

## *Research Capability Programme*

NHS-HE Forum, 22<sup>nd</sup> April 2009

### **UPDATE**

Alex Markham

Research Capability Programme - SRO

# *What is the Research Capability Programme?*

It is a formal programme of work within NHS CFH looking at how information held in the National Programme for IT systems may be used for research purposes.

It will take forward the recommendations in the “Report of Research Simulations” produced by the UKCRC Advisory Group to NHS CFH.

It has a Senior Responsible Owner, who is a nominee of the DH Director-General of R&D. A programme board and external reference group provide strong governance.

The primary objective is to enable research to achieve its full potential as a “core” activity for healthcare, alongside other uses of NHS data that lead to improvements in the quality and safety of care.

## *Background*

- Dec 2005 – Chancellor's commitment
- Jan 2006 – DH strategy *Best Research for Best Health*
- July 2006 – R&D advisory group to NHS CFH established by UKCRC
- June 2007 – UKCRC R&D advisory group report
- August 2007 – CRDB SUS working group report
- August 2007 – Research Capability Programme initiated
- September 2007 – Health Select Committee Report

## ***Guide to Acronyms***

**UKCRC** – United Kingdom Clinical Research Collaboration

**CRDB** – Care Record Development Board

**NIGB** – National Information Governance Board

**NHS CRS** – NHS Care Records Service

**SCR** – Summary Care Record

**DCR** – Detailed Care Record

**SUS** – Secondary Uses Service

**R&D** – Research and Development

ABPI GUIDELINES FOR THE SECONDARY USE OF DATA FOR MEDICAL RESEARCH PURPOSES

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The Association of the British Pharmaceutical Industry  
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Telephone: 020 7591 4113  
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Email: [abpi@abpi.org.uk](mailto:abpi@abpi.org.uk)  
Web: [www.abpi.org.uk](http://www.abpi.org.uk)

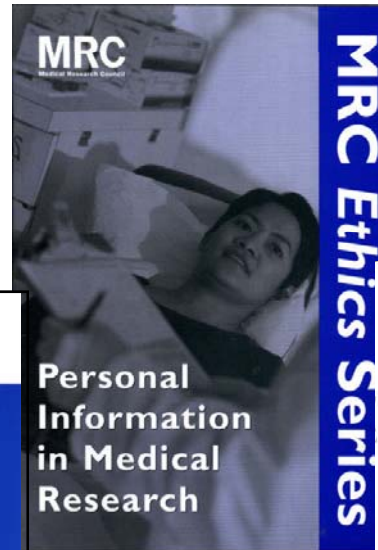
Care Record Development Board

Report of the Care Record Development Board Working Group on the Secondary Uses of Patient Information

MRC  
Medical Research Council

MRC Ethics Series


Personal Information in Medical Research



Patient Information

Confidentiality of Patient Information

Keeping Patients Informed



This leaflet is part of our campaign to provide patients with all the information they may require.

7700/05/17/05/2002

Your information

A guide to why the NHS collects information about you and how it is used

South West London **NHS**

## *Recent Reports discussing access to Personal Information*

- **“Better Use of Personal Information: Opportunities and Risks”** (2005), <http://www2.cst.gov.uk/cst/reports/files/personal-information/report.pdf>;
- **“Personal Data for Public Good: using Health Information in Medical Research”** (2006), <http://www.acmedsci.ac.uk/images/project/Personal.pdf>;
- **“UKCRC R&D Advisory Group to Connecting for Health: Report of Research Simulations”** (2007), <http://www.ukcrc.org/pdf/CfH%20report%20June%202007%20full.pdf>;
- **“Towards Consensus in the use of Electronic Patient Records for Research in General Practice”** (2008), the Wellcome Trust;
- The **“Health Informatics Review”** (2008), <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications>; and
- The **“Data Sharing Review”** (2008), <http://www.justice.gov.uk/docs/data-sharing-review.pdf>.
- The **“NHS Constitution”** (2008).

