



National Institute for Health Research

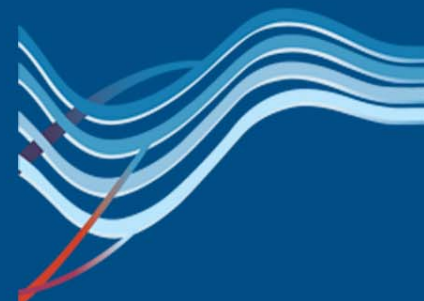
Coordinated System for gaining NHS Permission (NIHR CSP)

John Sitzia
Chief Operating Officer
NIHR CRN Coordinating Centre



The Challenge

Research & Development approval
and set up times
are a big factor affecting
the UK's competitiveness
in conducting clinical studies



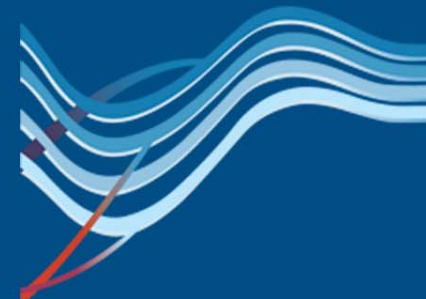
Speed

Association for British Pharmaceutical Industry (ABPI) metrics for 2008 show:

82 day median time from R&D notification to sign off

187 day median time from first submission to first patient / visit

Slow start up leads to reduced recruitment periods or site withdrawal for globally competitive studies



Predictability and Effectiveness

“Researchers drowning in bureaucracy” (BMJ 2004)

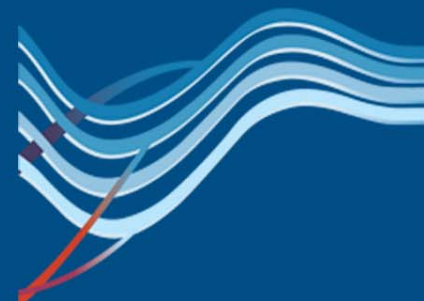
Enormous variability in criteria and processes among ~400 NHS Trusts (170 acute)

Separate, multiple applications required for multi-centre studies

No overall coordination, no standard timelines

Numerous recording systems, no quality control

Disconnect between R&D Departments and clinicians



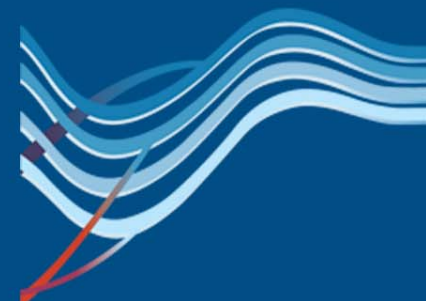
What is NIHR CSP?

A national system managed by a central CSP Unit and delivered through the Comprehensive Local Research Networks

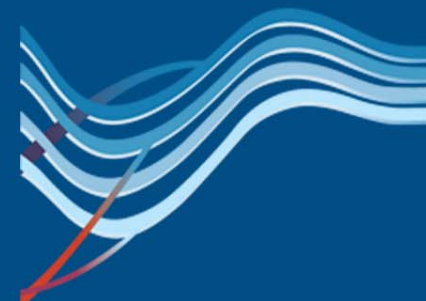
A standardised, quality assured process of evidence checks

