

**NIHR Information Systems
Programme
Phase 1 Outline Business Case**

Version 0.9, 30th June 2008

NIHR INFORMATION SYSTEMS PROGRAMME
PHASE 1 OUTLINE BUSINESS CASE
DRAFT

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1. EXECUTIVE SUMMARY

PURPOSE OF THIS BUSINESS CASE

- 1.1. The NIHR Programme Board requested a costed overview of the Programme's activities across the period April 2008 to March 2009. This document provides that overview.
- 1.2. The purpose of this business case is to secure approval from the Programme Board [for a substantive draft, to be circulated after comment on this initial draft] that:
 - The strategic drivers for the Programme, as described in the Strategic Case, are correct and complete.
 - The broad phasing and coverage of the investments as described in the Economic Case are appropriate and suit the needs of the business.
 - The budgetary estimates provided in the Financial Case are suitable for the coming year.
- 1.3. Once these key points have been confirmed, the Programme will further develop and refine the Phase 1 business case into specific procurement work packages, fit to drive the Phase 1 procurements. This will require further technical definition, in particular relating to the Technical Architecture Strategy. The Programme has secured appropriate resource to do this work, subject to Programme Board approval.

STATUS OF THE BUSINESS CASE

- 1.4. This business case is a working draft. Some planned activity cannot be accurately costed until procurement is completed. Contract awards as a result of the individual procurements will be subject to further approvals, which:
 - Will each require an appropriate FBC;
 - May require Programme Board approval.
- 1.5. This initial draft, outline business case is for comment following discussion at the Programme Board on 19th March 2008.

SUMMARY OF THE BUSINESS CASE

- 1.6. The work for 2008/09 is divided into the following high level strategic and tactical work packages, whose strategic drivers are described in Section 2, with detail of the work packages contained in Section 3:

Strategic Foundation Work Packages

- SF1 - Enterprise Architecture
- SF2 - Technical Architecture Strategy
- SF3 – NIHR Portal
- SF4 – ID Management And Role Based Authentication
- SF5 – People Database
- SF6 – Hosting
- SF7 – Programme Capability Build

Strategic Work Packages

- S1 – R&DMIS Phase 1
- S2 – Facilities Management and Reporting
- S3 – R&DMIS Local Study Resource Planning (BRC Module)
- S4 – Study Data Capture (BRC Module)
- S5 – Study Data Capture (CTU Module)
- S6 – People Database/ID Management & Authentication
- S7 – National Database of Health Research
- S8 – Legacy Management

Tactical Work Packages

- T1 – UKCRN Portfolio
- T2 – CSP
- T3 – NIHR Investigators' Database

- 1.7. Section 4 references a separate schedule of planned costs for the 2008/09 year. In summary, the cost of delivering these work packages for 2008/09 encompasses UKCRN IS Team staff costs, NIHR IS Programme staff costs, and a range of non-staff costs.
- 1.8. Sections 5 and 6 outline the management and procurement principles to be adopted for Phase 1 activities.

2. STRATEGIC CASE

STRATEGIC LANDSCAPE¹

CONTEXT AND DRIVERS

2.1. 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.

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

2.3. 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

2.4. The Programme Brief describes the plans and activities of the NIHR Information Systems Programme, which is intended to deliver *Implementation Plan 1.2. Bureaucracy busting: Research information systems*.

¹ The text for *Context and Drivers & Programme Scope and Objectives* is quoted unchanged from the Programme Brief. This text has been reproduced, here, to satisfy the OGC recommendation that the business case should be a stand-alone document.

PROGRAMME SCOPE AND OBJECTIVES

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

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

Function and Process Coverage

2.6. 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. This will include the provision of an automated link to IRAS.
- **Improve R&D approvals process.** 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.

2.7. 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.

Geographical Coverage

2.8. 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 wherever possible take a collaborative approach, seeking solutions compatible with the systems and processes these countries wish to apply 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.

2.9. 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.

Organisational Coverage

2.10. 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.

Specific Targets

2.11. The rollout of the NIHR Coordinated System for gaining NHS Permissions (CSP) is scheduled for the second half of 2008.

TACTICAL CONSIDERATIONS

DRIVERS FOR TACTICAL IMPROVEMENTS

2.12. Systems and data to support the research activity within the scope of this business case is patchy, limited, underdeveloped and in some cases completely inadequate. For example:

- Performance measurement and reporting capability within the existing UKCRN portfolio;
- Strategic hosting infrastructure.

2.13. Therefore, whilst making safe and planned progress towards achieving the strategic goals, the Programme must also seek to address these areas of inadequacy if at all possible, ahead of the development of the strategic solutions, whilst not prejudicing those longer term strategic solutions.

2.14. In addition, some business requirements are sufficiently pressing that they must be met prior to the introduction of the strategic solutions. In particular:

- CSP (NIHR Coordinated System for gaining NHS Permission) systems must be delivered to support the launch of the CSP process in the second half of 2008. Every attempt has been made to future-proof the procurement of a tactical solution to increase the likelihood that it will meet strategic need. However, this is by no means certain and will need to be tested by a future strategic procurement.
- An NIHR Investigators' database must be delivered rapidly to support the formation of the NIHR Faculty. Work has focussed on ensuring that the Faculty delivery can form the basis of a strategic NIHR contacts database containing details of all involved in the NIHR research process.
- UKCRN Portfolio improvements are urgently required to meet the pressing needs of the research networks. These improvements are required in order to meet a range of critical business needs, including performance management and accurate reporting. This is especially critical given that performance criteria will, in part, be used to establish network funding in the following financial year.

IMPLICATIONS OF TACTICAL IMPROVEMENTS

2.15. There are great potential benefits to be gained in pursuing tactical improvements. Yet there are also significant potential risks and costs, including:

- Drawing the Programme's resources and focus away from strategic developments, thereby delaying them.
- Putting in place non-strategic solutions which, for various reasons, may then be difficult to replace with strategic solutions (e.g. user resistance to change or retraining). This can prejudice the strategic solution.

2.16. Accordingly, the business case explores the interaction between tactical and strategic improvements, seeking to find a balance between the two that delivers early benefit in tactical areas whilst preserving the value and integrity of the strategic solutions.

TREATMENT OF TACTICAL WORK IN THIS BUSINESS CASE

2.17. The speed at which tactical problems need to be resolved means that they cannot be included for consideration and approval in annual business cases. Rather, they are worked through and initiated individually.

2.18. This business case includes details of all tactical work that is either underway or has been scheduled for completion over the course of the coming year.

2.19. Any additional tactical work that arises mid-year by definition will not be covered by the funding and resource estimates contained in this business case.

INTERACTIONS WITH OTHER SYSTEMS

2.20. There is a range of systems which need to be woven into the strategic enterprise architecture. They are considered further in the packaging analysis in the economic case. They include:

- NRES IRAS
- BRCs
- NETSCC

RESPONSIBILITIES OF OTHER ORGANISATIONS

2.21. Guided by the Programme Brief, this business case justifies investment in ICT solutions to support various research functions and organisations. However, it is not responsible for delivering any process or organisational change which may be opportune as a result of the deployment of the ICT solutions outlined in this business case.

2.22. Such work, if required, is the responsibility of each individual organisation to identify, plan and execute. Where the programme is aware of such activities, these are highlighted in this business case. Where such activities may need to take place, then this is highlighted in the business case.

NIHR PROGRAMME APPROACH - OVERVIEW

2.23. The NIHR IS team has been tasked with delivering the far-reaching objectives listed above. An IS Programme has been initiated, using MSP principles and best practice,² and has been established as a formal Programme of work with planned delivery spanning the financial years 08/09, 09/10 and 10/11. This business case is primarily concerned with setting out the planned deliveries for 08/09; it will be refreshed to reflect detailed plans for the following two years at the end of 08/09.

