Extending the clinical research network approach to all of healthcare

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The development of Clinical Research Networks (CRN) has been central to the work conducted by Health Departments and research funders to promote and support clinical research within the NHS in the UK. In England, the National Institute for Health Research has supported the delivery of clinical research within the NHS primarily through CRN. CRN provide the essential infrastructure within the NHS for the set up and delivery of clinical research within a high-quality peer-reviewed portfolio of studies. The success of the National Cancer Research Network is summarized in Chapter 5. In this chapter progress in five other topics, and more recently in primary care and comprehensively across the NHS, is summarized. In each of the ‘topic-specific’ networks (Dementias and Neurodegenerative Diseases, Diabetes, Medicines for Children, Mental Health, Stroke) there has been a rapid and substantial increase in portfolios and in the recruitment of patients into studies in these portfolios. The processes and the key success factors are described.

The CRN have worked to support research supported by pharmaceutical, biotechnology and medical device companies and there has been substantial progress in improving the speed, cost and delivery of these ‘industry’ studies. In particular, work to support the increased speed of set up and delivery of industry studies, and to embed this firmly in the NHS, was explored in the North West of England in an Exemplar Programme which showed substantial reductions in study set-up times and improved recruitment into studies and showed how healthcare (NHS) organizations can overcome delays in set up times when they actively manage the process. Seven out of 20 international studies reported that the first patient to be entered anywhere in the world was from the UK. In addition, the CRN have supported research management and governance, workforce development and clinical trials unit collaboration and coordination. International peer reviews of all of the CRN have been positive and resulted in the continuation of the system for a further 5 years in all cases.

introduction

The benefits for patients that result from major improvements in the delivery of clinical research within healthcare systems are likely to be substantial. More rapid creation and dissemination of the evidence base for advances in clinical care, strengthening the delivery of healthcare research in both the commercial and academic/non-commercial sectors, and the dissemination of clinical excellence through research experience may be essential elements. Within this strategic context, the introduction of Clinical Research Networks (CRN) has been a key development in the National Institute for Health Research in England and in the National Health Service across the whole of the UK. This chapter provides a brief overview of the outcomes so far of this undertaking.

The National Cancer Research Network (NCRN) was introduced in 2001 [1] (see also Chapter 5 [2]) and a range of health topics was selected for the formation of new networks. The formation of a Mental Health Research Network (MHRN) in 2003 was followed in 2005/06 by networks for Stroke (SRN), Dementias and Neurodegenerative Diseases (DeNDRoN), and Diabetes (DRN). As with cancer, these topics were all of high priority as they result in high morbidity and/or mortality. In addition, Medicines for Children was selected as a topic network specifically to respond to the European Union recognition of the lack of data on those medicines most widely used in children (MCRN, 2005/06). In 2006, these six ‘topic specific’ CRN were supplemented by a separate Primary Care Research Network (PCRN) designed to facilitate the recruitment, assessment and follow up of participants in general practice and other primary care settings.

The topic-specific networks had the remit to both develop and deliver a portfolio of clinical trials and other well-designed studies. The provision of clinical infrastructure within the NHS to support both the set up and delivery of research was based on local CRN which for the cancer and primary care CRNs cover...
the whole of England but for the other topics have partial geographical coverage. This expansion of the clinical research network was not limited to England, with parallel and linked developments in Scotland, Northern Ireland and Wales from 2005 creating the ‘UK Clinical Research Network’. Following the publication of a new all-embracing and radical government strategy for health research in the NHS in England in 2006, the National Institute for Health Research (NIHR) was developed. In 2007, the concept of a clinical research network extended to all of healthcare was realized as the NIHR Comprehensive CRN. The Comprehensive CRN provides full coverage of all NHS organizations in England, and incorporated the opportunity to begin to streamline NHS research management and governance processes to reduce the regulatory burden and bureaucracy, which were limiting the set up and delivery of clinical research.

The eight CRN in England are now collectively referred to as the NIHR CRN. The roles and functions of NIHR CRN include the provision of infrastructure (both staff, particularly research nurses and trials support posts, and non-staff services) for clinical research within the NHS which ensure study delivery. CRN does not fund research costs (such as study design, conduct and analysis or associated laboratory and translational work) which are provided by individual research funders.

progress to date
The development of the CRN has led to a period of rapid growth and exciting and progressive change. It has been shown conclusively that the new approaches have resulted in rapid growth in research portfolios and in participation in clinical research by patients, with close involvement of patients at all stages of the process (Chapter 9 [3]). There is also already strong evidence of improvements in the delivery of clinical research to time and target. However, the real goal of these initiatives is to bring benefits to patients through the conduct of excellent research in a timely way to provide an increased evidence base for service improvements and the initiatives are now becoming sufficiently mature to begin to show these outcomes. Future evaluation of the CRNs will focus on the demonstration of improved patient experience and outcomes.

Within the eight national networks, are a total of 102 Local Research Networks (LRN), each with clinical leadership, formal governance and management arrangements, balancing local ownership with national consistency. The CRN now supports clinical research in all health topics, and over 95% of NHS organizations in England are now hosting and delivering CRN Portfolio studies. NIHR CRN has worked on a series of underpinning supporting initiatives. These include methods to cost and support commercial research; to promote Patient and Public Involvement (Chapter 9 [3]); workforce development; research management and governance, coordination of Clinical Trials Units; and experimental medicine linked to trials.

