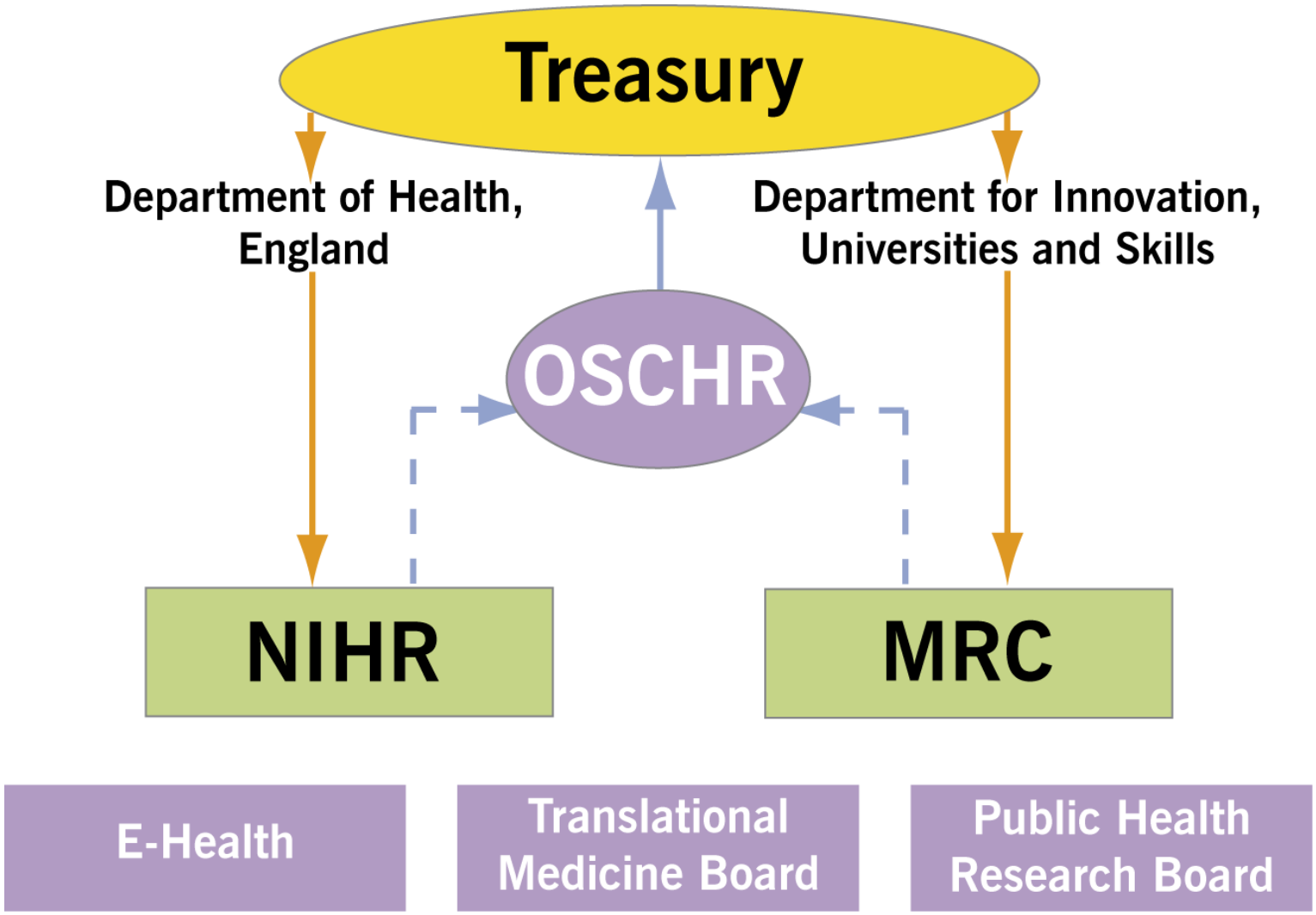
NHS
National Institute for Health Research

The Research Capability Programme

Peter Knight, Group Programme Director

NHS
National Institute for Health Research

NHS
National Institute for Health Research



NHS
National Institute for
Health Research

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

What is the Research Capability Programme?

NHS National Institute for Health Research

- It is a formal programme of work within NIHR 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.