**Also, a variety of changes in relevant legislation.....**

## *Research Capability Programme*

### High level overview:

- Enabling Phase, August 07-June 08
- Implementation Phase, July 08-March 09 and beyond
- Key Partnerships
- Key Deliverables
- Key Challenges

## *Enabling Phase*

### Has achieved:

- Appointment of Programme Chair (SRO) and Group Programme Director
- Establishment of a Programme Board
- An agreed phase 1 **Programme Initiation Document**
- Agreed terms of reference for an **External Reference Group** operating under the aegis of the Office for Strategic Co-ordination of Health Research (OSCHR)
- Engagement with **stakeholders** to create a common vision
- Substantial progress on the recommendations identified in the UKCRC report
- A defined scope of work for the Programme and for related initiatives
- Production of a high level requirements documentations **PD00 to PD20**
- An approved **Strategic Outline Case**
- An agreed **Programme Initiation Document** for the Full Programme
- Development of the genesis of an **Outline Business Case**
- Completed an Office of Government Commerce **Gateway 0** review



***We produced a total of 21 documents running to about 800 pages in the Enabling Phase via 6 work streams***



**RCP work streams**

**Areas of focus**

Infrastructure

Honest broker(s) and business model,  
Safe havens

Functional scope

Services to be provided centrally;  
business models

Data quality and standards

Data standards, terminologies, options  
for linkage of datasets

Technical architecture

How data will be stored and accessed

Information Governance

Data security and measures to  
manage the threats, patient consent

Communications and  
stakeholder engagement

Initial consultation exercise;  
communications with public/physicians  
and with research community

## *RCP Data Sources?*

- Assessing feasibility of:
  - Demographic Data (NHS patient index)
  - Vital events (births, deaths)
  - Primary care clinical records (GP system extracts, research collections)
  - Secondary care clinical records (Hospital system extracts, research collections)
  - NHS National Data Collections (HES/MHMDS)
  - NHS CRS National Systems (Summary Care Record, Choose and Book, Electronic Prescription Service)
  - Disease Registries (National and Regional)
  - Diagnostic data (Laboratory tests)
  - NHS Specialist Collections (Clinical Audit)
  - Other data collections (research datasets, education, social care, deprivation, socio-economic)

## Functional scope: those research capabilities that the RCP aims to deliver



RCP will increase data available; provide services to support research; and provide services to reduce the need for identified data

### *In scope*

- NPfIT data and systems
- Access to other healthcare data
- Catalogues
- Linkage mechanisms
- Functions to reduce need for identified data

### *Out of scope*

- Access to non-English NHS data
- Research services
- Support for the detailed operation of research studies

Health Research Support Services (HRSS): the overall solution provided by the programme

## Examples of services that are within the scope of the RCP would include:



Negotiating agreements with current data custodians for existing databases to be made available through the HRSS

Developing new linkages between a GP database and a secondary care database such that the combined data can be used for research

Providing access to data sources

Providing regular reports from new datasets built on systems being established within the NPfIT