² OGC Managing Successful Programmes (MSP) 2003

2.24. In addition to following OGC MSP guidance, the Programme has also taken account of relevant recommendations made by the Public Accounts Committee (PAC) and the National Audit Office. These bodies have conducted an analysis of comparable public-sector IT change programmes; this analysis has identified a number of significant failures³. In light of these failures, the National Audit Office and PAC have made the following observations/recommendations regarding the sound management of public sector IS projects and programmes:

- Do not start a project/programme unless there is a clear business case;
- Involve users in the design and implementation – avoid working on assumptions;
- Split larger projects into manageable pieces. Avoid a “big bang” approach;
- Engage and listen to suppliers;
- Ensure that contracts with suppliers are professionally drawn up and that competitive pressure is maintained to avoid overcharging and profiteering;
- Adopt a process-driven approach (i.e. avoid delivering IT solutions on the back of broken or disjointed processes);
- Test and pilot new systems before implementation;
- Carefully manage consultants;
- Review failures and act upon lessons learned when planning future IT systems.

2.25. The approach adopted to the IS Programme takes account of each of the above points:

Do Not Start Project/Programme Unless There Is A Clear Business Case

2.26. This document, in conjunction with the Programme Brief fulfils this requirement. The Programme of work is complex, with many interdependencies, and this may require further iterations of this outline case. In addition, all significant contract award decisions will be subject to Full Business Case justification.

³ E.g. The Magistrate Courts' Libra project; the Passport Agency's Digital Passport programme; CRB IS programme.

Involve Users in Design & Implementation - Avoid Assumptions

- 2.27. Significant effort has been expended over the last year understanding the diverse needs of the research community and ensuring that the IS architectural design will enable these needs to be met. To this end, the Programme has commissioned work on the definition of an Enterprise Architecture (EA). The EA provides the conceptual blueprint that defines the structure and operation of the NIHR IS infrastructure. 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 an architecture, it would not be possible to deliver applications and services that are seamless, unified and deliver user requirements. This work has been ongoing for several months and is due to conclude early in 08/09.
- 2.28. The outputs from this work will be refined in a Technical Architecture Strategy (TAS). In broad terms, the EA provides the high level, conceptual framework and the TAS sets out how this will be realised in technical terms. These are described in more detail in the Economic Case.

Split Larger Projects into Manageable Pieces, Avoid “Big Bang”

- 2.29. A modular, component-based approach will be taken to the design and development of the solutions. A phased implementation approach will ensure that benefits can be gained as early as possible, risk can be managed effectively and the rate of change for the user community controlled.
- 2.30. This approach is developed in the Economic Case.

Engage and Listen To Suppliers

- 2.31. Before firming up the approach outlined above, the Programme sought to learn from industry and, to this end, ran a Market Review exercise from August to October 07. The work was conducted in accordance with the Office of Government Commerce best practice guidance as described in “Early Market Engagement: Principles and Tools of Good Practice”⁴

⁴See
[www.ogc.gov.uk/procurement_documents_procurement_policy_and_practice.a
sp](http://www.ogc.gov.uk/procurement_documents_procurement_policy_and_practice.asp)

2.32. The learning from that work validated and refined thinking in the planning of subsequent procurements. If necessary, further market review work will be undertaken to validate forthcoming procurements.

Ensure Robust Procurement

2.33. The Programme must ensure that contracts with suppliers are professionally drawn up and that competitive pressure is maintained to avoid overcharging and profiteering.

2.34. The main methods used to ensure this are:

- The Programme has engaged procurement and legal advisers who have substantial and direct skills and experience of designing and managing the types of procurements required by the programme.
- Every procurement is designed and positioned carefully through the preparation of a procurement strategy. This includes consideration of the market, maximising competition, minimising procurement effort, and delivering beneficial outputs as quickly as is safely possible.
- Every procurement is supported by a business case. Larger and more complex procurements are supported by both outline and full business cases.
- The procurement and negotiation processes are robust because they are driven by the procurement strategy, and focused on the business benefit because they are driven by a business case.
- Every procurement complies with University of Leeds procurement rules.

Adopt a Process Driven Approach

2.35. The processes underpinning clinical research in the UK are complex and, in some cases, not clearly documented. The IS Programme has adopted a process-driven approach and is currently engaged in mapping high-level, end processes to provide a baseline understanding of the domain.

2.36. One area where substantial progress has been made is R&D Approvals. The approvals processes for clinical research developed over a long period of time in a rather uncoordinated way. This has given rise to a proliferation of information systems that were developed to meet specific national and local requirements but which:

- Have neither overarching systems architecture nor an underpinning set of data standards. This means that systems cannot “talk to each other”;
- Force people involved in the various aspects of the life cycle to access and input information into multiple systems;
- Have resulted in poor quality information;
- Do not enable an easy or accurate view of the current state of research and research projects at either a national or local level;
- Mean that significant time and effort is consumed in the processes associated with monitoring and management rather than in research.

2.37. Since the start of the NIHR IS Programme, considerable work has been undertaken by DH, NRES and their UKCRC partners to simplify some of the processes that underlie R&D approvals and these changes are beginning to have an effect. However many other aspects of business process still require support and there remain issues that require resolution. This is being driven, in the first instance, through the process definition stream within the Solutions Architecture workpackage. The objective of the process definition is to ensure that:

- processes are clearly defined, understood and agreed;
- broken processes are fixed;
- the benefit of IS developments is not dissipated by broken or disjointed processes.

Test and Pilot New Systems Before Implementation

- 2.38. This represents accepted best practice. This been a challenge for the NIHR IS Programme when building systems, as opposed to buying or procuring them from external suppliers. This is because the UKCRN IS team is the NIHR programme's "in-house" delivery and service management arm but, historically, UKCRN has not had the tools or resources to manage development or service delivery in line with best practice. Often, development has taken place in the live environment (i.e. development changes have been made to live instances of operational systems) and developers have also been required to provide systems support. Work is currently underway to address these issues through the expansion and appropriate resourcing of the UKCRN IS team. This will include the provision of virtualised development and test environments and the expansion of team resources to ensure an industry strength development and service management capability.
- 2.39. For these reasons, the costs associated with the expansion of the UKCRN IS team have been included in this Business Case, thus providing a true reflection of the overall cost of the NIHR IS Programme.

Carefully Manage Consultants

- 2.40. The IS Programme has sourced its specialist consultancy via a competitive OJEU process conducted in 2006. In addition, short-term Programme capacity has been augmented where appropriate through short term contracts let under a "three quotes" process in line with Leeds University standard procurement processes.
- 2.41. The IS Programme is currently conducting a competitive OJEU procurement to replace the initial consultancy contracts. The structure of these replacement contracts allows the Programme to call off support in discrete work packages over time, as and when the requirements arise. There is also provision for competition for such work packages between those consultants placed on the call-off register. This contract will not preclude the sourcing of additional support via a "three quotes" route, should the need arise.
- 2.42. All consultant work packages are well defined in terms of the outputs required, and performance is reviewed periodically against these by the Programme Manager and Programme Director.

Review Failures and Act Upon Lessons Learned

- 2.43. The IS Programme has sought to incorporate best practice and has carefully considered the findings from bodies such as the National Audit Office and Public Accounts Committee when designing the Programme. Moreover, a Programme lessons learned log is maintained and stored on the Programme SharePoint site to help inform decisions throughout the life of the Programme.
- 2.44. Given the relatively long duration of Programme activities, and the complexity of the tasks it faces, it is particularly important for the Programme to learn lessons from its own actions in order to refine its forward plans.

3. ECONOMIC CASE

INVESTMENT OBJECTIVES AND EVALUATION CRITERIA

3.1. Drawing from the strategic drivers, the following evaluation criteria will be used to test the merit of each work package identified in this business case.