What are building?

NHS
National Institute for Health Research

So what is HRSS?

- Technology (hardware, software and development)
- Services (helpdesk, users guidance, analytical, research informatics expertise)
- Information Governance services (assistance, guidance and audit)
- Data sources (ONS, IC, Cancer, Heart disease etc)
- Data Processing (meta-data, linkage etc)
- Secure tools and environment for research to access data and work (main procurement only not pilot).

NHS
National Institute for Health Research

What are the potential benefits for research?

- More timely access to better integrated information for research purposes
- More streamlined protocols for access to information
- Support for ground-breaking work on the health of the population
- Facilitation of recruitment of patients for clinical trials
- Enhance the UK as a centre for research excellence with associated economic benefits

Status of the Programme

NHS
National Institute for Health Research

So what are we doing for the research community?

- Getting the business case approved so we can buy and build the HRSS!
- Making the pilots a real demonstrator!
- Working with Funders to ensure training for the scientists includes the use of data to make use of HRSS!
- Progressing on the governance issues (working with science, ethics and information governance committees to streamline processes and gain their trust).
- Embedding the Patient Public Involvement at the heart of the Programme as this is something that patients want.

The HRSS Pilot Programme

NHS
National Institute for Health Research

BACKGROUND:

- A sub Programme of the Research Capability Programme
- Working alongside the main procurement and Information Governance and Compliance areas
- Planning to implement the *initial* RCP capability – using a Pilot / demonstrator approach

OBJECTIVES:

- Prove the functionality and feasibility of the Pilot HRSS
- Demonstrate some initial benefits to engender confidence (Quick Wins)
- Identify, record and communicate useful learning (to inform the main procurement)

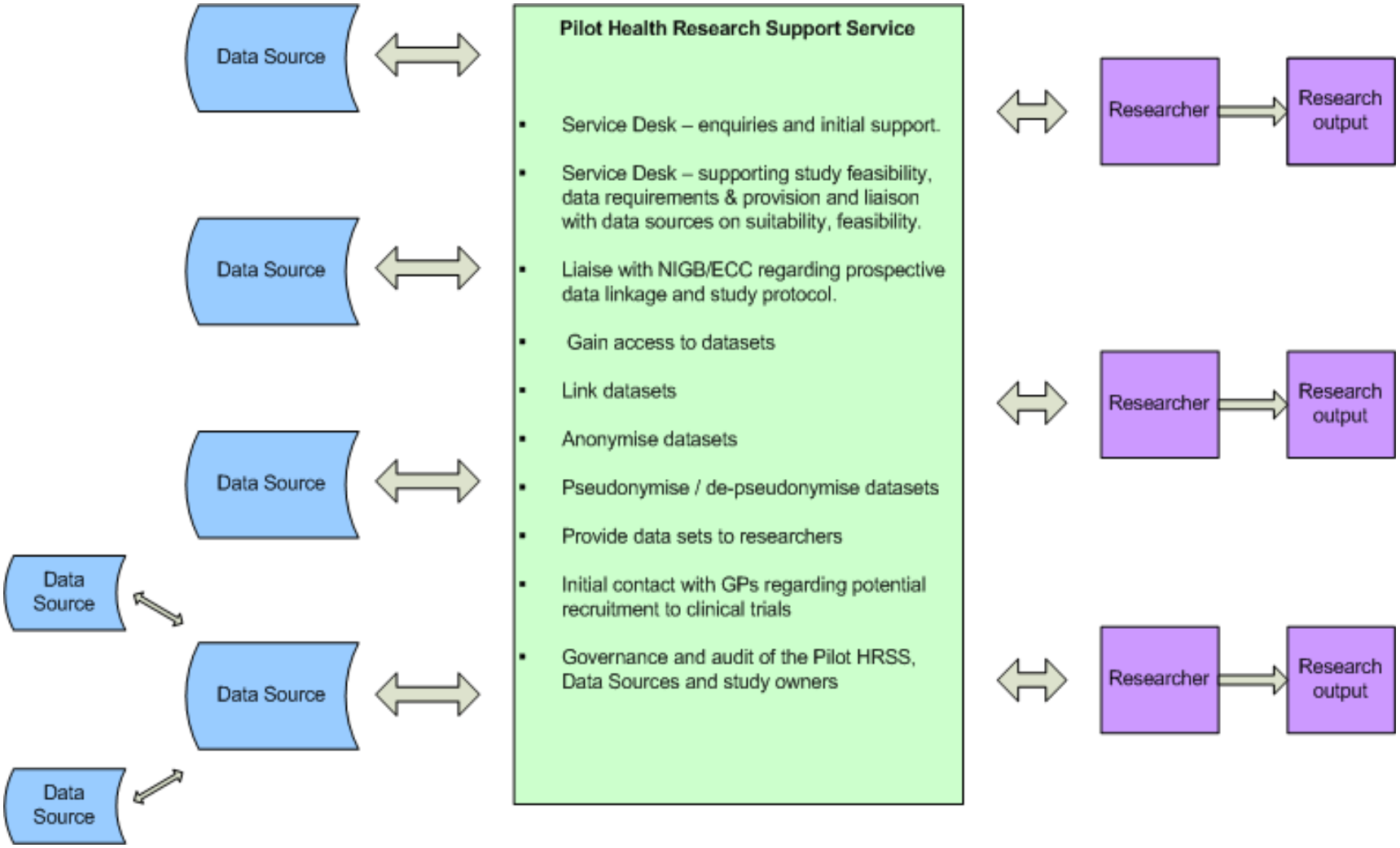
What is the Pilot HRSS?

