

How to optimise research support and funding via the UKCRN

Plan for workshop

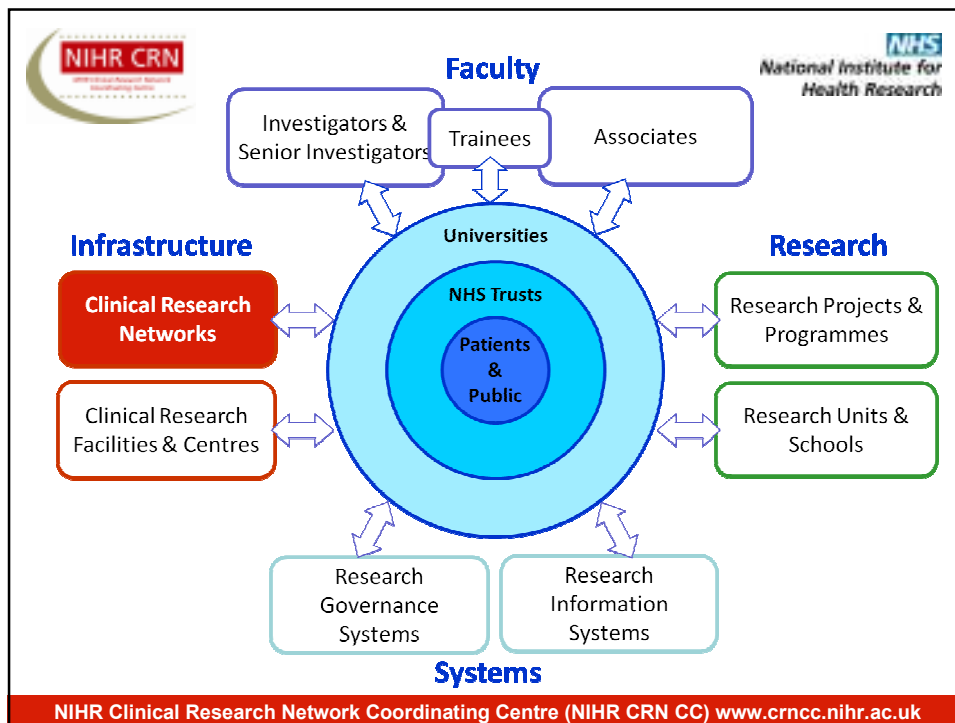
- Overview of NIHR and the NIHR Clinical Research Network (CRN)
- The Comprehensive CRN – how to work with it to support clinical research in HIV infection
- How Specialty Groups can support HIV research
- “Busting bureaucracy”

Overview of NIHR CRN & the NIHR Clinical Research Network (CRN)

Background: New Government Strategy

- “*Best Research for Best Health: A New National Health Research Strategy*” was launched in January 2006 with the aim of making the UK ‘the best place in the world for health research, development and education’
- The mission is to **create a health research system in which the NHS supports outstanding individuals, working in world class facilities, conducting leading edge research, focused on the needs of patients and the public**
- The vision: **to improve the health and wealth of the nation through research**





Research and Innovation: at the heart of the NHS	
The NHS	<p>NHS Constitution NHS commitment to the promotion and conduct of research</p> <p>NHS Operating Framework NHS must play its full part in supporting research; National ambition to double the number of patients in clinical research</p>
Strategic Health Authorities	<p>NHS Operating Framework SHAs to ensure that NHS trusts work with NIHR Clinical Research Network locally to contribute to the increased numbers of patients in clinical research</p> <p>Duty to Promote Innovation SHAs to support NIHR Clinical Research Networks locally; SHAs to develop the capacity of the NHS to support research</p>
NHS Providers Primary Care Trusts	<p>NHS Operating Framework All providers to increase their participation in research</p> <p>Quality Accounts All providers to report on the number of patients in clinical research</p>
NHS Patients	<p>Handbook to NHS Constitution The NHS will do all it can to ensure that patients are made aware of research that is of particular relevance to them</p>

