



**National Institute for  
Health Research**

**BEST RESEARCH FOR BEST HEALTH**

**IMPLEMENTATION PLAN 4.2**

**BUREAUCRACY BUSTING:  
RESEARCH INFORMATION SYSTEMS**

*Best Research for Best Health*<sup>1</sup> set out a 5-year Research and Development Strategy for the NHS in England. This Implementation Plan provides more details on one of the components which will together provide systems underpinning the National Institute for Health Research: **INFORMATION SYSTEMS**

It should be read with the implementation plans for **GOVERNANCE, ADVICE AND ETHICS SYSTEMS** and the **COMPREHENSIVE RESEARCH NETWORK**

This document will be regularly updated. The latest version should be used.

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**Aim**

- To support a vibrant and efficient research environment that commands public confidence and protects research participants; through
  - world-class networks for research management and governance; and
  - action to simplify processes that use research time.

**Purpose**

- To create, with partners, an integrated set of national systems for health research and research management that will
  - unify and simplify the administrative procedures associated with regulation, governance, reporting and research administration,
  - enable procedures and input of data to occur once and once only,
  - make information supporting regulatory approvals and permissions available via secure systems and processes to everyone who needs to act on it.

<sup>1</sup> *Best Research for Best Health: A New National Health Research Strategy*. The NHS contribution to health research in England. Department of Health. 2006.

## Nature

This work stream will

- deliver and manage a national portal from 2007;
- develop the national R&D information management system; and
- work with all the relevant bodies to define data standards and processes for research within the National Institute for Health Research (NIHR).

The ***national portal*** will

- support individuals who are involved or want to become involved in health and social care research, including researchers, R&D managers, policy makers, patients, service users and the public;
- enable single entry of information required for ethics review, NHS site-specific permissions and authorisation of clinical trials;
- give easy access to information, documents, guidance and people to help investigators and R&D managers work efficiently and consistently,
- offer a central resource of information on each study's design, organisation and progress to facilitate R&D management; and
- provide access to a national repository (or network of repositories), where all NIHR investigators can archive protocols, data and conclusions.

The ***R&D information management systems*** will

- enable researchers and research managers to access and manage the information and guidance required to operate efficiently and participate in high quality R&D with proper governance;
- provide standard underpinning systems and services to support the operation of all the main elements of the NIHR;
- provide web-oriented application programme interfaces and infrastructure to promote integration of existing systems;
- reduce the administrative burden of proposals, applications and reporting, releasing effort to manage outcomes and enable more effective monitoring and review.

The ***data standards and handling processes*** will

- review, define and publish standards and workflow processes;
- maintain a repository of data standards for the NIHR and its partners;
- enable researchers to exchange standard data sets and documents with organisations that require reports and outputs for regulation, accountability, or the administration of grants and contracts.
- in particular, enable exchange of standard data sets between

- NIHR research networks/organisations;
  - NIHR programmes;
  - Research funders;
  - Research ethics service;
  - MHRA/EUdraCT;
  - other regulators; and
  - recognised trial registers and other registers of relevant studies.
- enable standard data sets and documents to be linked to UK Pubmed, and to the relevant elements of the NHS National Knowledge Service and other systems providing access to research outputs.

### **Benefits**

The work stream will deliver the following benefits:

- improve the efficiency and effectiveness of research commissioning and initiation by giving policy makers, commissioners and researchers a clearer view of research requirements; and by supporting researchers and research networks;
- reduce the time taken in seeking ethical and regulatory review by simplifying, clarifying and integrating processes; implementing web-based submission systems, research passports, advice and other services;
- help increase recruitment by enabling clinicians, patients and the public to gain easy access to information about current trials and other well-designed studies;
- improve the uptake of findings by increasing the visibility of NIHR research findings and ensuring they are readily available through systems used by decision-makers.

### **Approach**

This work stream is being delivered by the NIHR Information Systems team working through the NIHR Comprehensive Research Network from the UKCRN Coordinating Centre. It will include the development, integration and standardisation of previous investments in NHS R&D management information systems.

The programme director and his team will

- engage with stakeholders (including local NHS communities through the NIHR Comprehensive Local Research Networks) to define needs and priorities;
- undertake business and technical analysis to define and maintain requirements, system architecture and standards;

- explore opportunities for integration with key technical stakeholders in the NHS, Higher Education, Research Councils UK (RCUK), charities, industry, UK government and international research community;
- undertake quick expert studies to take stock of developments in electronic research management, identifying opportunities, limitations and barriers to integration. Reference points will include the National Science Foundation's FastLane application system and RCUK's Joint Electronic Submission.

