



The Government plan for a secure data service

*Strengthening the international competitiveness
of UK life sciences research*

The Government plan for a secure data service: Strengthening the international competitiveness of UK life sciences research

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce Management	Commissioning
Planning / Performance	IM & T
	Finance
	Social Care / Partnership Working

Document Purpose Gathering DATA

Gateway Reference 16821

Title The Government plan for a secure data service: Strengthening the international competitiveness of UK life sciences research

Author Research & Development Directorate

Publication Date 31 Oct 2011

Target Audience Life Sciences Industry

Circulation List

Description The plan details the approach the Department of Health's National Institute for Health Research and the Medicines and Healthcare products Regulatory Agency is taking to address some of the key action points detailed in *The Plan for Growth* (March 2011). It will do this by creating a new service: the Clinical Practice Research Datalink.

Cross Ref

Superseded Docs

Action Required N/A

Timing

Contact Details Peter Knight
 Research & Development Directorate
 Area 132, Richmond House
 79 Whitehall, London
 SW1A 2NS
 020 7210 5670
www.dh.gov.uk/health/category/publications

For Recipient's Use

The Government plan for a secure data service

Strengthening the international competitiveness of UK life sciences research

Prepared by Research & Development Directorate

© Crown copyright October 2011

First published 31 October 2011

Published to DH website, in electronic PDF format only.

<http://www.dh.gov.uk/publications>

Contents

Purpose of document	5
Background and context	6
<i>The Plan for Growth</i>	6
Implementing <i>The Plan for Growth</i>	7
Building on the existing capability	7
Features of the new Clinical Practice Research Datalink.....	8
Delivering the Clinical Practice Research Datalink	8
Annex A.....	10
Key delivery milestones for the Clinical Practice Research Datalink (CPRD) relating to actions identified in <i>The Plan for Growth</i>	10

Purpose of document

This document details the forward plan in which the Department of Health's National Institute for Health Research (NIHR) in partnership with the Medicines and Healthcare products Regulatory Agency (MHRA) will address some of the key action points (particularly paragraph 2.198) detailed in *The Plan for Growth*(March 2011). It will do this by creating a new service: the Clinical Practice Research Datalink.

The document provides an overview of this new service, and explains the ways in which the delivery and refinement of this service and the products it offers, support the actions identified in *The Plan for Growth* (Healthcare and Life Sciences Review Actions)¹.

¹ Actions summarised on page 98 of *The Plan for Growth*, published in March 2011 by TSO

Background and context

The Plan for Growth

The Plan for Growth, is a “call to action”, detailing the steps the Government will take to enable the British economy to become more internationally competitive.

In the foreword, the Chancellor of the Exchequer and the Secretary of State for Business note, “Britain has to earn its way in the modern world. We have to become much more productive so we can be a leading high tech, highly skilled economy. We must build a new model of economic growth – where instead of borrowing ...we invest and we save and we export. Our economy must become more balanced”²

The Plan for Growth states that the life sciences and social care sectors employ huge numbers of people, across a vast skills range. The NHS itself is a huge purchaser, which in turn supports a number of supplier businesses and staff in the UK. Moreover, the sector is a huge investor in Research and Development. The potential benefits to the UK economy, and the health of the nation, as a result of a thriving healthcare and life sciences sector are clear.

This document is concerned with the Government’s commitment to address the following action from *The Plan for Growth*:

4) The Government will build a consensus on using e-health record data to create a unique position for the UK in health research.

2.198 The NHS could offer unique opportunities for this country’s international competitiveness in health research. Government can create the capacity to draw on the power of large linked data sets on a scale unprecedented here or elsewhere in the world. This would create unique opportunities for research in the UK, including more powerful uses of anonymised data sets and aggregated prescription data linked down to GP practice level. That can happen only if there is robust protection for individual patients’ confidentiality and privacy. Enabling access through a managed health research data service would support clinical innovation and strengthen evidence of effectiveness, improving health outcomes. The Government will work with the National Information Governance Board and partners in the public and private sectors to publish plans by the autumn for a secure data service that is viable and affordable, and is focussed on linking the data sets which do most to strengthen the international competitiveness of our life sciences research.

PP 93-94, *The Plan for Growth*, published March 2011 by TSO

² Page 3 (Foreword), *The Plan for Growth*, published in March 2011 by TSO

Implementing *The Plan for Growth*

The Research Capability Programme has identified business and technical requirements, corralled consensus on implementation and use of NHS data and piloted the delivery.

The approach detailed below builds upon existing work, the lessons learned, and a consensus established with a host of external stakeholders including the British Medical Association; the National Information Governance Board for Health and Social Care, and the Information Commissioner's Office. Patient and Public Involvement has been integrated throughout this programme of work, at local, regional and national levels. A collaborative approach between the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA) is key to the delivery of the new capability in a timely, effective way.

