope and objectives clearly defined in Programme Brief, approved by Programme Board and placed under Change Control.
True cost of delivering Programme is not known and may be significantly greater than initial estimates indicate	Overly optimistic cost estimates may lead to budgetary shortfall when true costs emerge.	Conduct analysis to determine possible impact of optimism bias, in line with HM Treasury and DH guidelines. Adopt a "bottom up" approach to estimating Programme resource requirements. Review and refine until confidence is reached that cost estimates are robust and complete.
Insufficient resource (both in numbers and required skills) to deliver Programme objectives within required timescales.	This may lead to projects being delayed and the quality of deliverables being adversely affected.	Complete Programme organisational design and agree Resource Management Strategy. Conduct consultancy OJEU to procure skilled resource, where internal equivalents are not available.
Transition to new ways of working will require careful management to ensure a seamless changeover to new NIHR processes and systems.	The absence of a well-managed transition is likely to lead to a failure to adopt new processes and systems, user/stakeholder confusion and a failure to achieve expected benefits.	Appoint a Business Change Manager (BCM) to manage the transition, acting as interface between the IS Programme and its stakeholders, including those external bodies that will be affected by the changes (e.g. MHRA, NRES, SDO, etc.).

High-level Risk	Impact	Risk mitigation
R&D hosting organisations are destabilised or excessively distracted from the day-to-day 'business as usual' by the activities of the IS Programme.	Dis-benefits are generated or achieving benefits is delayed.	The Benefits Forum and the BCM will be actively involved in transition planning to ensure effective change management and seamless integration of the new IS capabilities delivered by the Programme.

The risks will be defined more fully in a risk register that will form part of the Programme management activities.

## 6 Financial Case

### 6.1 Programme Cost, Resource and Timescales

The NIHR IS Programme is adopting a strategic approach to the development of health Research and Development IS. The Programme will respond to new requirements as they emerge. Consequently, the funding requirement for the IS Programme has not been fully determined, at this stage.

The Programme has adopted a "bottom-up" approach to resource estimation. Initial estimates have been drawn up based on an evaluation of those projects already identified as within scope.

Based on this, the best estimate at this stage of the Programme is that the cost of the known work will be in the region of £6.5 - £8M over three years from April 2007. However, there is much work that still needs to be done before these figures can be properly validated, for example:

- Testing the Enterprise Architecture on the supplier market;
- Finalising options for systems hosting;
- Agreeing the approach for supporting the Biomedical Research Centres in developing the BRC proposal;
- Agreeing procurement and build options for the R&DMIS components.

### 6.2 Optimism bias adjustments

In line with HM Treasury and DH guidelines, an analysis to determine the possible effects of Optimism Bias has been conducted. At this early stage in the Programme's life, Optimism Bias has been dealt with Programme-wide.

The outcome of the analysis is that:

- Provision for an additional 100%-200% costs should be factored into the Programme. This is in line with DH guidance, based on the fact that the software development components of the work are complex, involve bespoke development and potentially include many interfaces to legacy systems.
- The Optimism Bias figure cannot at this stage be reduced significantly from the DH guidance figure because the reducing actions are planned for later in the Programme's development. This is not unusual for a Programme of this type at this early stage.
- Therefore, the projected actual resource requirement becomes £6.5M + 100% to £8M + 200% which equates to £13M - £24M from April 07.

### 6.3 Financial Case Review and Update

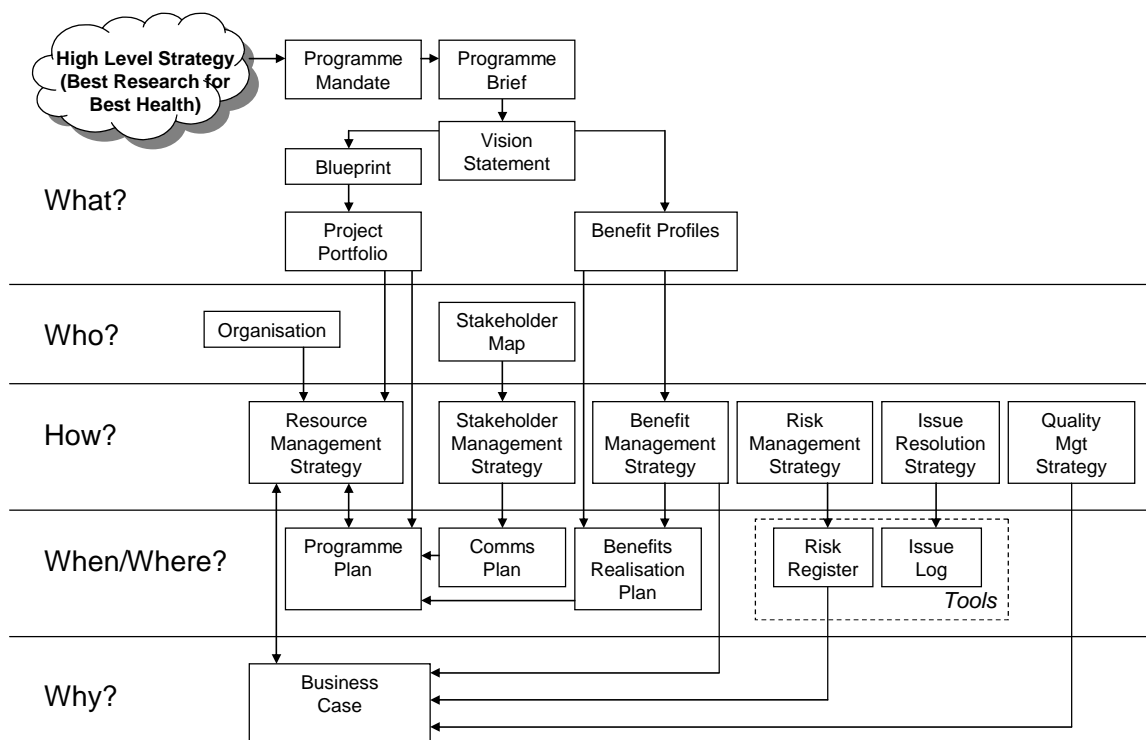
The Optimism Bias adjustment will be refined as the Programme proceeds and gains greater clarity on options, issues and requirements, stakeholder buy-in, selection of contractors and interfaces with other systems and organisations. As above, this is in