1. Meets relevant public targets
 - 1a. NIHR Coordinated System for gaining NHS Permissions (CSP) rollout – autumn 2008
 - 1b. Faculty - date TBC
2. Front-loaded benefits release
3. Back-loaded complexity
4. Back-loaded risk
5. Fit with working practices
6. Fit between tactical and strategic to the benefit of both
7. Fit with relevant foreign systems
8. Fit with relevant business process change

SUMMARY EVALUATION OF WORK PACKAGES

3.2. The table below summarises the fit of each work package against the evaluation criteria. The fit is colour-coded as follows:

- **White:** work package is not relevant to this criterion.
- **Green:** work package fully in line with this criterion.
- **Amber:** work package is reasonably well in line with the criterion, although some compromise has been required, which is described in the detailed work package definition later in this section.
- **Blue:** work package is not in line with the criterion, and this represents a significant compromise, for reasons described in the detail of the work package later in this section. This does not mean the work package is invalid or should not go ahead, but that there is a significant compromise that should be understood by all parties.

Work package	1a	1b	2	3	4	5	6	7	8
SF1 Enterprise Architecture			■	■	■	■	■	■	■
SF2 Technical Architecture Strategy			■	■	■	■	■	■	■
SF3 NIHR Portal		■	■	■	■	■	■	■	■
SF4 ID Mgt & RBA			■	■	■	■	■	■	■
SF5 People Database			■	■	■	■	■	■	■
SF6 Hosting			■	■	■	■	■	■	■
SF7 Programme Capability Build			■	■	■	■	■	■	■
S1 R&DMIS Phase 1			■	■	■	■	■	■	■
S2 Facilities Management & Reporting			■	■	■	■	■	■	■
S3 R&DMIS Local Study Resource Planning			■	■	■	■	■	■	■
S4 Study Data Capture (BRC)			■	■	■	■	■	■	■
S5 Study Data Capture (CTU)			■	■	■	■	■	■	■
S6 People Database/ID Management			■	■	■	■	■	■	■
S7 National Database of Health Research			■	■	■	■	■	■	■
S8 Legacy Management			■	■	■	■	■	■	■
T1 UKCRN Portfolio			■	■	■	■	■	■	■
T2 CSP	■		■	■	■	■	■	■	■
T3 NIHR Investigators' Database		■	■	■	■	■	■	■	■

3.3. From the summary table it can be seen that:

- There is a high level of alignment between the workpackages and the evaluation criteria.
- The tactical CSP workpackage entails considerable front-loaded complexity and associated risk. This is attributable to the date-driven approach with a solution needing to be in place to support the rollout of CSP in the autumn, 2008.

OVERVIEW OF WORK PACKAGES

3.4. The work packages are described on the following pages under the following headings.

Strategic Foundation Work Packages

SF1 - Enterprise Architecture

SF2 - Technical Architecture Strategy

SF3 – NIHR Portal

SF4 – ID Management And Role Based Authentication

SF5 – People Database

SF6 – Hosting

SF7 – Programme Capability Build

Strategic Work Packages

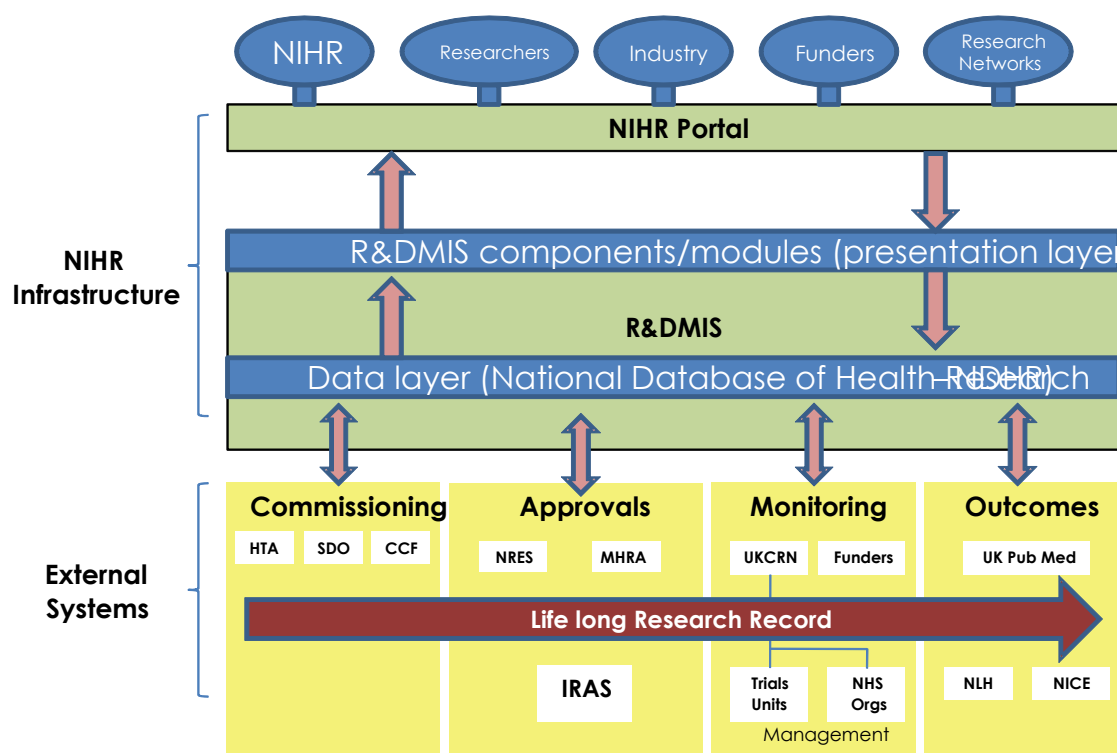
- S1 – R&DMIS Phase 1
- S2 – Facilities Management and Reporting
- S3 – R&DMIS Local Study Resource Planning (BRC Module)
- S4 – Study Data Capture (BRC Module)
- S5 – Study Data Capture (CTU Module)
- S6 – People Database/ID Management & Authentication
- S7 – National Database of Health Research
- S8 – Legacy Management

Tactical Work Packages

- T1 – UKCRN Portfolio
- T2 – CSP
- T3 – NIHR Investigators' Database

STRATEGIC FOUNDATION WORK PACKAGES

3.5. At the highest level, the NIHR systems architecture can be depicted as follows:

High Level Systems Architecture

- 3.6. The red arrow, Lifelong Research Record, depicts the data items that will be generated during the life of a study. These data items will be added to the National Database of Health Research (NDHR), with the long-term objective (as indicated in this diagram) being integration between NIHR and external systems enabling the automatic population of the NDHR within the constraints established in the LRR data model that underpins it.
- 3.7. The Strategic Foundation work packages aim to provide a sound basis for constructing and connecting the various applications required and depicted above.

SF1 - Enterprise Architecture

- 3.8. Before the formation of the NIHR IS Programme, there was 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 resulted in local rules being applied to the storage of data relating to people, funding, infrastructure and projects. This led to inconsistency, disjointed IT, duplication of data and data integrity issues.
- 3.9. The business processes, together with the systems that automate and support them, need to be underpinned by consistent and unified data architecture. Without such architecture, it will not be possible to deliver applications and services that are seamless and unified.
- 3.10. 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) or physical resource used by or funded by the NIHR to support research.

3.11. 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.

3.12. 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.

3.13. In summary, the Enterprise Architecture will provide the conceptual blueprint that defines the structure and operation of the NIHR IS infrastructure. The task of defining the Enterprise Architecture commenced in Q1, 2007/08 and will complete in Q1, 2008/09.

