NHS
National Institute for Health Research

Clinical Research Network
Coordinating Centre

The North West Exemplar Programme:

An introduction

What is the North West Exemplar Programme?

The North West Exemplar Programme is an initiative which aims to demonstrate that the NHS is a viable environment for commercially-sponsored clinical trials, and that England can match the rest of Europe in carrying out high quality studies quickly, efficiently, and in line with patient recruitment targets.

Why is it needed?

As the UK-based divisions of the major pharmaceutical and biotech companies know only too well, the UK must compete against the rest of the world to be selected as the location for a clinical trial.

Being selected depends on the host country's ability to deliver the trial effectively – with speed and simplicity of set-up, and reliable recruitment of suitable patients, being the key factors.

UK-based industry research directors were concerned that long set-up times and limited research capability were making the NHS less attractive as a location for clinical trials – a situation which was resulting in fewer commercially-sponsored trials taking place in the UK.

Not only was this situation threatening to undermine the position of an industry that makes a significant contribution to the UK economy, it was also impacting upon patient care. Fewer trials meant fewer opportunities for NHS patients to benefit from breakthrough treatments, both through studies themselves and through products being brought to market more quickly in trial countries.

Senior industry representatives, together with the National Institute for Health Research Clinical Research Network Coordinating Centre, decided a programme was needed to demonstrate that recent investment had resulted in a step change in the NHS research environment. In consequence, study set-up and delivery could now compare with the EU best.

How does it work?

The North West Exemplar Programme takes 20 commercially-sponsored studies and applies practical solutions to streamline permission processes, reduce the administrative burden on industry researchers, and support patient recruitment and study delivery.

Use of CSP – the "Coordinated System for Gaining NHS Permission". This system means that industry researchers need only complete one standardised data-set for multi-site studies, rather than having to apply to every site individually

Use of "standard contracts" for all NHS sites, which reduces the need for individual contract negotiations

Use of a "standard costing template", providing greater transparency on the cost of delivering studies for industry sponsors and the NHS

Adoption of a "rapid escalation process", so that any issues encountered in the set-up process are quickly referred upwards to the appropriate authority for quick resolution

Provision of a Clinical Research Network lead contact for each study, to help manage set-up, provide advice on appropriate recruitment sites, monitor patient recruitment against plan, and suggest alternative recruitment centres if recruitment falls behind schedule

Who is involved?

The North West Exemplar Programme is a joint initiative between:

The National Institute for Health Research Clinical Research Network, and its specialist Industry Team in the Coordinating Centre

The North West Strategic Health Authority

The pharma industry itself, with steering group representation from Novartis

The Programme involves:

The National Institute for Health Research Comprehensive Clinical Research Network, and its three Local Research Networks in the North West

The National Institute for Health Research Clinical Research Networks for: Cancer, Dementia & Neurodegenerative Diseases, Diabetes, Medicines for Children, Mental Health, Primary Care and Stroke

Acute and Specialist NHS Trusts in the North West

Primary Care Trusts in the North West

Mental Health Trusts in the North West

Measuring achievement

The performance of the twenty trials in the North West Exemplar Programme is measured using criteria including the following:

Time taken from submission of R&D form to granting of NHS permission for first research site

Time taken from receipt of NHS site permission to first patient recruited

Delivery to planned time and recruitment target (study and site level)

Percentage of non-recruiting studies/non-recruiting sites

Patient retention rates

The key measurement points are:

May 2010 – when all 20 studies have been set up, allowing set-up metrics to be published

December 2010 – when a full evaluation will be published. This will include qualitative data, "lessons learned", recommendations for rolling out good practice across other NHS regions in England, and suggestions for industry

Further information

For additional information on the North West Exemplar programme, visit the National Institute for Health Research, Clinical Research Network web pages at:

http://nwexemplar.nihr.ac.uk

To sign up for the Exemplar monthly e-bulletin, send an email with "Exemplar Bulletin" in the subject bar to: exemplar@nihr.ac.uk

About the National Institute for Health Research, Clinical Research Network

The National Institute for Health Research (NIHR) was established in April 2009 by the Department of Health. Its vision is to improve the health and wealth of the nation through clinical research.

The Clinical Research Network is one part of the overall organisation. Its role is to make both commercially-sponsored and non-commercial studies "work" effectively in the NHS context.

In practice, this means:

Advising researchers on the feasibility of a study, regarding practical delivery in the NHS

Running systems to streamline the bureaucracy associated with gaining permission to run a clinical trial in the NHS, and reducing the set-up time for trials

Funding and supporting an infrastructure of trained research support staff in the NHS, so that researchers have access to a broad base of experienced people to collect samples, compile data and run clinics

Maintaining a "knowledge base" of NHS sites and their research strengths and capabilities, for researchers to tap into

Monitoring the numbers of patients participating in individual trials, and offering a "trouble-shooting" service to help trials that are falling behind recruitment targets

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