line with HM Treasury and DH guidance. The expectation is that Optimism Bias for any given Programme investment will reduce to 0% only at the time the Full Business Case is prepared.

## 7 Management Case

### 7.1 Programme Approach

The diagram, below, sets out the structure of the NIHR IS Programme showing how the various management documents relate to support Programme governance and ensure effective control.



#### 7.1.1 Programme Mandate

The Programme Mandate describes what the Programme is intended to deliver, how health research and management will be improved from the standpoint of funders, researchers and research management. It also relates the Programme back to Best Research for Best Health setting out how the Programme will contribute to delivering the over-arching strategy.

#### 7.1.2 Vision Statement

This sets out the “end goal” of the Programme and should be used to ensure consistent communication of the Programme’s objectives and the improvements it will deliver to stakeholders and Programme team members.

The Vision will be agreed by the Programme Board.

### 7.1.3 Blueprint

The Blueprint will describe the “future state” to be delivered by the Programme. It will be used to maintain the Programme’s focus on what needs to be delivered and to ensure consistency of approach, going forward.

The Blueprint will include:

- Business models of functions, processes and operations, including indicative operational costs and performance levels and measures relating to the processes that support research studies (approvals, management and publication/dissemination), HR & CRM and financial management (e.g. Budget setting and funding allocation).
- The organisation structures, staffing requirements, roles and skills required to support the future health research and management processes.
- The enterprise architecture required for the future operation. This will clarify the requirement for new infrastructure and the reuse of existing infrastructure.
- The data and information architecture required to underpin the future enterprise architecture together with detail of how existing data and information will be changed or developed to ensure that the applications and services used by those in health research and management are effective and joined-up.

The Programme Blueprint will be developed in consultation with Programme stakeholders. Active buy-in and contribution will be sought and ongoing dialogue maintained, primarily via the Benefit Forum.

### 7.1.4 Project Portfolio

This will list all of the projects and workstream activity that, together, comprise the NIHR IS Programme. The Portfolio will contain a summary overview of each contributing Project Brief and will set out:

- Outputs;
- Timescales;
- Resource requirements;
- Dependencies with other projects;
- A summary of the contribution that each project will make to delivering Programme benefits.

The Project Portfolio will define how the Programme is going to deliver the Programme Vision and associated benefits.

The Programme will deliver capability (IT, processes, etc.) which will be leveraged to deliver benefit and fulfil the Vision.

It is expected that the requirements for many of the components to be delivered by the Programme will emerge over time. For this reason, and to de-risk the development process, the Programme will place emphasis on a modular development approach using proto-typing and iterative requirement and development cycles.

#### 7.1.5 Stakeholder Management Strategy

The Programme's effectiveness in managing its stakeholders and their aspirations will, to a large degree, determine the success (perceived or real) of the overall Programme.

The Stakeholder Management Strategy must be developed in conjunction with the NIHR-wide stakeholder strategy to ensure a consistent approach across the wider programme.

The Stakeholder Management Strategy will:

- List stakeholders by interest group;
- Provide an analysis of influence and impact for each stakeholder group;
- Include a stakeholder map showing the different stakeholder interests in the Programme;
- Establish how the Benefit Forum will be used to engage with stakeholders and generate two-way dialogue for receiving and responding to feedback;
- Measures to determine how well the communication process is engaging with stakeholders;
- Inform and shape the Programme Comms Strategy.

#### 7.1.6 Comms Plan

The overarching Comms Strategy is the same as that for the NIHR as a whole, and relates to communicating the high level benefits of the reforms set out in Best Research for Best Health.

Since the IS Programme will in general deliver capability that supports other elements of the developing NIHR, the mechanisms for communication will also be largely the same as for the relevant parts of the NIHR.