Following on from the release of *The Plan for Growth*, an opportunity has been identified to address point 4 above: the combination of two existing services, in order to create a new, enhanced service that constitutes a £60 million investment. This new service will be known as the Clinical Practice Research Datalink (CPRD), and it will take forward a number of the Healthcare and Life Sciences Review actions from *The Plan for Growth*, as detailed in the table at Annex A. The business case for the CPRD is still under review, and confirmation of the Department funding is subject to the successful completion of the business case.

Building on the existing capability

The existing services to be merged are:

- 1) **The Health Research Support Service** established by the Research Capability Programme, which helps researchers to access and analyse a wide range of health-care and other relevant information to support their research projects. The Pilot version of this Service is now established and has proven the feasibility of accessing, matching, linking and anonymising national scale datasets, within a rigorous governance framework.
- 2) **The GPRD (General Practice Research Database)** is the world's largest computerised database of anonymised longitudinal medical records from primary care that is linked with other healthcare data. The GPRD Division, which is hosted in the MHRA, provides data, research and other services as well as tools to support medical and public health research.

Features of the new Clinical Practice Research Datalink

The Clinical Practice Research Datalink (CPRD) will be established by 1 April 2012 and its functionality will be increased in stages over the next four years, applying the lessons learned and building upon the existing consensus. It will provide services to enable health research both nationally and internationally, support improvements to the health, and wealth of the nation.

The CPRD will provide capability, products and services across the following areas:

- **Data Services:** Access to data for researchers (NHS, social care and others); data matching and linkage services, data validation and access to real time data to facilitate surveillance activities and support the public health agenda.
- **Interventional research services:** Feasibility of research proposal (i.e. *are there enough research subjects in a given area to provide a meaningful research result?*); site and patient level recruitment; full electronic-data (e-data) services; Linkage services for clinical trials, full clinical trial input; biological sample collection and linkage; patient reported outcomes collection and linkage.
- **Research services:** Advise on research methodology, research governance and feasibility of research proposals; provide consultancy services including the provision of patient and / or healthcare professional input; ability to undertake research studies on behalf of customers.

Delivering the Clinical Practice Research Datalink

The CPRD will be delivered incrementally over 4 years from April 2012, with some of the services being available for researchers in 2012. It will be hosted in the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the Department of Health's National Institute for Health Research (NIHR) and the MHRA.

The approach to create the CPRD, by building on existing capabilities, represents significant value for money and means the service will be available to researchers from April 2012. Further development and refinement of products and services will take place in parallel up to March 2016. Realisation plans are being created, that will provide details of which benefits will be delivered and when over this period. These will be closely allied to the Healthcare and Life Sciences Review actions, detailed in *The Plan for Growth*.

By March 2016, all planned products and services will have been delivered and made available to the research community, both in the UK and across the world.

Delivery milestones

The table at Annex A, details the key delivery milestones for the CPRD, mapped against the corresponding *Plan for Growth* actions, to which they contribute.

The actions defined in the table will provide solid foundations for the establishment of the CPRD: a key piece of the health research infrastructure in England, which will contribute to the competitiveness of the UK economy as a whole.

Annex A

Key delivery milestones for the Clinical Practice Research Datalink (CPRD) relating to actions identified in *The Plan for Growth*

Year and Task	Planned Activity	Planned date	Responsibility for delivery
0.1	Engagement work commences with Primary Care Research Networks (PCRN) and General Practices, initially working to add further GP Practices to the existing capability.	Year 0 Sept 2011 – March 2012	MHRA, NIHR
0.2	Complete first stage meetings with IT vendors (re: access to data and improved CT recruitment capability through changes to existing systems).	Year 0 Sept 2011- Nov 2011	MHRA, NIHR
0.3	Update the Privacy Impact Assessment for CPRD.	Year 0 February 2012	MHRA, NIHR
0.4	Agree governance arrangements peri- and post-transition (based on existing GPRD work and HRSS model) with NIGB, ECC and the Research Ethics Committee (REC).	Year 0 Sept 2011- March 2012	NIHR, MHRA
0.5	Maintain watching brief regarding arrangements for the Health Research Authority – conducting impact assessments and readiness activities when and where appropriate.	Year 0 From Sept 2011	NIHR, MHRA
0.6	Commence discussions on surveillance requirements with HPA and Public Health Observatories.	Year 0 From Sept 2011	MHRA
0.7	NIHR RCP Delivery Phase FBC, PID and detailed plan agreed by DH RDD, DH Finance, CIB, MHRA Finance and MHRA Agency Board.	Year 0 Oct/Nov 2011	NIHR, MHRA
0.8	MHRA ‘makes ready’ internal organisation and infrastructure, in preparation for transition.	Year 0 Oct-Dec 2011	MHRA, NIHR
0.9	Announcement in the Chancellor’s Statement.	Year 0 Nov 2011	DH, NIHR, MHRA