NHS
National Institute for Health Research

- Will link to a number of (initial) data sources through a single point of access
- Link datasets and analyse data and linkage quality
- Anonymise / pseudonymise / de-pseudonymise data
- Provide data to Health Researchers (within the agreed regulatory framework) to support observational studies and clinical trials
- Forge initial working relationships and business processes between HRSS and other bodies, in order reduce the volume of administration associated with research
- Work within the agreed Information Governance (IG) Framework and subject to independent IG audit (created by the IG and Compliance Programme of the NHSIC)

How will the Pilot HRSS work?

NHS
National Institute for Health Research



Planned Pilot Studies

NHS
National Institute for Health Research

Organisation	Area of study
Kings College, London	Mental disorder and cancer
National Cancer Intelligence Network	Post colonoscopy complications
Imperial College, London	Migratory movements amongst births in England
Health Protection Agency	Monitoring Hepatitis C related care
	Gynaecological complications following Chlamydia diagnoses
GlaxoSmithKline	Paediatric Pilot Study: The Utility of Linking Additional Patient-Level Data Sources in England for Epidemiological Studies
UK Renal Registry	Measuring quality and driving change in renal services using routinely collected data
MEMO/Hypertension Research, University of Dundee	The Standard care versus Celecoxib Outcome Trial (SCOT): A Large Streamlined Safety Study
University of Oxford Clinical Trial Service Unit & Epidemiological Studies Unit	ASCEND (A Study of Cardiovascular Events in Diabetes)
	Study of Heart and Renal Protection (SHARP)
Eli Lilly	Efficacy and safety of Tadalafil one a day in patients with lower urinary tract symptoms/benign prostatic discontinuing from alpha-blocker therapy due to lack of efficacy or adverse events

