The Shrewsbury and Telford Hospital NHS

NHS Trust

The Shrewsbury and Telford Hospital NHS Trust Research & Development (R&D) Annual Report 2011/12

Authors: Dr Nigel Capps, Director of R&D and Marion Adams, R&D Manager

Aims:

- Improve outcomes in health care through research within a high quality caring environment.
- To promote high quality research across the Trust within a framework of effective, efficient research governance and Good Clinical Practice (GCP) and develop the infrastructure to support this core NHS work.
- Meet national requirement for recruitment into portfolio trials to time and target.
- Maintain good financial governance.

Background:

The Trust has been active in research for many years. This has grown and developed since the Department of Health (DoH) set up the National Institute for Health Research (NIHR) in 2006 to create a world-class health system within the NHS. Within this framework Comprehensive Clinical Research Networks (CCRN) and Comprehensive Local Research Networks (CLRNs) were established to provide the infrastructure to support high-quality clinical research and enable a doubling of recruitment into national portfolio trials over a 5 year period from 2009 to 2014. Our Trust is part of the West Midlands North CLRN.

Research is one of the tripartite agenda items for the NHS and continues to be essential for the Health and Wealth of the Nation. It provides the evidence base for improving care and health outcomes. It crosses across all the clinical services, with the R&D department providing the essential infrastructure for all specialities to have the opportunity to offer their patients participation in clinical trials.

The Research & Development Committee provides a strategic vision in the implementation of the National Research Governance Framework and supporting the implementation of the Comprehensive Local Research Network (CLRN) objectives to:

- Increase the number of patients participating in clinical trials
- Improve the speed, quality and integration of research
- Provide equity of access to high quality research

R&D Objectives:

- To ensure all research taking place within the Trust is run in accordance with current legislation and GCP.
- To encourage current Investigators and potential new Principal Investigators (PIs) to develop their research activity with a focus on UKCRN portfolio studies and Industry funded commercial studies.
- To identify barriers to research and work towards overcoming these.
- To double recruitment into clinical research studies over the 5 years to 2014, in line with DoH strategy, making available to patients as wide a variety of high quality clinical studies as Trust resources will support.
- To provide the infrastructure, support and advice required by potential and active researchers.

- To maintain an overview of current research with respect to governance, GCP and recruitment and take appropriate action where inadequacies are identified.

- To ensure adequate funding from the Research network(s) and commercial activity to support the service.

Achievements

Recruitment:
The target for patients recruited into national portfolio trials for 2011/12 was 1300. The Trust recruited 1389. Within Cancer there is a sub target of 172 patients (7.5% of cancer incidence) to be recruited into randomised controlled trials (RCT). Although overall recruitment into cancer trials exceeded expectations only 97 patients entered cancer RCTs.

Specialty	***Total no of studies 2011/12***	***Recruitment 2011/12***
Cancer	*33*	*624*
Cardiovascular	*2*	*47*
Gastro-Intestinal	*14*	*467*
Stroke	*3*	*62*
Respiratory	*3*	*19*
Reproductive Health	*3*	*10*
Medicines for Children	*5*	*16*
Renal	*4*	*16*
Surgical	*2*	*7*
Dementia	*1*	*62*
Dermatology	*1*	*4*
Other	*1*	*54*
Totals	***71***	***1389***

Where trials are adopted by more than 1 specialty they have been assigned to the specialty of the PI

- Of the above studies, 8 were industry commercial studies which recruited 79 of the 1389 patients, with 1 non-portfolio industry commercial study recruiting a further 4 patients.

- There was 1 local research study open during the year which recruited 49 patients.

- The Trust also acts as a Continuing Care site for local children recruited into cancer studies at Birmingham, delivering all the treatment and follow up care.

- Time to recruitment of the first patient following the opening of a study has been considerably reduced with the introduction of lean working practices and a parallel process for study governance review and clinical set-up. This work has been presented across the WMN CLRN

Research Governance:

- 24 new portfolio studies and 2 non-portfolio studies were approved during the year with R&D advising on 7 service evaluations and a number of education projects. Time to approval continues to improve with the majority of portfolio studies approved within the required 30 days of receiving the complete document set for governance review.

- Risk assessments were undertaken with PIs prior to approving new studies within the Trust.

- Research nurse/allied health professionals (AHPs) and administrative support were provided from the Clinical Trials team within R&D to support national portfolio and commercial research. A Lead Research Nurse for the Trust has been appointed.

- Where specialist nurses/AHPs become involved in research within their main clinical role they have been given training and support by R&D. A research nurse/AHP forum has been established to support CPD, provide peer mentoring, quality review and service improvement.