The Government plan for a secure data service: Strengthening the international competitiveness of UK life sciences research

Year and Task	Planned Activity	Planned date	Responsibility for delivery
0.10	MHRA takes formal responsibility for CPRD.	Year 0 Nov 2011	MHRA
0.11	Joint MHRA – NIHR follow-up announcement on implementation of CPRD.	Year 0 Dec 2011	MHRA, NIHR
0.12	MHRA scientific governance changes in place (ongoing activity, but will accommodate incoming CPRD requirements).	Year 0 Mid Nov 2011	MHRA
0.13	Public facing event: European Outcomes meeting.	Year 0 5-8 Nov 2011	MHRA
0.14	Commence and complete recruitment of CPRD staff – to come on board from April 2012.	Year 0 Mid Nov 2011 – End Mar 2012	MHRA
0.15	Appoint members to CPRD Expert Advisory Group.	Year 0 Nov-Dec 2011	MHRA
0.16	Contract meetings with IT vendors, regarding the changes required in existing systems to enable data access and facilitate Clinical Trials recruitment.	Year 0 From Dec 2011	MHRA with support from NIHR
0.17	Stage 0 enhanced CT system operating in GPRD (trial module from ongoing GPRD work).	Year 0 Dec 2011	MHRA
0.18	Commence and complete contracts arrangements with relevant suppliers to both MHRA (GPRD) and RCP.	Year 0 Dec 2011 – March 2012	MHRA, NIHR
0.19	Plan and complete set up of enhanced PPI function in MHRA (incorporating the new CPRD).	Year 0 Dec 2011-Feb 2012	MHRA
0.20	Physical transition of assets and collateral from the RCP Pilot Programme to the MHRA.	Year 0 Dec 2011-Mar 2012	MHRA, NIHR
0.21	Start arrangements for access to data from existing RCP GP Practices.	Year 0 From Dec 2011	NIHR, MHRA
0.22	Deliver agree final profile of for Information Systems budgets across years 1-4, based upon supplier meetings.	Year 0 From Dec 2011	MHRA
0.23	CPRD Expert Advisory Group first meeting held.	Year 0 Jan 2012	MHRA

The Government plan for a secure data service: Strengthening the international competitiveness of UK life sciences research

Year and Task	Planned Activity	Planned date	Responsibility for delivery
0.24	Detailed stakeholder marketing plans complete.	Year 0 Jan 2012	MHRA
0.25	Preparation and planning for CPRD NHS Information Governance Toolkit Assessment.	Year 0 Jan – Mar 2012	MHRA
0.26	Key CPRD posts in place.	Year 0 Feb 2012	MHRA
0.27	CPRD in place (merging of existing RCP and GPRD capabilities completed, governance framework up and running, people, processes and tools in place).	Year 0 November 2011 - Mar 2012	MHRA, NIHR (with support from NIGB)
0.28	10 national datasets available for linkage.	Year 0 From Mar 2012	MHRA
0.29	Validate engagement work with PCRN to assess amount of new primary care buy-in at launch (as per 0.1 above).	Year 0 Mar 2012	MHRA
0.30	Joint NIHR-MHRA formal CPRD launch meeting.	Year 0 Late Mar 2012	MHRA, NIHR
0.31	Public facing event: Euro DIA meeting.	Year 0 26-28 Mar 2011	MHRA
1.1	Recruitment completed and CPRD core team are in place.	Year 1 From April 2012	MHRA
1.2	Commence and complete work to ensure staff levels and skill sets are in place to achieve the deliverables set out across the 4 year plan.	Year 1 From April – June 2012	MHRA
1.3	Additional services purchased, for enhanced CT requirements.	Year 1 From April 2012	MHRA
1.4	Plan and execute nationally facing General Practice engagement programme.	Year 1 From April 2012	MHRA
1.5	Conduct and submit Information Governance Toolkit assessment for CPRD.	Year 1 April 2012	MHRA
1.6	Prescribing data available. CPRD starts discussions re: availability of prescribing dataset.	Year 1 April 2012	MHRA
1.7	Create, maintain internal knowledge base, for validation of data sources, quality of data and linkages and outputs to researchers.	Year 1 April 2012	

The Government plan for a secure data service: Strengthening the international competitiveness of UK life sciences research