NIHR Clinical Research Network Coordinating Centre



NIHR Clinical Research Network Aims

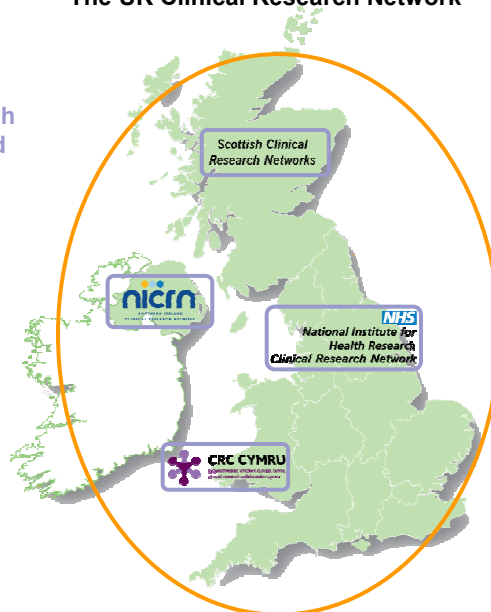

National Institute for
Health Research

- To develop UK-wide infrastructure embedded within the NHS to support high quality research across all areas of health and clinical need funded by both commercial and non-commercial funders
- To ensure that patients and healthcare professionals from all parts of the country are able to participate in and benefit from clinical research
- To integrate health research and patient care
- To improve the quality, speed and coordination of clinical research by removing the barriers to research in the NHS
- To strengthen research collaboration with industry and ensure the NHS can meet the health research needs of industry

NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) www.crncc.nihr.ac.uk

The UK Clinical Research Network

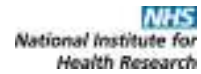
National research
networks funded
by Health
Departments



UKCRC Board
provides strategic
oversight



UKCRN Key Stages in Evolution



2000 Cancer

2003 Mental Health

2005 UK Clinical Research Network

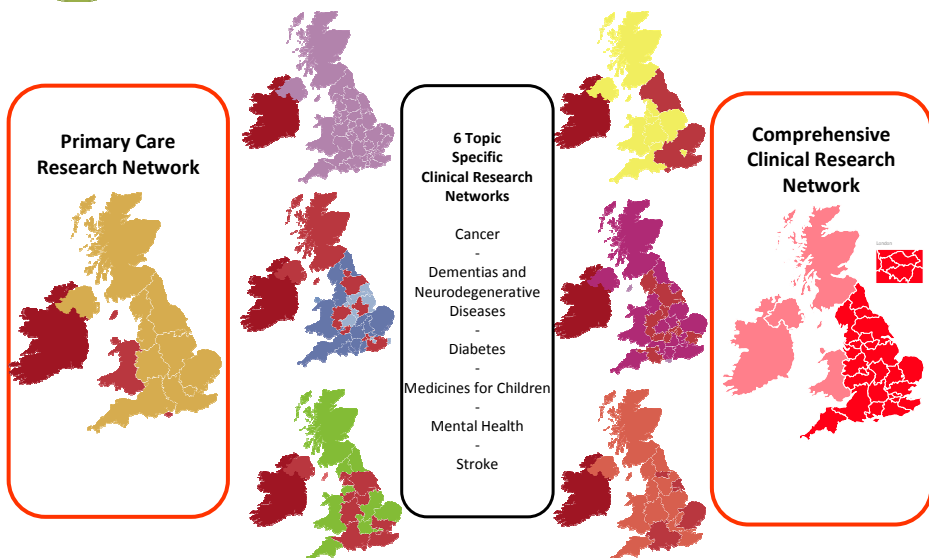
Diabetes, Stroke, Medicines for Children and
Dementia and Neurodegenerative Diseases
Primary Care