Storing and archiving data

Verifying data

Providing cohort management services

Anonymising or coding data

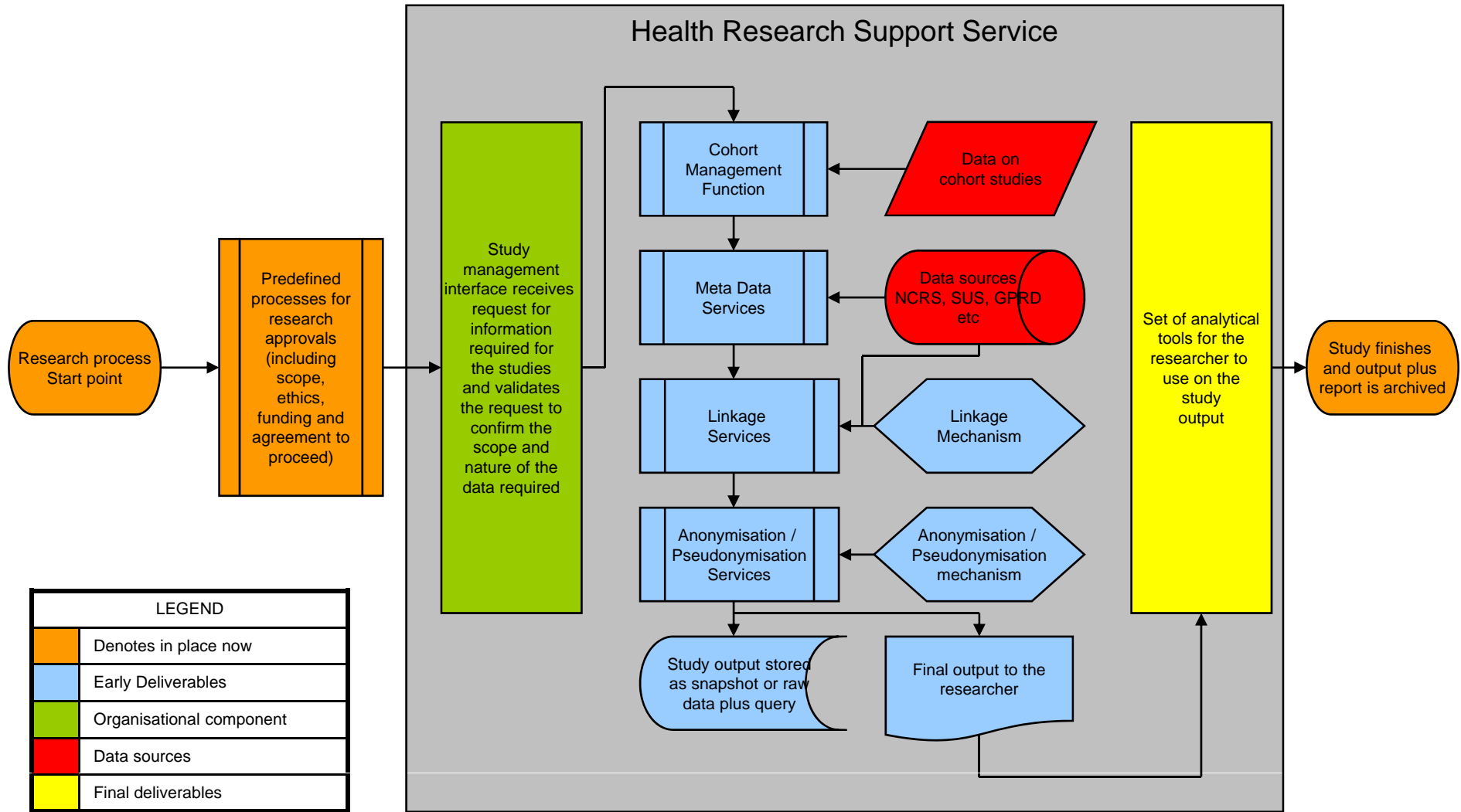
Re-identifying individuals from coded data

# ...but these cannot be seen in isolation: they build upon what we have now and what is being developed



## Examples

Building on what we have now:	Building on what is coming...		
	...through RCP	...elsewhere in CfH	...other initiatives
Excellent primary care data	Honest broker	Information on prescriptions dispensed (ETP)	Standard costs for clinical trials
Some hospital data, eg HES	Infrastructure	Imaging data (PACS)	Streamlined study approval processes
Clinical Research Networks	Linkage and anonymisation services	Use of a unique patient identifier	
Governance on use of data	Access to data sets		
	Catalogues and advice		



## *How were stakeholders engaged?*

### Representation on the External Reference Group:

The External Reference Group has been established and has common membership with the OSCHR E-Health Research Board, as well as the same chair, in order to ensure coordination of activities. It includes representation from a wide range of stakeholders (academia, ABPI, BIA, NHS etc) as well as Patients/Public Reps and UK Devolved Administrations.

### A public consultation

To test the findings and recommendations of the CRDB SUS working group report with professionals and patients and to probe public attitudes towards the use of medical information for research purposes. Launched September 2008. Report completed March 2009. Currently with Ministers for approval. I hope you were able to respond.