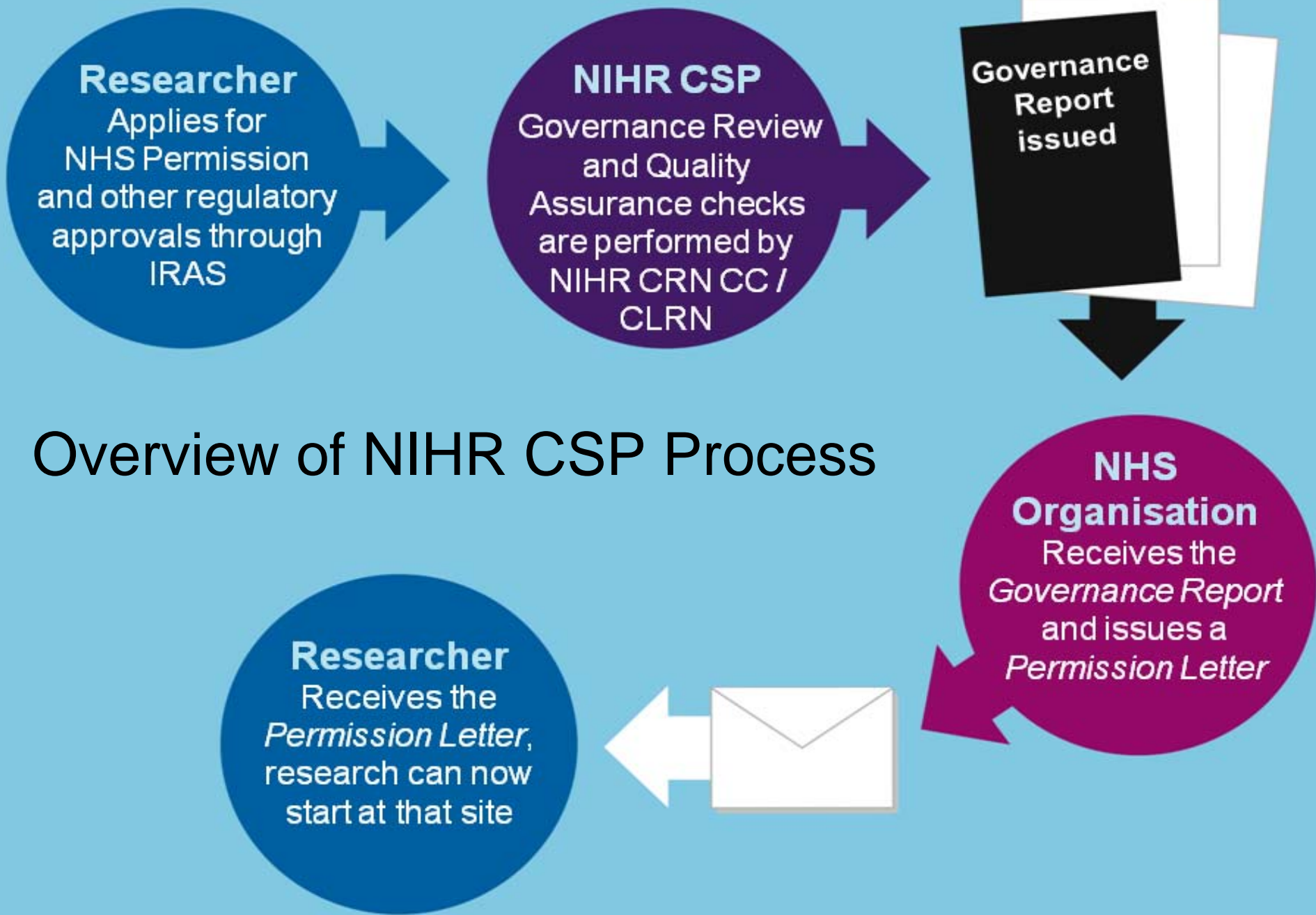
A single application point for NHS permission, through the **Integrated Research Application System (IRAS)**, for multi-site and single site studies

Built upon best practice in research governance already in place within the NHS



- A consistent and comprehensive set of governance checks, appropriate to study type
- Specific checks only conducted once for multi-centre studies, with clear distinction between local and national checks
- Trained staff working to a suite of detailed SOPs
- Single, secure online database and document repository
- Integration with NIHR Portfolio processes, and other NIHR and UK processes over time
- A national performance framework to measure and drive improvement





Overview of NIHR CSP Process

NIHR CSP Delivery

People & Training

NIHR CSP is coordinated by a national NIHR CSP Unit

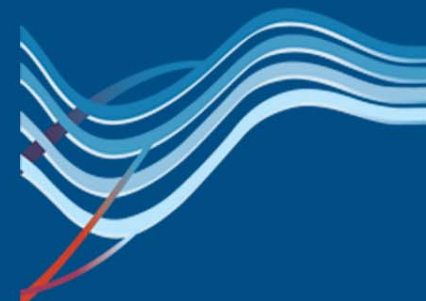
CSP Unit works in close collaboration with the 25 CLRN, who employ trained CSP staff within their local NHS organisations

Information Systems

A web-based system (CSP ReDA) with electronic document repository facilitates NIHR CSP processing between the national CSP Unit and CLRNs

Oversight

NIHR Network Coordinating Centre work with key partners to ensure effective governance



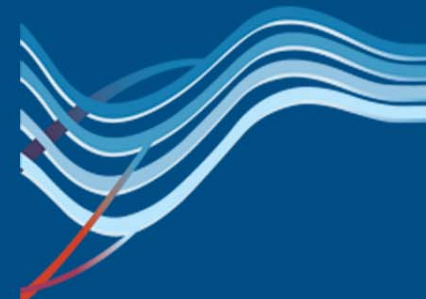
NIHR CSP Implementation

NIHR CSP went live in the NHS on 18 November 2008

Transition phase from November 2008 to end of March 2009

April 2009 all NIHR CRN Portfolio studies use NIHR CSP

Further developments to optimise the process



NIHR CSP Progress

302 'Portfolio Application Forms' received (24 commercial)