SF2 - Technical Architecture Strategy

3.14. The NIHR Enterprise Architecture is now sufficiently mature for work to start on the Technical Architecture Strategy. The framework approach that is to be adopted will encompass:

- High level definition of NIHR process model and workflows
- An assessment of current applications and technology landscape
- Baseline of the current technology architecture & computing philosophy
- ICT organisations management strategy and capability matrix
- Future application management strategy
- A comprehensive technology strategy
- A first pass migration plan from existing systems and applications

- Establishing a process for lifecycle management of the technical architecture

SF3 – NIHR Portal

3.15. The NIHR Portal is an installation of Microsoft Office SharePoint Server 2007 optimised for use by the health research community, with a strategic aim of becoming the primary host for all publicly accessible information regarding the NIHR, and a secure gateway to related systems and services including funding and ethical approval for studies. It will achieve this aim by providing:

- Shared collaborative workspace for organisations, networks, groups and teams
- Identity management of research personnel including single sign on to related trusted systems
- Central document storage and document management capability
- Communications both internally (intranet) and externally (websites)
- Unified content management – workflow driven approval and publishing system for both internal and external content from a single interface
- Data-level connectivity with trusted systems – record your data once, pass to many systems without duplication

3.16. The NIHR Portal Project was formally initiated on 14 March 2007. It currently supports over 1,200 users across UKCRN, the Topic-specific Clinical Research Networks, Department of Health R&D and the NIHR IS Programme. The public face of the NIHR Portal at <http://portal.nihr.ac.uk> currently promotes the concept of applying for Portal access at an organisational level, and there are several new sites under construction and requests under review. It is also the only accessible interface with the National Research Register archive, and provides a public search tool for the active Portfolio Database.

3.17. In order to support the strategic aim, the NIHR Portal Project recently completed an evaluation process with suppliers of SharePoint and Portal design capability. The selected partner was Concentra, who have previously supplied hosting and training services to the NIHR IS Programme. We have begun an intensive phase of strategic design work with our partner organisation which will include workshops for Business Requirements, User Requirements, Information Architecture, Interaction Design, Navigation and Graphic Design. The outcome of the design phase is to produce a blueprint for the NIHR Portal to achieve its strategic aim and provide a single efficient, attractive and usable gateway to all NIHR systems and services, and to provide a platform support for all other appropriate elements of the NIHR IS Programme.

SF4 – ID Management and Role Based Authentication

3.18. A strong identity management and role-based user authentication system will be required to manage user access to systems via the Portal. The principles of this authentication mechanism will be: the user logs-on once, when he/she accesses the Portal, without having to enter additional user IDs/passwords to access different systems through the Portal; system-level access rights will be determined by the user's role within a specific study – i.e. an individual (e.g. Professor Smith) has different access rights as CI for study A, to the rights that she has as a researcher for Study B.

SF5 – People Database

3.19. For the authentication mechanism, described above, to work there must be a database of users. In the first instance, this will be a database of Faculty members, only (the NIHR Investigators' Database). This database has been built and will be made available in Q1, 08/09. Further, incremental development is planned, thereafter, to expand this database into one that meets the wider needs of NIHR.

SF6 – Hosting

3.20. The NIHR IS Programme has a requirement for secure and reliable hosting of servers, storage and other computer hardware in order to fulfil its programme, project and operational requirements. NIHR IS Programme systems are currently hosted in two main locations – servers located in the University of Leeds administrated by UKCRN IS (Portfolio Database and related systems), and the London Hosting Centre administrated by Telstra via our hosting partner, Concentra (NIHR Portal and related systems).

3.21. We participated in an OJEU ITT (Official Journal of the European Union Invitation to Tender) in order to secure a long term solution to our hosting needs. This resulted in Concentra being selected as our strategic hosting partner. Their engagement provides the NIHR with a significant, secure, robust and scalable hardware hosting and service support capability. We will build upon this in 2008, working within industry standards such as ISO 27001 (Information Security) and ITIL (Service Support). Enhancements will include:

- Security monitoring and incident management
- Enhanced business continuity contingency
- Detailed reporting and problem management
- High availability and system uptime
- Improved user support and user experience

SF7 – Programme Capability Build

3.22. The scope and scale of IS delivery will increase significantly in the coming year. Up until now, the Programme has employed a very “light touch” to programme and project management governance. This has been appropriate as the Programme has moved through initiation and into delivery. However, governance now needs to be bolstered with more formal processes and controls in place and a fully resourced Programme Management Office providing the support which has largely, to date, been lacking.

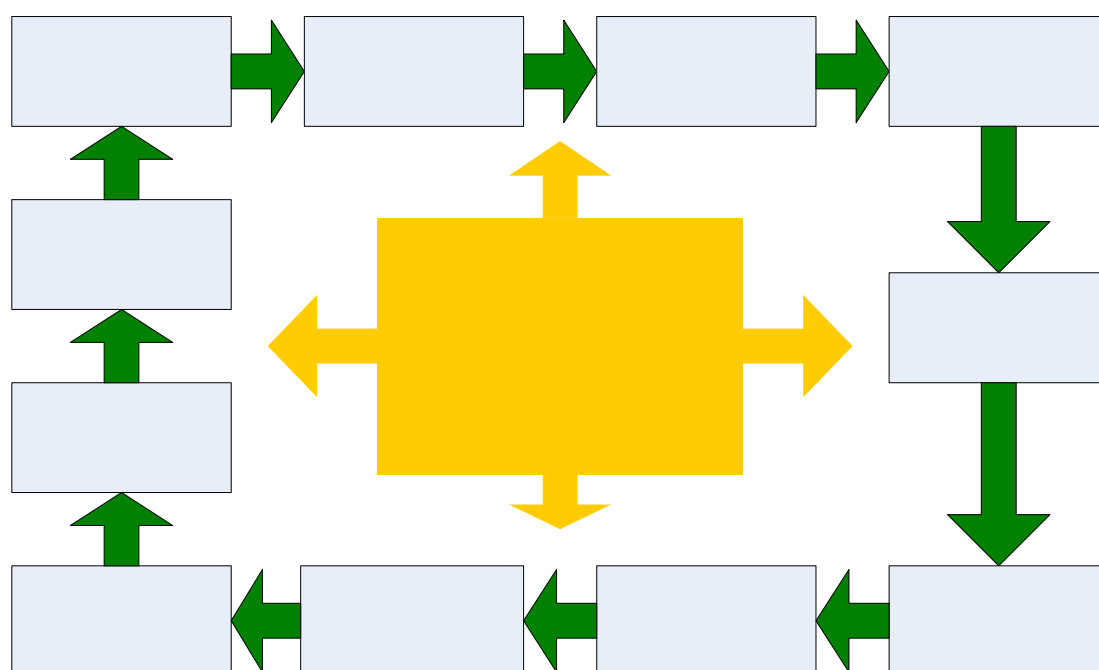
3.23. This module will include, but will not be limited to:

- Establishing a consistent, more structured approach to risk management;
- Providing standard templates for all key project & programme documentation;

- Providing enhanced reporting, particularly focussing on the need to balance resources across projects and manage project inter-dependencies;
- Providing formalised configuration management and formal document library;
- Introduction of more robust and granular processes for managing programme budget.

STRATEGIC WORK PACKAGES

3.24. The strategic solutions architecture will be designed to provide tools to enable the efficient management of the whole lifecycle of clinical research projects, as indicated in the diagram below:



3.25. These tools will comprise what, collectively, has been termed the R&DMIS (Research and Development Management Information Systems) and will be accessed via the NIHR Portal.

3.26. The sequence in which R&DMIS modules are delivered is largely determined by the Life-Long Research Record (LRR), the data model that:

- sets out the formal description of how data is to be stored and accessed;
- Sets out the data structures that should be used when creating databases;
- Establishes the rules & constraints to be applied to these data structures to ensure data integrity.