### Series of Town Meetings, Spring and Autumn 2008

Regular presentations to a wide range of interested stakeholders



Connecting for Health

# **Research Capability Programme**

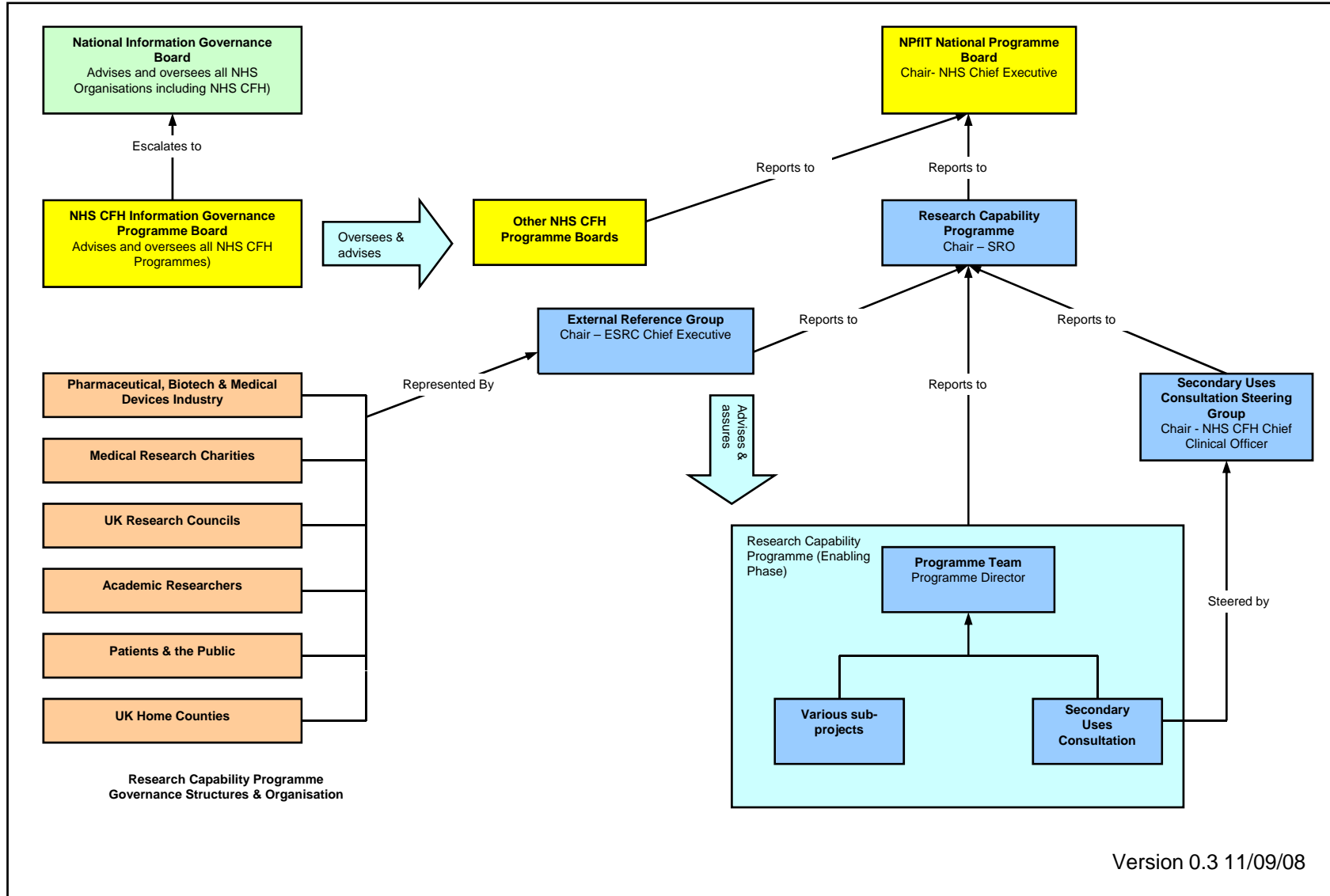
## **External Reference Group Membership**