- Where appropriate, research nurses/AHPs have been enabled to take written consent in clinical trials, provided they are competent to do so. There is a clear, up to date policy for this.

- Mandatory Accredited Clinical Trial Good Clinical Practice training and 2 yearly updates were provided free of charge for 51 Trust staff.

Financial

- The research and development department is funded from external income. This comes from 3 sources: Comprehensive Local Research Network, Cancer Research Network and Commercial studies.

- Network incomes are ring fenced and can only be used for the additional staff costs and service support costs resulting from involvement in national portfolio research. This includes research nurses/allied health professionals, trials data co-ordinators and facilitators, PI's time and to the support services i.e. Pharmacy, Pathology, Radiology, Cardiorespiratory and Radiotherapy physics. A quarterly breakdown of named research staff costs is required by the Networks.

- Commercial studies are costed using the national Costing template. A Standard Operating Procedure has been put in place based on national Guidelines and this has been shared across the Network. Trial income is shared between the service delivery unit in which the research takes place, the support services involved and the R&D department who provide the trials staff to support the PI.

- The capacity build element of commercial trial income has funded the work undertaken reviewing educational projects and service evaluations and for non pay items. A carry over of funds was agreed to help fund the relocation/enlargement of the R&D/Clinical Trials departments.

Additional benefits from participation in research

Participation in clinical research often brings immediate benefits which are frequently not recognised.

Examples of immediate improvement to practice resulting from involvement in research during 2011/12:

- Introduction of Intensity Modulated Radiotherapy for non trial patients founded on the quality assurance work for radiotherapy trials

- Patient information cards, for contra-indicated medications for cancer trial medication, extended to non trial patients.

- Facilitated introduction of national guidelines to standard practice for gastro-intestinal trial patients.

- Local clinical protocols for the introduction of new cancer drugs produced based on previous experience of the drugs in trials e.g. Lapatinib

- Improved referral pathways driven by need to meet tight time frames for trial entry both in cancer and gastro-intestinal services

- Cancer drug cost savings.

Challenges

- Recruitment must continue to grow to meet our national target of 1600 patients recruited during 2012/13 into portfolio trials, whilst delivering a balance of studies across all disease areas in line with national priorities, in particular Topic Specific Networks, Local Specialities, Cancer Peer Review and Improving Outcomes Guidance.

- Cancer research target for RCTs of 172

- Meeting national metrics of time to approval, time to first recruitment and recruitment to target.

- Continuing to increase the number of commercial studies in the Trust to provide additional opportunities for patients to access new drugs and bring in income.

- The severe shortage of clinical, office and storage accommodation at RSH and PRH for the additional staff and paperwork that research generates restricts growth. Alternative accommodation has been identified for the department at RSH but this is not available until the end of 2012. The outcome of the reconfiguration is awaited to address the pressing accommodation needs at PRH.

Objectives and Priorities for 2012/13

Maximise engagement and increase recruitment:

- The R&D department are working with the CLRN disease specialty groups to increase the opportunity for patients to participate in clinical trials for a wider variety of illnesses.

- Across the Trust we are developing and strengthening links with the research team and clinical directors and managers within the centres to increase awareness of research opportunities, infrastructure and support.

- We will continue to raise the profile and promote research and development at all levels within the Trust from wards and departments to executives and the Board.

Facilitate speedy set-up of NIHR CRN Portfolio studies:

- In order that research commences at the earliest opportunity we are aiming to increase the proportion of studies approved within 30 days.
- We are working towards all studies, which involve 12 or more patients, to recruit the first patient within 30 days of the study opening.
- We have introduced a parallel process for approval and opening of new studies to facilitate this.

Increase industry sponsored clinical research

- Ensuring that we maximise the potential revenue from outside of the NHS will enable us to increase the level of research within the Trust. We will actively work to increase our participation into pharmaceutical company sponsored trials to give patients access to the newest treatments and drugs not yet funded by NICE.

- Commercially funded trials will provide a funding stream for drugs associated with each trial. We will maximise opportunities whenever possible to ensure that we do not rely on our existing NHS resources.

- We will also continue to promote the Trusts reputation through the NIHR Capability Statement. This will raise the profile of our activities and enable us to participate in national and international clinical trials to attract new research.

Ensure compliance with research governance:

It is essential that the staff who are developing and undertaking research projects are fully trained, our Research and Development Department will continue to;

- provide training and support for existing and potential researchers

- undertake risk assessments of research and service evaluations

- provide Standard Operating Procedures in line with current research legislation

Ensure all research infrastructure costs are covered through research income

Research infrastructure is partly funded by the DoH and partly funded through additional income received from the Cancer Research Network and industry sponsored trials. The R&D Department continuously review and assess options to identify new funding streams to support research.