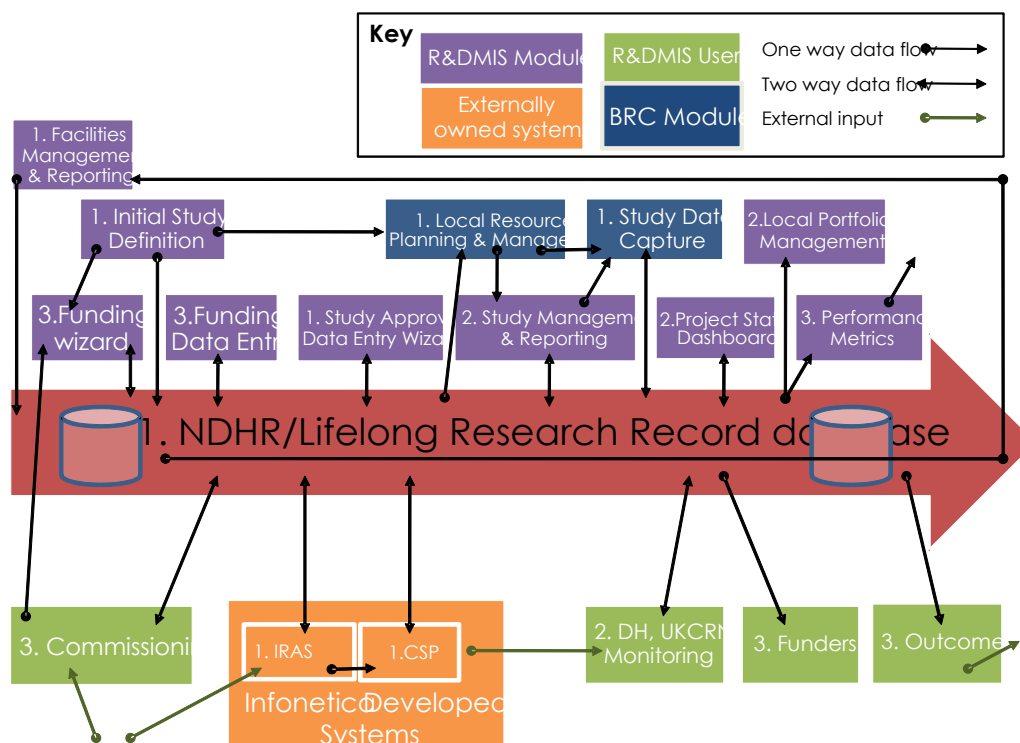
3.27. Two factors largely determine the implementation approach:

- The logical dependencies that define the sequence in which modules must be implemented;
- The sequence of implementation that will deliver optimal benefit.

3.28. The NIHR IS architecture aims to deliver unified access to a *Life-Long Research Record* (LRR). The LRR is, essentially, the data model⁵ that underpins the planned National Database of Health Research (NDHR). The NDHR will replace the existing UKCRN Portfolio database; as such, it must meet the needs of UKCRN as well as NIHR and the Department of Health requirements. It will be a single data repository enabling the user to access research study data from initial study definition (i.e. from the inception of a study) through to final publication and dissemination of study reports (i.e. completion of a study).

3.29. The components that comprise the R&DMIS will interact with the NDHR and, in some cases, with each other. These components, and their interactions, are depicted in the diagram below:

⁵ A data model provides a formal description of how data can be stored and accessed. It sets out the data structures that should be used when creating databases and it establishes the rules & constraints to be applied to these data structures to ensure data integrity.



National Database of Health Research (NDHR) and Lifelong Research Record (LRR) & its relationship with R&DMIS modules Conceptual Overview

N.B. Numbers against R&DMIS modules denote the Phase in which that module or interface is to be delivered

3.30. Each R&DMIS module and each user interface will be developed as a separate component. This facilitates a phased delivery with the projected timeline for each phase as follows:

- Phase 1 – April 2008 to March 2009;
 - Initial study definition
 - Study approval/data entry wizard, encompassing R&D approvals and IRAS
 - Study management and reporting
- Phase 2 – April 2009 to March 2010;
 - Project status dashboard
 - Local portfolio management
- Phase 3 – April 2010 to March 2011.
 - Funding wizard
 - Funding data entry
 - Full performance metrics (complete overview of national R&D programme)

- 3.31. The numbers shown against the modules, external system deliveries and interfaces indicate the phase in which they will be delivered.
- 3.32. Note that the outputs for Phase 2 and 3 will be the subject of further business cases and are not considered in detail in this business case. Further detail on these phases can be found in Annex B.

S1 – R&DMIS Phase 1

3.33. In this Phase, the supporting infrastructure for the LRR will be implemented together with part of the data structure. The supporting infrastructure will comprise:

- A nationally hosted database with sufficient capacity to handle the expected numbers of studies, users and the interfacing processes defined for this phase.
- The means of authenticating user and process access of all types, specifically Create, Read, Write and Update using a role based security model.
- A full audit log capable of recording all activity in the database.
- The means of logging transactions so that the database is managed in a secure fashion. This will include the capability to roll back/forward transactions as necessary.
- The support infrastructure to manage the database, including system administrators, DBAs, etc.
- A suitable Portal based interface that will allow controlled access to data records for ad-hoc queries.

3.34. In addition to the infrastructure, the database scheme will be sufficiently developed to support the following parts of the study lifecycle:

- Study approval/data entry support for users
- Partial study management and reporting capability
- Integrated approvals capability
- Systems support for central sign-off process
- Facilities management and Reporting
- IRAS interface

3.35. No data migration will be undertaken as part of LRR Phase 1, only new studies will be added to the LRR.

Initial Study Definition

- 3.36. The Initial Study Definition module creates a study record and supporting documentation. It is the starting point for all activities that can change the state of the study through its entire lifecycle. A study starts with a simple minimal data set that enables it to be reviewed locally before it is released as a fully defined study. Many organisations need the ability to review a study within the organisation before it is permitted to proceed, and in particular before it is submitted for ethics and other approvals.
- 3.37. The study definition consists of some structured data in the form of the study data record and (optionally) any number of textual documents such as CVs, details of statistical approach, other relevant reports, etc. The combination of the study record and these documents comprises the study document set.
- 3.38. It is the responsibility of the research employer to provide a suitable local review of research initiated by its employees. This would require a defined workflow, mark-up of documents and a final sign-off, with digital signatures.
- 3.39. Once the study has achieved acceptance locally, the lead researcher and the responsible organisation should be able to release the study into the LRR. This implies the creation of a record in the LRR matching that in the local record, and marking the local record so that the data that has been released into the LRR is frozen in the local study record.
- 3.40. Once released in to the LRR, strictly controlled editing will be possible, controlled by role based authentication control mechanisms. It will be possible to continue editing a study record in the LRR, and in particular add data to it, until that study is made available to IRAS for ethics and other approvals.
- 3.41. Local resource planning and management can be driven directly from the local definition of the study. This module is not part of the main R&DMIS scope but will be used by BRCs and other organisations that wish to carry out detailed local planning of activities, budgets, etc.

Study Approval Data Entry System

- 3.42. Study approval is a fundamentally important part of the process of ensuring that only studies that are ethically and scientifically valid are allowed to commence. A number of approving bodies that are outside the scope of NIHR carry out this approval process.

- 3.43. One of the major problems faced by researchers wishing to gain approvals for a study is that multiple approvals may be required depending on the type of study and interpretations of policy and legislation. This can cause confusion. The NRES IRAS system is intended to solve this problem, ensuring that users only need to enter data that is relevant to their specific study.
- 3.44. The NIHR Coordinated System for gaining NHS Permission (CSP) is a relatively new process for gaining permissions from the NHS to undertake clinical research intended for entry into the UKCRN Portfolio. CSP is a consistent, standardised process for gaining NHS permission, designed to reduce both the time taken to start a study and the associated bureaucracy.
- 3.45. In conjunction with the 25 Comprehensive Local Research Networks (CLRNs), investigators will submit applications for regulatory and ethics approval in the usual way and this information will be used by the central CSP unit and CLRNs to gain permission from participating NHS organisations.
- 3.46. CSP will ensure that trials requiring NHS service support will follow a uniform sign-off process which will be accepted as definitive by all interested parties.
- 3.47. This module will seek to provide an interface between the NDHR (NIHR Database of Health Research) and IRAS and between IRAS and CSP. This means that the study data already collected in the Initial Study Definition module and released to the NDHR can be used to populate the IRAS form where there is a direct mapping from the NDHR study definition to the IRAS data. Users will have to supply additional data to complete the process of filling out the IRAS forms. Once the forms are completed, some of the additional data captured in the IRAS system will be added to the NDHR. The IRAS system will have the responsibility to update the NDHR study data. Once the study has completed the approvals process, the IRAS system will update the NDHR to show the status of the study record.
- 3.48. Not all studies will have used the Initial Study Definition module; those that haven't will, consequently, have no record in the NDHR at the point where approvals are sought. In this case, the IRAS form-filling system will be used to capture the same data as the Initial Study Definition and the IRAS system will have the responsibility to create the record in the NDHR, through CSP; this will be achieved via the creation of a CSP/Portfolio (NDHR) interface. From that point on, the process will be the same as outlined above.