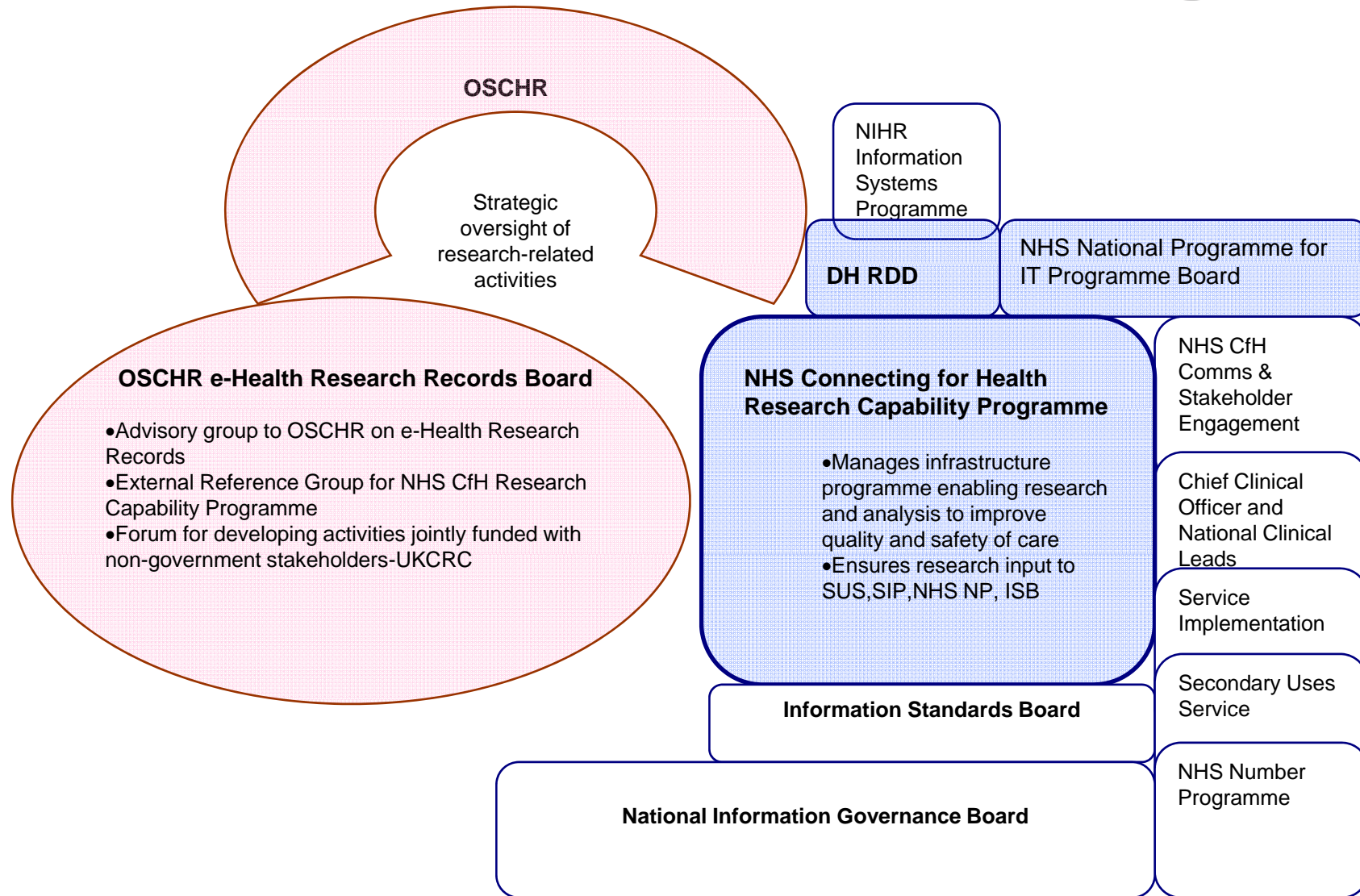
<b>Professor Ian Diamond</b>	<b>ESRC</b>	<b>Professor Rory Collins</b>	<b>UK Biobank</b>
<b>Dr Richard Barker</b>	<b>ABPI</b>		<b>University of Oxford</b>
<b>Rob Thwaites</b>	<b>GSK</b>	<b>Professor Carol Dezateux</b>	<b>ICH, UCL</b>
<b>Dr Cathy Emmas</b>	<b>Astra Zeneca</b>	<b>Professor Paul Elliot</b>	<b>Imperial College</b>
<b>Dr Charles Brigden</b>	<b>Amgen</b>	<b>Professor John Williams</b>	<b>University of Swansea</b>
<b>Dr David Roblin</b>	<b>Pfizer Global R&amp;D</b>	<b>Dr Louise Wood</b>	<b>NIHR</b>
<b>Dr Paul Cload</b>	<b>GE Healthcare</b>	<b>Dr Tim Hubbard</b>	<b>Wellcome Trust Sanger Centre</b>
<b>Dr John Parkinson</b>	<b>GPRD, MHRA</b>	<b>Dr Janet Valentine</b>	<b>MRC</b>
<b>Professor Ronan Lyons</b>	<b>HIRU</b>	<b>Christine Vial</b>	<b>Patient / Public Member</b>
<b>Professor Tony Avery</b>	<b>University of Nottingham</b>	<b>Tony Sargeant</b>	<b>Patient / Public Member</b>
<b>Professor Frank Sullivan</b>	<b>University of Dundee</b>	<b>Nick Partridge</b>	<b>INVOLVE</b>