2007 NIHR Comprehensive Clinical Research
Network (CCRN)

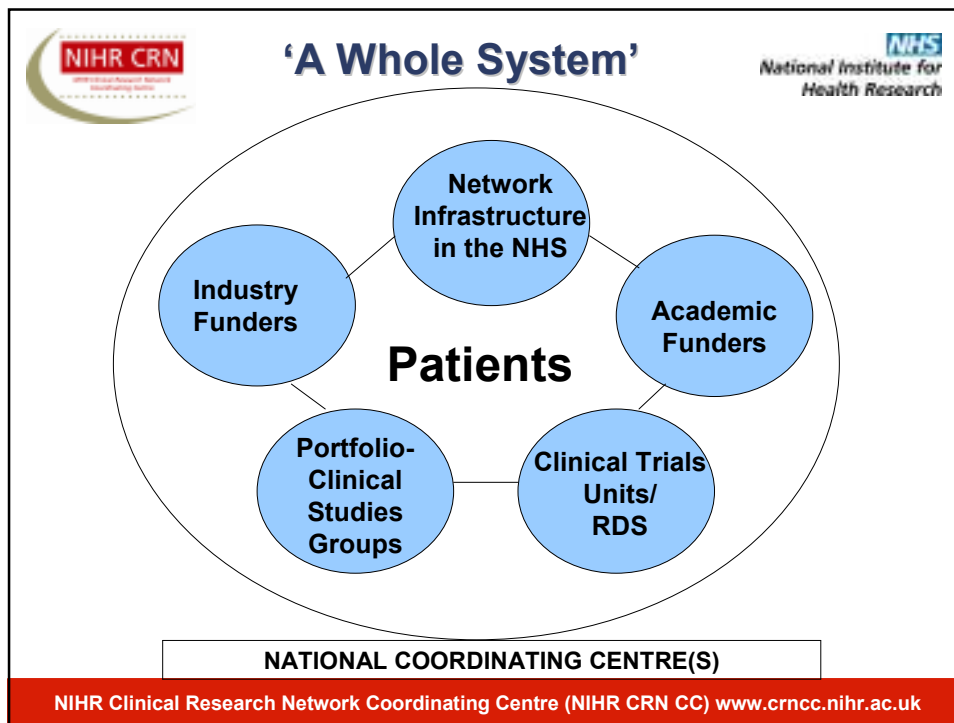
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NIHR Clinical Research Networks



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UKCRN **UKCRN Portfolio** **NHS**
National Institute for Health Research

- National register of all eligible studies
 - NIHR Portfolio in England – funded in open national competition with independent peer review
 - Portfolios in Northern Ireland, Wales, Scotland
 - UK-wide working within portfolios
 - Overseas governments e.g. NIH, CIHR, EU have intermediate priority
- Includes multi centre and single centre studies
- Includes commercial and non-commercial studies-including investigator initiated studies which meet the criteria
- Details of current portfolio available on UKCRN website (www.ukcrn.org.uk)

UK Clinical Research Network (UKCRN)



Experimental Medicine

- Working closely with the UK Clinical Research Collaboration:
- Facilitate links between experimental medicine studies and later phase clinical trials in the UKCRN portfolio
- UKCRC Experimental Medicine Resources developed as a central information repository which links directly to experimental medicine facilities and investigators

www.ukcrcepm.org.uk



How will we measure success?

- Balance of portfolio - % commercial studies and % RCTs
- Speed – of study set up and completion
- Recruitment – to target and on time
- And – most important – patient benefit

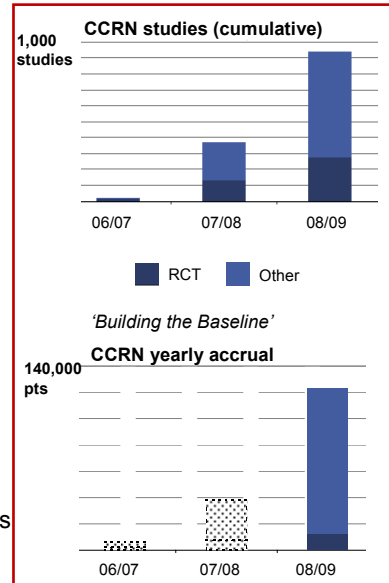
NIHR CRN and the NHS Operating Framework

'Ambition to double participation in 5 years linked to Comprehensive CRN'

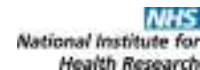
- Realism (avoid underestimating the challenge)
- Comprehensive CRN is very different from Topic CRNs
- More excellent trials (and studies)

NEED

- Actively managed approach
- Partnerships (Patients, Funders, NHS Trusts, CRNs, Government)
- Excellent and larger portfolios
- Funder engagement including portfolio development
- Adequate capacity eg Clinical Trial Units
- Coordination via CRN CC and Specialty Groups
- Adequately resourced



Conclusion



- A wonderful research opportunity
- A huge amount of change rapidly
- Broad support but anxious academic, clinical and research management communities
- Bureaucratic limitations remain a real challenge - we can fix some things!
- Our goal is to make research fun again!