3.49. Ultimately, IRAS and all associated systems must be accessible through the NIHR portal in order to meet the overall goals of BRfBH.

Study Management and Reporting

3.50. In early drafts of the R&DMIS User Requirements Specification, this module was described as *Integrated Clinical Research Progress Reporting*. The scope of this functionality has now been increased to cover all of the statutory reporting and management functions that are necessary for a clinical study.

3.51. Not all of the functionality described in this section will be implemented in R&DMIS Phase 1. This restriction is necessary because the data that is required for a comprehensive reporting and management control will not exist in the LRR in Phase 1 because many of the “upstream” modules will not be implemented. In addition, DH has yet to define what its requirements will be for annual reporting.

3.52. In summary, this workpackage will deliver of some the national reporting facilities that will present a view of the LRR.

3.53. The purpose of this function is to:

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

3.54. Later phases of the R&DMIS will revisit this module and add further functionality to match the added modules that will join the R&DMIS.

S2 – Facilities Management and Reporting

- 3.55. One of the current problems with managing research and research associated activities is that information is often ambiguous or incomplete because of the lack of nationally defined lists of names of organisations and facilities. For example, minor differences in the way in which a NHS Trust is referenced could result in multiple counting of the same research study in various activities. In addition to the absence of a uniform and well defined information resource at the level of an organisation, there is even greater difficulty in collecting and using information about facilities and resources for research within those organisations. For example, CLRNs may need to establish which Trusts within an area have a particular type of capital equipment and related expertise that are necessary for a study. No such lists are currently available and these therefore have to be prepared locally on a case by case basis. Without unified information it will be difficult to improve the management of NHS support and facilities which account for a significant proportion of public spending through the NIHR.
- 3.56. A significant part of the scope of the LRR is concerned with organisations and facilities, so it seems logical to bring the management of information associated with these within its scope. However, simply expanding the scope of the LRR database to cover this is not sufficient; it is necessary to have business processes and operational systems that will maintain this information.
- 3.57. The scope in R&DMIS Phase 1 is restricted to the delivery and management of a single authoritative list of organisations that are (or could be) involved in research in the NIHR. The list will utilise existing authoritative resources where possible (e.g. the Terminology Reference Data Update Distribution Service, TRUD, and the Quality and Outcomes Framework, QOF) and supplement it with additional organisational details where this is required. This activity will be driven largely by study definers rather than centrally.

S3 – R&DMIS Local Study Resource Planning (BRC Module)

- 3.58. Research units usually do quite detailed planning for a study so that the required local resources (people, equipment, money, etc.) are available when needed.

3.59. This planning is the responsibility of the organisations that employ the authors of research protocols. Many details of the planning process will not form part of the Lifelong Research Record (LRR) but will be held and managed locally. As a result, this functionality is not part of the core R&DMIS systems and will not be delivered as part of the R&DMIS. However, such functionality is very important for both the comprehensive and specialist BRCs, and other research employers, so this requirement is documented, here, for completeness.

3.60. Ideally a study needs to be planned and managed as a project with a clear picture of what will happen on a day to day basis. A project plan for a study is based on the protocol and perhaps a study flow chart. A plan might include:

- A Diary Card;
- A schedule of procedures;
- A schedule of clinic visits;
- Any other events involving the subject.

3.61. The Diary Card is a planning document that will show what should happen for each study subject and record what actually did happen.

3.62. These will be based on a pre-defined schedule of:

- National holidays;
- Local staff holidays;
- other fixed scheduled events.

3.63. It should be possible to determine what should happen for a given subject at any visit, deriving this information from the flowchart.

3.64. The planning system should be capable of sending messages when:

- A specified procedure is due to happen;
- A specified procedure did not occur ;
- Any other nominated event in the plan occurs.

3.65. It should be possible to record what actually happens on any particular event within the plan. For example:

- The planned event occurred as planned (tick the box);
- Something else happened (specify or select from a list);

- 3.66. It is also necessary to plan the costs and resources required to carry out a study. This should be brought together in the form of a financial report that shows the predicted, planned costs. Most of the information required to do this should be drawn from the early study set up and initiation.
- 3.67. The recording of actual v planned expenditure should be possible on a day to day basis so that the actual financial position of the centre is easily understood.
- 3.68. Other resources that are needed to carry out a study also need management in a similar way. For example, the use of large capital equipment and a specific individual's time might be covered as part of the plan.

S4 – Study Data Capture (BRC Module)

- 3.69. This module is a part of the BRC required functionality. There is the option of bringing this module within scope, and it may be suitable for implementation also for non-BRC use. These decisions are subject to a separate business case. For the time being, it is included in this paper for completeness.
- 3.70. Study Data Capture provides the means for planning the capture of raw data in a study and for the direct capture of the data either directly in an electronic form or via paper as a temporary medium. Study Data Capture makes the data available in a number of different formats for further analysis and use in the production of reports. The study data do not form part of the LRR data.

S5 – Study Data Capture (CTU Module)

- 3.71. The Clinical Trials Units (CTUs) require an Electronic Data Capture (EDC) solution encompassing both EDC and clinical data management systems (CDMS). The solution should be based on emerging industry standards and should be scalable and cost effective, applicable to the handling of a single clinical trial or a large, multi-centre implementation.
- The solution will provide a web-enabled graphical user interface for data entry, accessible via the NIHR Portal;
 - A validation component to check user data;
 - A reporting tool for analysis of the collected data.
- 3.72. Implementation of an EDC solution is expected to increase data accuracy whilst decreasing the time taken to collect study data.

3.73. This module represents a late extension to Programme scope. Initial steps will include a review of standards, to be undertaken in conjunction with the UKCRC CTU Oversight Group, coupled with a review of the existing market for EDC/CDMS solutions. Completion of this review will enable the Programme to determine whether the buy or build approach, or a combination of the two, is optimal. It will also support a decision whether these systems should be provided through the NIHR IS Programme, through the Research Capability Programme of NHS Connecting for Health, or in collaboration with the RCP and other partners.

S6 – People Database/ID Management & Authentication

3.74. For the authentication mechanism, described above (NIHR Portal), to work there must be a database of users. In the first instance, this will be a database of Faculty members, only - the NIHR Investigators' Database, as described in the Tactical workpackages section.

3.75. The NIHR Investigators' Database will be expanded to provide an NIHR "people" database – a secure, searchable repository of all NIHR users. This will be made available for use, via the Portal, as a standard contacts database to meet a key requirement of NIHR users.

3.76. However, the People database will also be used to populate the identity management system that will be used to authenticate NIHR users. The principles of this authentication mechanism will be:

- the user logs-on once, when he/she accesses the Portal;
- the user will not then have to enter separate additional user IDs/passwords to access systems (e.g. R&DMIS) that are available via the Portal;
- system-level access rights will be determined by the user's role – i.e. an individual (Professor Bloggs) has different access rights when she logs on as CI for study A, to the rights that she has when she logs on as a member of the research team for Study B.

3.77. The principal objective of the strategic approach is to provide benefit to users of the NIHR systems by reducing bureaucracy and streamlining systems access in line with the objectives set out in Implementation Plan 1.2. Users may be Faculty members, industry researchers or individuals in supporting roles associated with research activities. Users will access the required services via the portal which will provide the option to store and manage contact details and profile information enabling ready reuse and sharing with the appropriate authorisation.