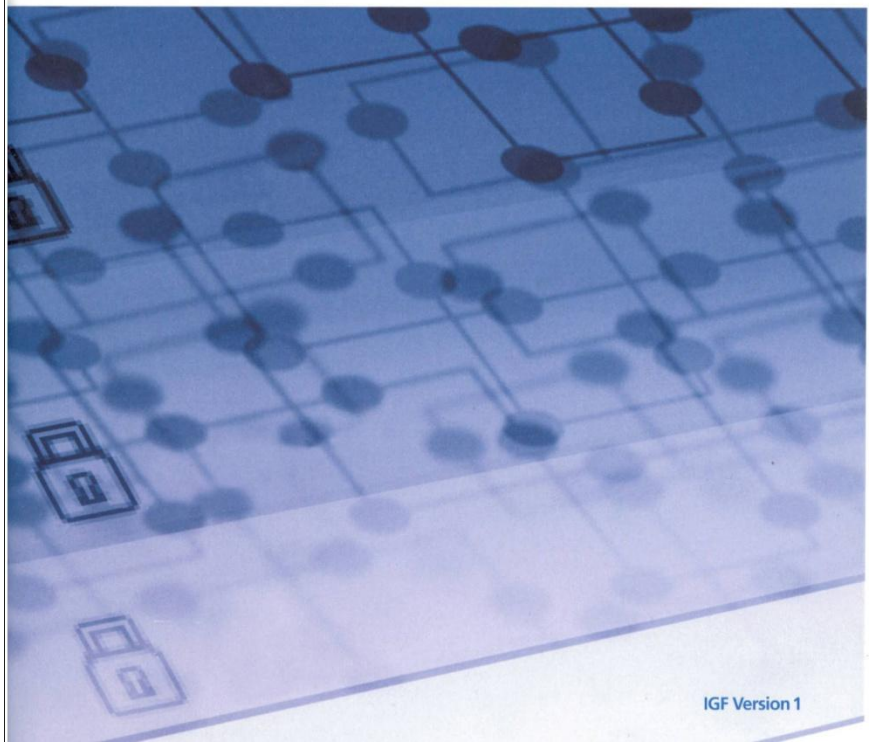
Planned Pilot Data Sources

NHS National Institute for Health Research

Coronary Care Audit Database or CCAD (MINAP/BCIS)	Primary Care (Multiple physical source acquisition strategy)
Local CTSU Recruited Cohorts X 2	NHS IC HES/GPRD/IMS linkage data
UK Renal Registry	National Cancer Data Repository(NCIN) / National Cancer Register (ONS)
Thames Cancer Registry	Socio-economic reference data
Local Dundee Recruited Cohorts	Medical Research Information Service
Cancer Screening Programme: Bowel	Birth Registrations (ONS)
SLAM BRC Case Register	Address point (via Imperial)
Death Registrations (ONS / NHS IC)	Demographics
Hospital Episode Statistics (HES / NHS IC)	

NHS

Information Governance Framework
for the processing of patient information for secondary purposes



NHS
National Institute for Health Research

NHS Connecting for Health	In Confidence HRSS Pilot Programme: Overarching Governance Framework			
	Programme	NPFIT	**Document Record ID Key**	
	Sub-Prog Project	RCP – HRSS Pilot Programme	NPFIT-RCP-PIL-0020	
	Prog. Director	Peter Knight	Status	Approved
	Owner	Kerrie Woods	Version	v1.3
	Author	Kerrie Woods	Version Date	16th October 2009

RCP HRSS Pilot Programme:

Overarching Governance Framework

PLT013

Governing the Pilot HRSS (i)

NHS National Institute for Health Research

- Created and agreed an **Overarching Governance Framework (OGF)** for the Service (includes principles, policies and operating procedures centred around:

  - **Scientific Governance**
  - **Ethical Governance**
  - **Information Governance**
  - **Patient Public Involvement**

- Scientific Governance: Working with the MHRA Independent Scientific Advisory Committee or ISAC (commenced with first 2 study protocols)
- Ethical Governance: Working with the National Research Ethics Service (NRES) and the South East Coast Research Ethics Committee (REC) to gain ethical endorsement for the Pilot study protocols

Governing the Pilot HRSS (ii)

NHS National Institute for Health Research

- Information Governance: (IG) Working with National Information Governance Board (NIGB) to gain endorsement of the IG mechanisms that will be part of the Pilot HRSS
- Information Governance: Working with the Ethics and Confidentiality Committee (ECC) to gain class support for the Pilot studies and design specific support for the RCP moving forwards.
- Information Governance: Conform to the Information Governance Framework (IGF) and subject to independent audit by the IG Compliance Unit (IGCU)
- Patient and Public Involvement: Working to incorporate patient & public input to the research process

What can researchers expect?

NHS National Institute for Health Research

Deliverable	Planned Date
Service available for initial 10 Pilot studies	From Spring 2010
Communication of initial benefits to the research community from research community (ongoing process)	From July 2010
All Pilot studies commenced (access to all data sources via the Pilot HRSS)	By November 2010
Greater base of primary care data available to support clinical trials research	By December 2010
Transition to full solution (includes capability and maturity, benefits and lessons learned and any ongoing studies)	Around December 2010
Full service available to researchers	Spring / Summer 2011
Research findings published	From 2011

NHS
National Institute for
Health Research

Questions?