NIHR Comprehensive CRN

How to work with it to support clinical research in HIV infection



How is the NIHR CCRN structured?

- Consists of 25 Comprehensive Local Research Networks (CLRN) across England:
 - CLRN the primary vehicle providing infrastructure to support study involvement
 - provide a coordinated and efficient infrastructure of research personnel and facilities to support recruitment
 - encourage participation in the range of high quality studies contained within the NIHR portfolio.



Comprehensive Local Research Networks (CLRNs) in England



UK Clinical Research Network (UKCRN)



What do networks provide?

- Enthusiasm and expertise of researchers in specialties – National Specialty Groups
- Support for site identification, feasibility and study set up
- Streamlined research management and governance support
- Infrastructure support for clinical research e.g. research nurses to support recruitment in the NHS, and other NHS service support costs

Funding NIHR CRN Portfolio Research

Costs	Funding Source
Direct research →	Research funding organisation e.g. MRC/BHF/industry
Excess Treatment →	Commissioning bodies e.g. local Trust
Service Support →	NIHR Clinical Research Networks (TCRNs, PCRN & CCRN)

NHS Service Support Costs (SSCs)

- SSCs are usually provided via access to resources and are seldom a direct transfer of funds
- Service Support Costs are **not** a form of secondary grant application i.e. they *cannot* supplement elements which were omitted from the original grant application
- Consulting with the Lead Network with regard to costings **prior** to the submission of a grant application will help you to ensure all eligible direct research costs are included and identify NHS SSCs this will speed up study set-up times

- Moving towards a 'Lead Network' service for multi-centre studies – coordination across networks
- Lead Network acts as the central point of contact and support for the duration of the study
- Lead Network supports CI in facilitating study set up, negotiation of NHS infrastructure support for study across recruitment sites
- Lead Network is *usually* where the CI is geographically based
- Principle has received wide and strong support
- Has been very effective for swine flu studies
- Commitment from network management teams to implement as a priority

What does the Lead Network do?

- Identifies elements of service support provided by Networks
- On behalf of CI - liaises with other NIHR CRNs to confirm support
- Acts as conduit for queries and keep CI informed of progress at other sites and help resolve any issues
- Provides support for NHS Approvals Process (N.B - IRAS & CSP - single repository for regulatory submission paperwork - data entered **once and only once**)



Who do I contact?

- Your first point of contact should be your local R&D department. If they are not able to help you directly, they should sign-post you to the CLRN Senior Manager
- Further details about the CLRNs including contact details are available via this link:
<http://www.crncc.nihr.ac.uk/index/networks/comprehensive/clrns.html>



How Specialty Groups can support Clinical Research



Topic specific advice: Specialty Groups

- A national network of topic based expertise to:
 - advise on 'do-ability' of potential studies (commercial and non-commercial)
 - provide detailed feasibility in relation to patients, potential investigators and sites
 - provide network based contact for groups supported by research funders or professional bodies to develop clinical research portfolio

UK Clinical Research Network (UKCRN)



<u>Specialty Group</u>	<u>Number of CLRNs</u>	<u>Specialty Group</u>	<u>Number of CLRNs prioritising</u>
Non malignant haematology	8	Nervous system disorders	13
Cardiovascular	23	Oral & dental	8
Clinical genetics	11	Gastrointestinal	21
Ear, nose & throat	10	Hepatology	16
Ophthalmology	16	Renal	22
Infectious diseases & microbiology	17	Urogenital	10
Immunology & inflammation	12	Reproductive Health & Childbirth	21
Injuries and accidents	10	Respiratory	23
Metabolic & Endocrine (not diabetes)	18	Dermatology	16
Musculoskeletal	24	Public Health	18
		Health Services Research	12
		Paediatrics (non medicines)	21
		Age and aging	16
		Critical care	19
		Surgery	8
		Anaesthetics	15

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Participation - National Specialty Groups