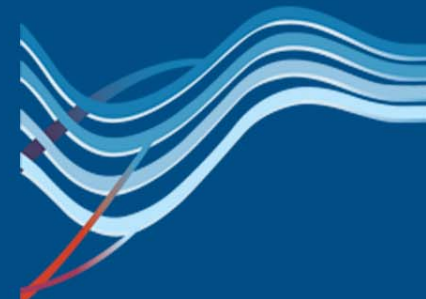
118 R&D Forms received and validated

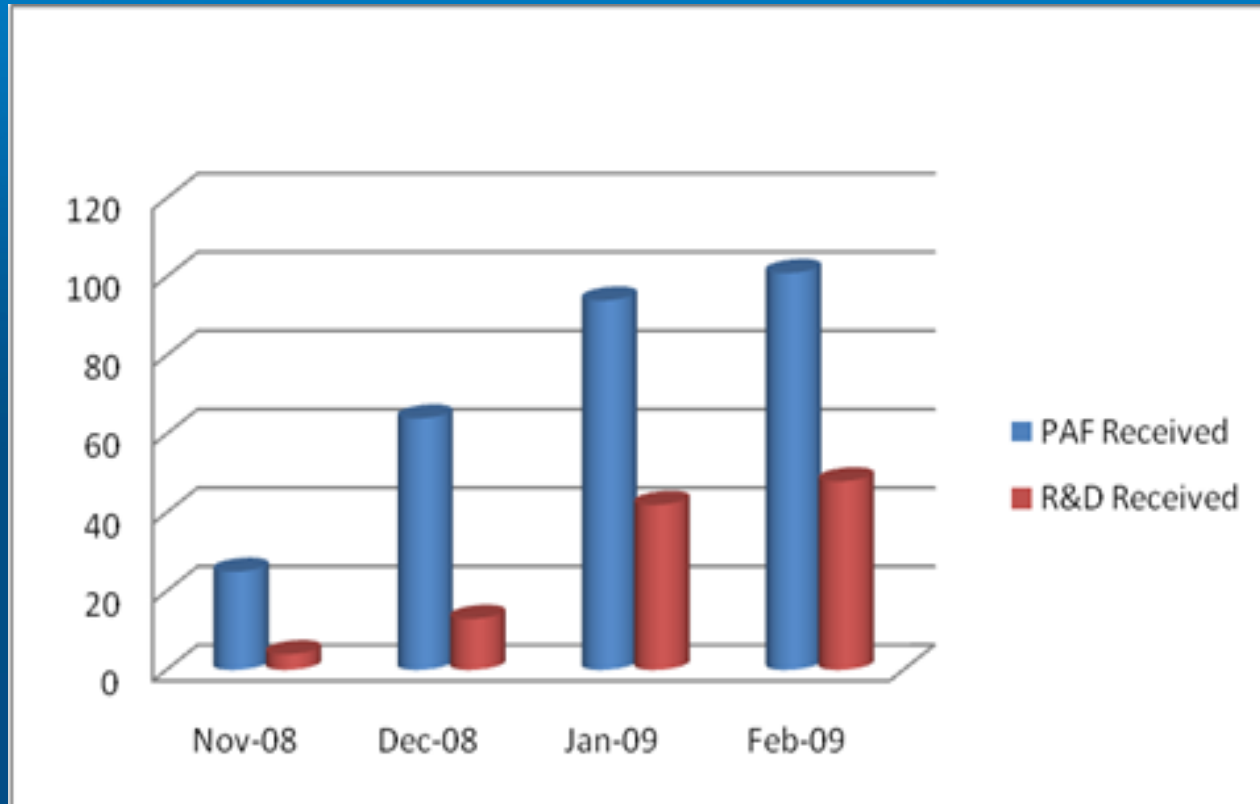
5 studies (19 sites) have gained NHS approval

First site median approval time = 51 days

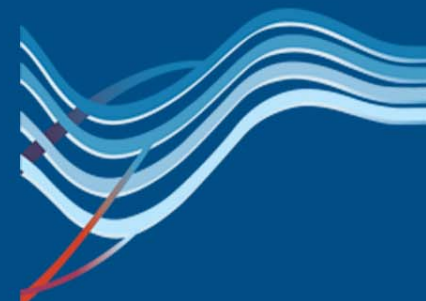
All sites median approval time = 68 days

Data to 6 March 2009





Data to 6 March 2009



Visit the website for further information

<http://csp.crncc.nihr.ac.uk>

Or contact the CSP Helpdesk at:

crncc.csp@nihr.ac.uk

For NIHR Portal users visit

<http://portal.nihr.ac.uk/sites/ukcrn/CSPint>

For IRAS visit

<https://www.myresearchproject.org.uk/>