3.78. Key objectives are to implement:

- Management and maintenance processes to ensure that the database remains accurate and comprehensive
- A data model that supports the requirements for identity management and the wider set necessary for other NIHR applications
- Single sign-on to allow users to access the NIHR portal and all approved applications securely but with the minimum requirement for maintaining different usernames and passwords
- The capability for users to manage and optionally share information about themselves and the roles they are authorised to perform.
- Facilities for cooperative working and networking with colleagues and research organisations
- Facilities for organisations to validate information entered by users on their behalf (for example when the user is a contractor authorised to enter information but the organisation authorises someone else to sign it off for a particular use).

3.79. To meet these objectives, a solution architecture has been developed that will utilise federated identity management (Athens, as used in the NHS) that is familiar to much of the research community and which also recognises existing and anticipated infrastructure that will be required to support NIHR systems.

S7 – NIHR Database of Health Research

- 3.80. The NIHR Database of Health Research projects will provide an integrated data repository of all research funded or adopted by the NIHR. In addition to the UKCRN Portfolio of clinical trials it will include, for example, research undertaken by Bio-Medical Research Centres, and the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), as well as research which is funded by partner organisations and adopted by the NIHR.
- 3.81. The NDHR is intended to meet the information needs of a very broad community of users responsible for the conduct and management of health research across the whole of the NIHR, including the Department of Health and its contractors outside the UKCRN. It will subsume the National Research Register and the current UKCRN Portfolio Database and will be integrated with external systems including those of the partners in IRAS. The NIHR Database of Health Research will enable comprehensive answers to be provided to questions such as *“How much research involving children is supported by the Department of Health?”* By agreement, the system may hold information about research which is not the responsibility of the NIHR – such as research funded by or conducted with the support of the other UK Health Departments. If so, that research will be clearly flagged as such. The NDHR will include the facility to record a study on a trial register, publicly accessible via the Portal, which complies with WHO standards, by extracting and submitting the required data fields automatically when the CI gives permission to do so.
- 3.82. The construction of the Database will be seamless to the user who will access it via the NIHR Portal. The Database will be compliant with the Enterprise and Solution Architecture of the NIHR IS Programme and will be underpinned by the Life-Long Research Record, the data model that has been used as the foundation for the design of the R&DMIS.

S8 – Legacy Management

- 3.83. The investment in strategic solutions needs to be made in the context of a range of existing systems that will either need to be replaced by the strategic systems, or interfaced in some way to them. In either case, the work of moving from the current situation with the “legacy” systems to the future state needs to be managed carefully.
- 3.84. The legacy management work will commence with the creation of a **legacy inventory exercise** to:

- Identify all legacy systems or potential legacy systems.
 - Understand any current plans to replace or enhance them.
 - Assess the commercial and contractual position in terms of potential restrictions regarding their enhancement or replacement.
- 3.85. Once the inventory is complete, and in parallel with the development of more detailed procurement plans for strategic systems, **legacy analysis** will determine what, if anything, needs to be done to bring the legacy systems in line with the strategic solutions.
- 3.86. Once the analysis is complete, the actions arising from the legacy analysis can commence. The cost of managing the legacy systems will be determined following completion of the analysis.

TACTICAL WORK PACKAGES

- 3.87. The following tactical work packages will be conducted across the course of the year.

T1 – UKCRN Portfolio

- 3.88. Tactical improvements are required to the current UKCRN Portfolio system in order to address critical business issues. The priority of the tactical improvements is driven by the following business objectives:
- For all Topic networks, except Mental Health, the progress and status of Clinical Trials will be subjected to a review for the period April 2008 to January 2009. It is imperative that performance reporting can be achieved in an efficient and timely manner, to satisfy the specific requirements of the audit as well as reporting to satisfy the overall accountability of the NIHR.
 - To enable the review, a series of new Performance Measures / KPIs will be developed.
 - To obtain the fairest and most accurate reviews, the business requires data quality processes to be in place to ensure that accurate, complete and up to date (core) data about studies that are “owned” by data providers and networks is stored in the Portfolio Database.

- Ongoing Portfolio Management requires the business to have access to reports that are generated from quality data and which meet the management needs of UKCRN. These reports must be provided in a timely manner and the data and information within those reports must be clearly understood.
- In addition to reports, Portfolio Management objectives include the use of a “Dashboard” within the User Interface to display key progress information for the Portfolio workflow of studies, and identify typical and exceptional tasks associated with managing the workflow.
- The business process objectives are to understand, document and consider impact assessment of the Comprehensive Networks on the Portfolio system.
- The current Industry business processes for accruals into studies is inefficient and time consuming and needs improvements to be implemented.

3.89. The requirements for Portfolio system changes and updates to functionality have been identified by the user community and result in the following improvements which are planned for delivery in Q1 and Q2, 08/09:

- **Data Management and Data Quality** – An analysis of the issues and plan to ensure accurate and complete (core) data in the Portfolio Database and ongoing data assurance.
- **Data Dictionary Updated** - Agreed data definitions established. This will address issues arising from misunderstanding and misinterpretation of data contained within management reports.
- **Performance Measures / KPIs** – Key performance measures will be delivered in searchable, tabular form and will be augmented with a series of consolidated “dashboard”, graphical reports with drill-down capability. In addition to enabling performance management of the networks, this will also support the NIHR’s relationship with OSCHR.
- **MIS Reports** – a prioritised set of reports for Performance Measures / KPIs is required. Updates to existing report functionality (defined by Change Requests raised by users) are planned.

- **User Interface - “Dashboard”** to assist with metrics and functionality that enable the management of Clinical Trials in the Portfolio. Initially, there will be a “Proof of Concept” followed by a number of staged releases of functionality, determined by agreed business priority.
- **Data Repository** - Additional data repository to hold data extracted from the database for flexible report production.
- **Comprehensive Networks - business processes** - Impact Assessment with plan for developing appropriate IT systems and business changes.
- **Accruals** - Improvements to the Industry Accruals Process.
- **Change Requests raised by users for functionality improvements** - A delivery of Change Requests in 2 tranches according to business priority, one tranche by the end of May 08 with a further tranche being delivered by the end of September 08.

3.90. The developments outlined above will deliver early benefit to users and will enable key business objectives, such as the audit of Topic Networks, to be met. However, the planned improvements are not designed to deliver a long-term strategic solution. Where possible, the changes made will be ported into the long-term strategic development, the NIHR Database of Health Research (NDHR). However, the extent to which this is possible will not be known until completion of NDHR user requirements capture and Functional Design Specification.

T2 – CSP

3.91. The NIHR Coordinated System for gaining NHS Permission (CSP) is a new process for gaining NHS approval, designed to reduce both the time taken to start a study and the associated bureaucracy. In conjunction with the 25 Comprehensive Local Research Networks (CLRNs), investigators will submit applications for regulatory and ethics approval following existing and established processes. By tracking progress and sharing information, the UKCRN central CSP Unit (CSPU) and the CLRNs will enable participating NHS organisations to deal promptly with local permissions, avoiding duplication of effort.

3.92. CSP is a key strategic initiative within the wider NIHR Programme. Following the successful development of a proto-type to establish requirements, the Programme has initiated the procurement of a proprietary system from Infonetica, the clinical research software development company that also delivered IRAS for NRES and its partners. The procurement has been a tactical one designed to ensure delivery of the system in the timescales required to support the CSP project plan. One of the limitations of this procurement is that expenditure is capped, limiting the number of licenses that can issued to 400 and restricting the scope for bespoke development. However, an OJEU procurement is planned for the autumn; this will remove the limitations and constraints that currently apply. Moreover, a full OJEU procurement will enable us to test the Infonetica solution against alternatives in an open and competitive procurement exercise.

T3 – NIHR Investigators' Database

3.93. The Faculty ID project was initiated in Q3, 07/08 and is due to complete at the end of Q1, 08/09. Its objective is to establish a database of Faculty members. Each of the commissioning bodies and the BRCs contributed to the initial data set of researchers by identifying Chief Investigators. These individuals were asked to provide their contact details and equality data plus contact names for the Principal Investigators employed on their studies. With a second round of requests for information from principal investigators, the data capture exercise was intended to provide a comprehensive listing of the current leaders of NIHR research. It will later extend to others involved in planning, conducting and managing NIHR research.