### Activities

- Working from the UKCRN Coordinating Centre with organisations in the NIHR Comprehensive Research Network to ensure that
  - a consistent and comprehensive approach to information systems; underpins the development of networks; and
  - systems used for R&D management are linked to integrated information management systems.
- Revision of *R&D Information for Health and Social Care* (DH, 2001)
- Development of user requirements, functional specifications, process descriptions, systems architecture and other documentation.
- Agreement on the scope of the IT system(s) and any joint funding between stakeholders including members of the UKCRC.
- Decision with UKCRC and other partners on a procurement process for the design of the system(s) and for the development and operation of unified R&D management systems.
- Development and/or procurement of
  - NIHR portal
  - Integrated set of national R&D information management systems
- Publication with partners of standards and protocols for the exchange of information between R&D systems relevant to health and social care.
- Exploration with Connecting for Health to determine scope for adopting compatible local and networked research management modules. If necessary, national call-off contracts.
- Providing training and support to help research networks and their constituent organisations adopt and routinely use standard national IT systems in place of local forms.

### Scope

- The IT system(s) will be designed primarily for researchers preparing and conducting studies within the responsibilities of the Secretary of State for Health.

- All organisations and individuals in England that provide care, fund research, employ researchers or review or regulate research will be eligible for access related to their needs.
- The main aim will be to provide specialist information services for research, and not services to the public or to business; but the information will be publicly accessible, subject to exemptions provided by the Freedom of Information Act and the Data Protection Act.

### **Funding**

- The indicative DH budget ceiling will rise to £2 million per annum by year three of the R&D Strategy transition.
- At each stage, UKCRC partners will be invited to contribute in cash or in kind, and to identify extra functionality for which they are willing to pay.

### **Governance, Monitoring and Performance Management**

- A national programme board will oversee the delivery of the planned systems. It will report to the Department of Health through the NIHR. Individual project boards with appropriate stakeholder representation will be established as required.
- The performance of the information management system(s) will be reviewed annually against metrics of user satisfaction.
- There will be an annual report to NIHR and UKCRC Boards, to be published after discussion.
- The implementation and use of the information management systems will be monitored to ensure they are being used as required and delivering the intended benefits.

### **Implementation Timetable**

The programme deliverables, planned benefits and implementation plan will be discussed with UKCRC partners. The aim will be to establish a timetable that

- addresses as a priority benefits that are easy to deliver;
- exploits opportunities to reduce bureaucracy through standardisation of processes and systems;
- maximises the opportunities for integration between the R&D information systems of all the UKCRC partners; and
- keeps step with the overall development of the National Institute for Health Research.

The planned timetable is as follows.

*Completed*

- January 2006 –
  - DH published R&D strategy confirming intention to establish integrated national IT system(s).
- April 2006 –
  - UKCRN appointed programme director.
- May 2006 –
  - UKCRN held first round of workshops with stakeholders.
- June 2006 –
  - UKCRN recruited interim implementation team.
- September 2006 –
  - Completed draft requirement and options appraisal for NIHR portal.
  - Completed recruitment of programme team and programme manager.
  - Established UKCRN programme board.
- December 2006 –
  - Published portal user requirement specification
  - Published discussion document on integrated national R&D management information systems

*January to March 2007*

- **Portal**  
Development and beta testing of NIHR Portal
- **Information Management System**  
Consultation on user requirements specification (NIHR 4.2\_URS003)  
Revision of user requirements.
- **Data standards and handling processes**  
Consultation and development of initial enterprise architecture;  
Identity management, focusing on meta-systems;  
Trials management systems.

*April 2007 to March 2008*

- **Portal**  
Launch of NIHR Portal  
Refinement and development in response to user feedback  
Incorporation of new functionality as it becomes available:

- Application wizard for approvals
- Research network services
- Document delivery services for NIHR Faculty
- News and information services
- Directory services
- Secure e-portal
  
- **Information Management System**  
Pilot, including
  - Identity management
  - Support for Research Passport
  - Research project management system
  
- **Data standards and handling processes**  
Engagement with
  - UK Cross Government Enterprise Architecture team
  - US NIH Enterprise Architecture team. (Seek involvement in NIH identity management programme.)
  - UK PubMed CentralEstablish technical standards, data standards and handling processes.  
Complete review of
  - ethics submission processes and workflows
  - financial management processes and workflows

*April 2008 to March 2009*

- **Portal**  
Continuous development and improvement
- **Information Management System**  
Development of integrated clinical research reporting  
Further development of financial management system  
Further development of APIs and toolkits
- **Data standards and handling processes**  
Develop technical standards, data standards and handling processes.

**Department of Health Lead:**

C Marc Taylor  
Head of R & D Systems and Governance  
[Marc.Taylor@dh.gsi.gov.uk](mailto:Marc.Taylor@dh.gsi.gov.uk)

**NIHR IS/UKCRN Lead:**

Steve Walker  
Programme Director  
[Steve.walker@ukbiobank.ac.uk](mailto:Steve.walker@ukbiobank.ac.uk)