# *Research Capability Programme Board Membership*

Professor Sir Alex Markham (Chair)	University of Leeds
Professor Ian Diamond	Economic and Social Research Council
Professor Michael Thick	NHS Connecting for Health
Dr Louise Wood (Observer)	Department of Health
Jeremy Thorp	NHS Connecting for Health
Marc Taylor	Department of Health
Peter Knight	NHS Connecting for Health
Marie von Hildebrand	Patient and Public Involvement





# *Full Programme Stages*

## Implementation Programme

- Stage 1 – Procurement, Pilot and Proof of Concept
- Stage 2 – Mobilisation
- Stage 3 – Building the infrastructure
- Stage 4 – Federating data sources
- Stage 5 – Transfer to Business as usual
- Stage 6 – Programme closure and benefits realisation

## *RCP Implementation Phase*

- Strategic Outline Case
- Outline Business Case
- Output Based Specification 1
- Output Based Specification 2
- Full Business Case
- Office of Government Commerce, Gateway Reviews
- Financial Approval Processes: NHS CFH, Department of Health, HM Treasury
- Pilot Studies
- Procurement
- Ongoing role for ERG/OSCHR E-Health Records Research Board
- Funders' Forum
- Continuing engagement with the research community

## ***RCP – Full Programme Stage 1***

The Programme structure:

- Business Cases and Procurement Project
- Commissioning of the IG Services Programme
- Pilot Programme
- Public Consultation Project
- Programme Communication
- Programme Assurance

# *RCP Key Partnerships*

## **Established Players** (in no particular order):

- Other NHS CFH Programmes
- NIHR IT Programme
- UK Biobank
- Secondary Uses Service
- The Information Centre for Health and Social Care
- GP Research Database/MHRA
- QResearch and other primary care datasets
- GP Extraction Service (Information Centre for Health and Social Care)
- Office for National Statistics/Registrar General
- Public Health Observatories
- National Cancer Intelligence Network
- University Health and Medical Librarians Group
- NHS-HE, Janet/N3 Forum

.....and many, many others.

## *RCP Key Partnerships*

### The Research Communities

- Public Health Researchers
- Observational Epidemiologists
- Clinical Trialists
- Health Services Researchers
- Pharmaco-“vigilantes”/ Post-marketing Surveillance



## *What challenges do we face?*

- Ensuring the opportunities are maximised
- Developing better linkage between new and existing databases
- Data quality and standards
- Information Governance:
  - Patient confidentiality;
  - Access – who, when, where, what, how, why;
  - Pseudonymisation / anonymisation; and
  - Patient consent and “consent for consent”.
- Consolidating different stakeholder views e.g. professional vs patient groups or across different professional groups

## *RCP Key Challenges*

Concepts that several colleagues in this area are addressing:

- Honest Brokers
- Safe Havens
- Trusted Third Parties

.....changing the terminology might help

# *RCP Key Challenges*

## INFORMATION GOVERNANCE

- National Information Governance Board (NIGB)/PIAG
- DH Chief Information Officer
- DH Information Policy Unit
- Information Commissioner
- General Medical Council
- British Medical Association
- Medical Royal Colleges
- Medical Insurers
- Caldicott Guardians
- SHA Chief Information Officers
- Public Health Observatories
- NHS CFH Information Governance Board
- Director, NPfIT
- Chief Statistician etc, etc, etc

...all set against a bewildering assortment of legislation..... and Parliamentary Statements as to what the laws are supposed to mean.....and conflicting views as to how the Parliamentary Statements are then to be interpreted

## ***Research Capability Programme Key Challenges***

- This is not going to be easy!!
- Essential to maintain stakeholder support and momentum
- Thank you for your invitation and in anticipation of your support in the future.