Therefore, the Comms Plan will be derived from the Stakeholder Management Strategy and will set out the following:

- Key messages and programme information to be communicated;
- The objectives in delivering these communications;
- Responsibilities for delivering key messages and other information about the Programme;
- A description of the communications channels to be used;
- A schedule of the communications channels to be used together with target audiences for each.

### 7.1.7 Resource Management Strategy

The Resource Management Strategy is used to capture:

- The resources needed to deliver the Programme;
- How these resources will be acquired;
- When they will be acquired;
- How they will be managed;
- The expenditure approval and financial reporting procedures that will apply.

Resources, in this context, include people, assets and technology.

### 7.1.8 Programme Plan

The Programme Plan will be used to design the shape of the programme and to monitor and control its progress. The plan will consist of explanatory text and a Microsoft Project Plan. It will be supported by more granular project plans for each of the projects within the Programme's portfolio.

In addition to setting out an overall Programme schedule, the Programme Plan will also:

- Summarise risks, assumptions and pre-requisites against successful achievement of the Plan;
- The Transition Plan showing when the outputs from the projects will be delivered to the business and what transition activities will be required;
- Monitoring, control and reporting requirements.

### 7.1.9 Risk Management Strategy

The Risk Management Strategy sets out how risks are to be identified and managed, how risk ownership will be managed and how decisions on risk management will be made including, for example, how tolerance levels will be set.

### 7.1.10 Issue Resolution Strategy

The Issue Resolution Strategy will set out how issues will be captured and assessed and by whom. Its purpose is to ensure that all issues are dealt with effectively with appropriate ownership and communication.

### 7.1.11 Quality Management Strategy

The Quality Management Strategy sets out the quality assurance, review and control processes for the Programme.

The OGC Gateway will be used to provide an external, objective assessment of project control; an external APMG P3M3 review will be undertaken to assess the

maturity and sustainability of the programme and project management approach, framework and controls.

### 7.1.12 Business Case

Individual Project Business Cases will be produced for each component project of the Programme to ensure that there is a sound business justification for each project to proceed. The rigour and complexity of each case will be determined according to the scale, complexity and risk of the associated investment.

Each business case will be guided by this Programme Brief in terms of:

- Scope
- Drivers and priorities
- Objectives
- Links and dependencies with other investments
- Stakeholder issues

This Programme Brief includes tabulated estimates of costs, benefits and risks arising from the Programme (available electronically). As part of the development of each individual Project business case, more detailed estimates of the project's costs, benefits and risks will be documented. This detail will be fed back into the Programme-level tabulations to ensure the Programme has the best possible Programme-wide view of these matters at all times.

## 7.2 Programme Resourcing

The scope and scale of the Programme's work requires many people to be involved, including stakeholders, internal specialist staff, external specialist advisers, technical contractors, ICT service providers and others. The appropriate and timely sourcing of all these individuals is critical to the success of the Programme.

## 7.3 Business Case Development Plan

At present, the following business cases have been identified and scheduled for development.

Project	Business case	OBC	FBC
Portal	Interim application development	n/a	July 2007
CSOU Phase 0	Interim application development	n/a <sup>1</sup>	July 2007

The major Programme business cases will be scoped and scheduled for completion once the major Market Review work has been completed.

<sup>1</sup> This is a small software development project using previously-procured development resource. Therefore there was no requirement to seek OBC approval to proceed to procurement.

## 7.4 Gateway Review

The Programme will be subject to Gateway Review via the DH Gateway Team.

The first review will be a Gate 0 on the entire Programme, to ensure that it is on an appropriate footing to move forward. This is planned to be conducted in Q1, 2008.

At the time of that review the DH Gateway Team will be consulted on the most appropriate timing for individual Project Gateway Reviews, and the timing of subsequent Gate 0 Programme reviews.

## 8 Commercial Case

### 8.1 Principles the Programme and its projects will follow

The Programme will undertake a series of procurements, some large and complex and others very small and simple. In each case the procurement route will be selected to match the items being procured.

In all cases, procurements will follow a set of key principles, drawn from published OGC best practice.

#### 8.1.1 Ensuring competition

All procurement will be subject to competition. A competitive process provides the best opportunity to procure the goods or services with value for money. It is possible, but unlikely, that there may be a valid exception to this principle, due to the nature of the requirement.

#### 8.1.2 Ensuring value for money

All procurement will be conducted on a value for money basis. Value for money includes both whole life costs and quality.

#### 8.1.3 Demonstrating transparency

All procurements will be fair, open and transparent. This is required by European Union procurement rules about not favouring or putting any potential supplier to a disadvantage. It is also required in this Programme on all procurements below the EU procurement thresholds. The Programme should also be seen to be acting in a fair manner.

#### 8.1.4 Stimulating market creation

There may potentially be limited response to some requirements because of the nature of the requirement or the state of the market. In such cases, the Programme will stimulate the market place and engage with potential suppliers as appropriate, whilst maintaining a level playing field. Thus, the Programme will ensure that its requirements are commercially viable and attractive to potential suppliers.

#### 8.1.5 Underpinned by business cases

Significant expenditure will be underpinned by one or more business cases which will be subject to formal approval at least internally within the Programme.

Andy Childerhouse  
30th November 2007