- Play an important role in ensuring that studies are feasible and "do-able" in the NHS
- Take an oversight of the portfolio of research within the specialty and highlight studies that require additional support to reach their target
- Work through local Specialty Group Leads to ensure that studies DELIVER to target
 - Feasibility assessments
 - Addressing national and local barriers
 - Providing a standing infrastructure to support studies in the specialty
 - Identifying new recruitment sites to boost recruitment into multicentre studies

HIV and Specialty Groups

- Falls under the remit of the Infectious Disease and Microbiology Specialty Group
- Has representation from 18/25 CLRNs as well as Scotland and Wales
- Chaired by Robert Read (Sheffield)
- There are currently 20 HIV studies on the portfolio of this Specialty Group
- Other eligible studies have been identified and we are working with the relevant CIs to get these added to the Portfolio

Current Priorities

- Emphasis on defining the portfolio (getting the information accurate) and increasing the proportion of studies recruiting to time and target through identifying national and local barriers and addressing these
 - 43% of studies in the Infectious Disease and Microbiology Specialty Group are recruiting to target (this is the average for all Specialty Groups)
 - 67% of HIV studies reporting accrual data are recruiting to target.

“Busting bureaucracy”

Research management

- “Bust bureaucracy” (or manage it?) by:
 - Research passports for researchers working across organisations
 - Co-ordinated System for gaining NHS Permission to conduct research studies (CSP)
 - Costing guidance for trials – with industry workstream
 - Standard agreements

- What is CSP?

CSP: Key characteristics

- A consistent and comprehensive set of governance checks
- Specific checks only conducted once for multi-centre studies, with clear distinction between local and national checks
- Standardised, managed, end-to-end 'business' processes
- Single application point through IRAS* for all NHS sites
- Single, secure online database and document repository
- Integration with NIHR Portfolio processes, and other NIHR and UK processes over time
- A performance framework to measure and drive improvement



CSP: Benefits

- Single application point through IRAS* for all NHS sites.
- A standardised, coordinated approach resulting in more rapid NHS permission for sites
- Single, secure online databases and document repository
- Specific checks are only conducted once for multi-centre studies, with clear distinction between local and national checks
- Built upon best practice in research governance already in place within the NHS



NIHR CSP Update

- Number of applications received: 1724
(of which 192 (11%) are commercial studies)
- Number of R&D forms validated: 1246
- Number of studies granted NHS approval: 664
- Median from R&D form to NHS Permission: 90
(calendar days, range 0 – 421 days)

Data accurate as of 9 April 2010

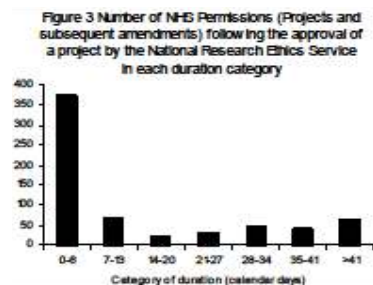
WHAT CAN BE ACHIEVED IN SET UP ?

North West Exemplar



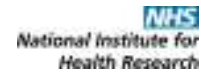
- Median approval time (R&D form to NHS permission) for NW Exemplar studies is **51 days**
- Performance increased for non-Exemplar studies in NW CLRNs with a median approval time of **64 days**
- All but one study has achieved NHS Permission ahead of the industry target of **70 days**
- For the first time in 5 years, Novartis has achieved UK recruitment of the first global patient
- DeNDRoN 040 screened the first patient in the world, and two studies screened the first patient in Europe
- All studies have begun to recruit patients and **recruitment trajectories are being met**

Swine 'Flu





NIHR CRN TODAY



- More than 2,000 people are providing frontline support for research across 100 Local Research Networks in the NHS
- Over 1 million individuals have participated in NIHR CRN Portfolio studies since April 2006
- 350 Industry studies have been adopted into the NIHR CRN Portfolio
- Networks have helped one company achieve UK recruitment of the first global patient for the first time in 5 years, as part of the North West Exemplar Project
- 95% of NHS organisations participated in NIHR CRN research in 2008/09
- Over 1000 studies have used the NIHR Coordinated System for gaining NHS Permission
- 26 Specialty Groups have been established across the UK to work with the Comprehensive Local Research Networks to harness the enthusiasm and expertise of the UK research community
- The NIHR Research Passport for streamlining NHS HR arrangements for researchers has been rolled out across all NHS organisations in England

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