3.94. The database will have two functions:

- This is the first contacts database for NIHR Faculty that can be used to populate an identity management system
- The data will be made accessible to appropriate organisations where there is a need to report on NIHR Faculty

3.95. To achieve these aims, the project objectives are to:

- Determine the detailed reporting requirements that organisations such as DH, UKCRN and the commissioning bodies might have for the NIHR Investigators' Database.

- Embed the Faculty ID database within the NIHR Portal.
- Develop functionality to query the database to fulfil reporting requirements.
- Decide with relevant organisations how to validate information provided by their employees and contractors; and whether to draw some information from other databases with permission from the individuals and organisations concerned.
- Develop the database to include details of NIHR Trainees.
- Determine DH requirements for information on NIHR Associates.
- Develop access to content and functionality to support researchers in NIHR Faculty.

4. FINANCIAL CASE

- 4.1. The estimated costs for the Programme are provided in a separate schedule, available upon request on a need to know basis.
- 4.2. In accordance with the principles and methodology described in the Programme Brief, benefits attributable to individual investment elements and work packages have not been included in financial schedule.

5. MANAGEMENT CASE

PROGRAMME MANAGEMENT ARRANGEMENTS

5.1. The work packages identified in this business case require a programme structure to deliver them, because there is significant overlap between the packages in terms of planning, business requirements, technology, and timing of deployment.

ORGANISATIONAL DEVELOPMENT

5.2. Some of the work packages will require organisational development within parts of the research community in order best to reap the benefits of the new technology, systems and data.

5.3. During the planning and development work relating to each work package, the Programme will identify those responsible within the business and ensure that they are informed of the potential need for such development. The Programme will also ensure that its deployment plans are aligned with any such developmental work.

RESPONSIBILITY FOR ACHIEVING BENEFITS

5.4. In line with the Programme Brief and the principles for organisational development outlined above, the research business and not the Programme will be responsible for identifying and achieving benefit. The Programme's responsibility is to deliver the supporting technology, systems and data as appropriate, and align deployment plans with the business's benefits realisation plans.

INVESTMENT APPROVAL

5.5. This is a high level OBC to justify the direction of travel for the Programme over the course of the next 12 months

5.6. It is intended to provide the basis for formal Programme delegation of the initiation of all described procurement activities to the Programme itself.

5.7. Contract awards as a result of the individual procurements will be subject to further approvals, which:

- Will each require an appropriate FBC
- May require Programme Board approval.

6. COMMERCIAL CASE

PRINCIPLES THE PROGRAMME AND ITS PROJECTS WILL FOLLOW

- 6.1. The following principles are taken from the Programme Brief.
- 6.2. 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.
- 6.3. In all cases, procurements will follow a set of key principles, drawn from published OGC best practice.

Ensuring Competition

- 6.4. 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.

Ensuring Value for Money

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

Demonstrating Transparency

- 6.6. 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.

Stimulating Market Creation

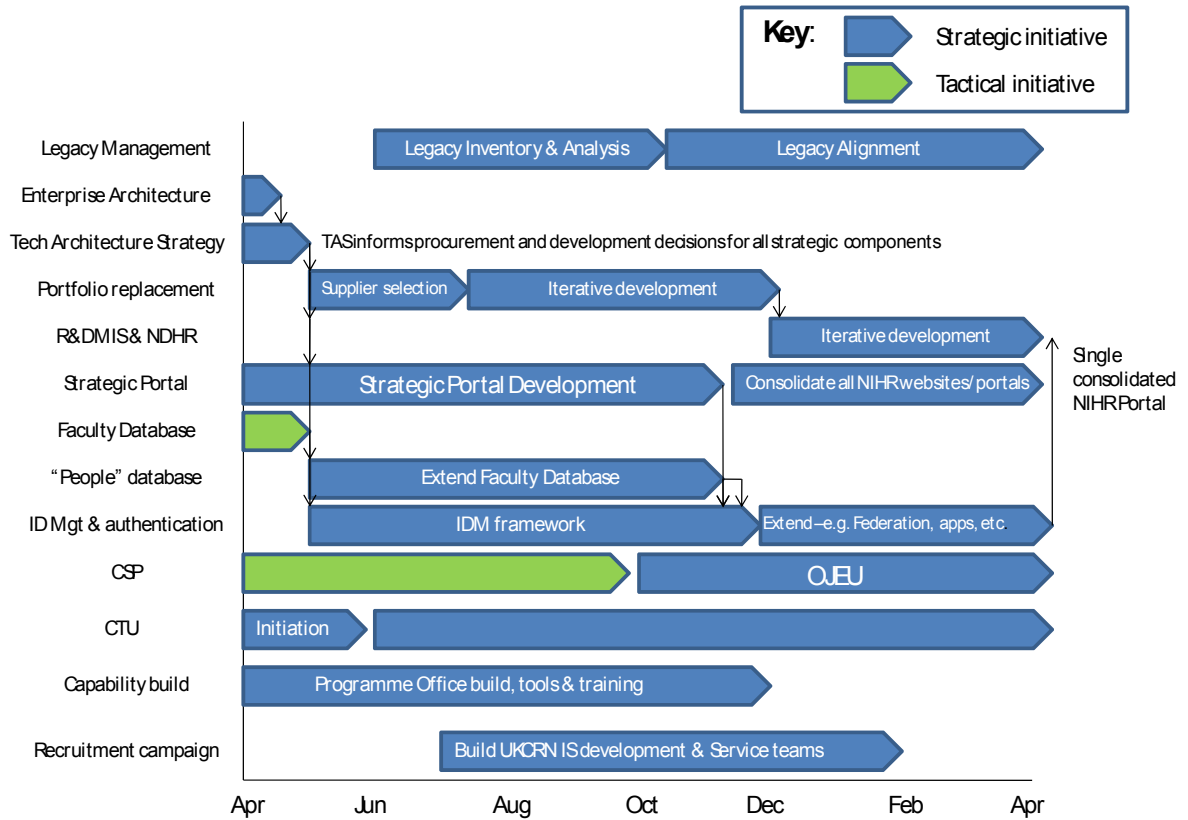
- 6.7. There may potentially be limited response to some requirements because of the nature of the requirement or the state of the market. In such cases, the Programme will stimulate the market place and engage with potential suppliers as appropriate, whilst maintaining a level playing field. Thus, the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

Underpinned By Business Cases

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

A. PROGRAMME PLAN

NIHR IS Programme Plan – 2008/ 09



B. R&DMIS PHASES 2 AND 3

R&DMIS PHASE 2

This phase will build on Phase 1 infrastructure, scaled as required to allow for a larger number of users and a greater amount of data.

In addition to the infrastructure, the database scheme must be sufficiently developed to support the following additional parts of the study lifecycle as well as those covered in Phase 1.

The modules to be delivered during this phase are:

- Full study management and reporting
- Project status dashboard
- Local portfolio management
- Study data capture
- DH, UKCRN monitoring
- NIHR Database of Research and supporting applications

Some data migration may be required in Phase 2 to cover those studies which are in progress but which do not have the full set of data required for interfacing with the new modules or external systems listed above. This work could be minimised if the LRR Data schema is fully developed before Phase 1 starts.

R&DMIS PHASE 3

This phase will build on Phase 1 and 2 infrastructure, scaled as required to allow for a larger number of users and a greater amount of data. This phase is intended to implement the full R&DMIS functionality, so all remaining interfaces must be covered.

In addition to the infrastructure, the database scheme must be sufficiently developed to support the following additional parts of the study lifecycle as well as those covered in phases 1 and 2.

The modules to be delivered in Phase 3 are as follows:

- Funding wizard/context specific workflow
- Funding data entry
- Performance metrics
- Commissioning
- Funders
- Outcomes