Year and Task	Planned Activity	Planned date	Responsibility for delivery
1.8	Engagement with topic specific research networks to identify and access to research datasets.	Year 1 April 2012	MHRA, NIHR
1.9	Changes implemented to existing systems, to enable data to flow and to facilitate Clinical Trials recruitment. Stage 1 enhanced CT system delivered and available (May 2012). Stage 2 enhanced CT system delivered and available (Dec 2012). Surveillance and Public Health system delivered and available (planned for delivery Dec 2012, subject to discussions with Public Health).	Year 1 May 2012	MHRA
1.10	PCRN Data Managers engaged to assist in train Practices on how to use the enhanced CT system (phase 1).	Year 1 May 2012	MHRA
1.11	Public facing event: Pharmaceutical Industry Board Directors of Research Annual Meeting.	Year 1 May 2012	MHRA
1.12	Public facing event: ISPOR Major Global Outcomes meeting.	Year 1 12-16 June 2012	MHRA
1.13	Additional datasets added to the CPRD offering to researchers (adding to cumulative total). It is noted that the exact type and number of datasets required will be decided in conjunction with the Expert Advisory Group for the CPRD. Milestone dates for planned dataset take on <ul style="list-style-type: none"> - Lot one @ March 2013 - Lot two @ March 2014 - Lot three @ March 2015 Additional General Practice engaged to the CPRD.	Year 1 June 2012 – March 2013	MHRA

The Government plan for a secure data service: Strengthening the international competitiveness of UK life sciences research

Year and Task	Planned Activity	Planned date	Responsibility for delivery
	Milestone dates for planned primary care activity: <ul style="list-style-type: none"> - Lot one @ June '12 - Lot two@ June '13 - Lot three@ June '14 		
1.14	CPRD linked to NIHR clinical trials gateway.	Year 1 End June 2012	MHRA, NIHR
1.15	CPRD engagement with the home countries regarding future collaboration.	Year 1 Aug 2012	MHRA
1.16	Public facing event: Global Medicines safety meeting.	Year 1 August 2012	MHRA
1.17	Completed changes required by new Health Research Authority (tools, interfaces, business processes).	Year 1 January 2013	MHRA
2.1	Conduct, submit Information Governance Toolkit assessment.	Year 2 April 2013	MHRA
2.2	Hold CPRD User Group meeting (UK).	Year 2 April 2013	MHRA
2.3	Hold CPRD User Group meeting (International).	Year 2 April 2013	MHRA
2.4	Work starts on engaging with Home Countries collaboration.	Year 2 From April 2013	MHRA
2.5	Social care data available as part of CPRD offering to researchers.	Year 2 June 2013	MHRA
2.6	Plan for and design Research and CT control system.	Year 2 - 3 August 2013 – July 2014	MHRA
2.7	Stage 3 enhanced CT system delivered and available (final stage).	Year 2 December 2013	MHRA
2.8	Additional datasets added to the CPRD offering to researchers (adding to cumulative total). It is noted that the exact type and number of datasets required will be decided in conjunction with the Expert Advisory Group for the CPRD.	Year 2 June 2013 - March 2014	MHRA

The Government plan for a secure data service: Strengthening the international competitiveness of UK life sciences research

Year and Task	Planned Activity	Planned date	Responsibility for delivery
	<p>Milestone dates for planned dataset take on</p> <ul style="list-style-type: none"> - Lot one @ March 2013 - Lot two @ March 2014 - Lot three @March 2015 <p>Additional General Practice engaged to the CPRD.</p> <p>Milestone dates for planned primary care activity:</p> <ul style="list-style-type: none"> - Lot one @June '12 - Lot two@ June '13 - Lot three@ June '14 		
3.1	Hold CPRD User Group meeting (UK).	Year 3 April 2014	MHRA
3.2	Hold CPRD User Group meeting (International).	Year 3 April 2014	MHRA
3.3	Full review of CPRD operation and recommendations re: modifications and / or extensions (consider further PIA if applicable).	Year 3 April 2014	MHRA, NIHR
3.4	Research and CT control system available to researchers.	Year 3 By June 2014	MHRA
3.5	<p>Additional datasets added to the CPRD offering to researchers (adding to cumulative total). It is noted that the exact type and number of datasets required will be decided in conjunction with the Expert Advisory Group for the CPRD.</p> <p>Milestone dates for planned dataset take on</p> <ul style="list-style-type: none"> - Lot one @ March 2013 - Lot two @ March 2014 - Lot three @March 2015 	Year 3 June 2014 – March 2015	MHRA

The Government plan for a secure data service: Strengthening the international competitiveness of UK life sciences research

Year and Task	Planned Activity	Planned date	Responsibility for delivery
	<p>Additional General Practice engaged to the CPRD.</p> <p>Milestone dates for planned primary care activity:</p> <ul style="list-style-type: none"> - Lot one @June '12 - Lot two@ June '13 - Lot three@ June '14 		
4.1	Enhanced CT system: part refresh.	Year 4 July 2015	MHRA
4.2	Joint NIHR and MHRA work to identify investment priorities.	Year 4 From Oct 2015	MHRA, NIHR
4.3	Home Countries collaboration complete, as part of CPRD offering to researchers.	Year 4 By Mar 2016	MHRA