‘Topic’ Clinical Research Networks (TCRN)
In 2009 all of the topic specific CRN underwent international peer review (except Mental Health, which had been reviewed in 2007). This noted impressive achievements and a huge scale of change, and recommended funding for a further 5 years. It was noted that:

- Six Topic CRN have been established in England with strong UK-wide links and there is clear evidence of impact which was relatively mature for NCRN and progressing well in the other Topic CRN. Six TCRN Coordinating Centres have been established providing effective leadership and support to the development and delivery of LRN, working to common national structures and operating frameworks.
- Clinical research is supported through the provision of support for protected time within their jobs for clinicians of all professions.
- There has been a substantial increase in the number of non-commercial studies with a corresponding increase in recruitment to TCRN Portfolio studies, from 29 000 in 2005/6 to 165 753 in 2009/10
- There has been substantial engagement with pharmaceutical, biotechnology and medical device companies across the TCRN leading to an increase in the total number of industry studies adopted onto the CRN Portfolio, from three studies in 2005/06 to 122 studies in 2009/10.
- Success was noted in workforce development, the involvement of patients and the public and increased, widespread understanding and support for involving NHS service users in the clinical research work.

The growth in participation in overall NIHR CRN portfolio studies is shown in Figure 1 and the number of portfolio studies are shown in Figure 2.

NCRN is discussed in Chapter 5 [5] and by Stead et al. [1]. Specific comments and references for the five other topics given below.

Mental Health Research Network
The Mental Health Research Network (MHRN) [4–6] portfolio was established in 2004 with three studies (an RCT, a cohort study and a national survey) but it contains 641 studies in 2011. Patient recruitment has grown exponentially – from 4000 to 60 000 in the same timeframe – with studies covering all ages and diagnoses, and with recruitment in hospitals and the community. In 2010 every mental health trust in England recruited to MHRN studies. This success is built on two main platforms. Firstly MHRN’s eight hubs (local research networks) provide expert advice and support for clinical studies and e-science officers, a workforce dedicated to help to identify and recruit participants as well as negotiating with the NHS on behalf of study teams. The second reason for success is that MHRN has involved people with experience of mental health problems and their families. Over the past 3 years, this involvement has grown and now provides key support for study feasibility and delivery.

The MHRN hosts a varied portfolio of studies addressing key clinical questions across the age spectrum as well as across most diagnoses, recruiting mainly in mental health NHS trusts both in hospitals as well as in the community.

For examples, an important randomized controlled trial completed recently tested whether psychological treatment was effective in reducing harm in patients who place high demands on mental health, community and forensic services – people
with a dual diagnosis (substance misuse and schizophrenia). These patients are more likely to relapse and be re-admitted, have more severe symptoms and high physical morbidity and mortality than others with a sole schizophrenia diagnosis. The trial [7] recruited more than 300 participants and showed that it was possible to reduce alcohol but not cannabis using this therapy. This is the first time a large trial has been conducted on this clinical group that is very hard to engage. Without the help of a research network to engage the community teams, it is highly unlikely that this study would have been successful.

Further studies in other difficult areas for recruitment have shown that adolescents do not benefit from cognitive behaviour therapy being added to anti-depressants [8] and this study is being followed up with another one in progress on the MHRN which will answer the further question of whether particular psychological treatments should be prescribed at all for adolescents with moderate to severe depression. This will be the largest study to date with 612 participants in more than 14 clinics across the UK and exemplifies well the capacity provided by MHRN to answer key questions in difficult settings.

**Dementias and Neurodegenerative Diseases Research Network**

The DeNDRoN [9–12] supports research delivery through seven LRNs covering 60% of England, and in partnership with other NIHR networks. The majority of the 120+ open studies recruit from secondary care – from 175 of the 223 NHS mental health and acute trusts in England. Access to research has increased, with the number of clinician-sites participating in studies growing from 50 in 2006/07 to 646 in 2010/11. Sites with DeNDRoN support have been shown to recruit twice as many patients as sites without [7]. DeNDRoN is working with PCRN to overcome reported recruitment difficulties in primary care [8, 9] and care homes [10]; 239 general practices and 53 care homes currently participate in DeNDRoN research. DeNDRoN has established UK-wide groups to support development of new research. The number of studies opening per year has quadrupled from 12 in 2005/06 to 48 in 2009/10. Recruitment has grown commensurately from 2000 in 2006/07 to over 14 200 in 2010/11.

The DeNDRoN portfolio contains a suite of studies covering Alzheimer and non-Alzheimer dementias (51% of total portfolio), Parkinson’s (21%), Huntington’s (9%), motor neurone disease (11%), and other neurodegenerative disorders (10%). These are conditions which generally affect the older population and are therefore increasing in prevalence, and for which satisfactory interventions are generally unavailable at present. DeNDRoN supports a wide range of trial designs including: early and late phase RCTs of new interventions and agents (31%) (e.g. immunotherapy of Alzheimer’s disease); identifying genetic risk factors for specific disorders (6%) (e.g. Alzheimer’s disease).
MND DNA Bank); and observational studies (57%) (e.g. of patient and carer outcomes, health economic factors and care pathways).

DeNDRoN has supported large RCT generating information about the best pharmacological management of later stage Alzheimer’s disease (DOMINO funded by UK MRC) and best control/adverse effect management of Parkinson’s disease (PD Med funded by NIHR Health Technology Assessment Board), both of which are due to report their findings and which are likely to have a major impact on patient and prescriber choice. DeNDRoN has also facilitated non-pharmacological studies examining the beneficial effects of exercise on functional and cognitive ability in Huntington’s disease (COMMET trial) generating new management options for this currently untreatable disorder; and demonstrating the role of non-invasive ventilation in the management of motor neurone disease (funded by the UK MND Association).

**Diabetes Research Network**

The DRN has a joint coordinating centre (Imperial College London and The University of Oxford) and eight LRN which cover about half of England, but which have a wider reach into their adjacent areas so that there are opportunities for all to participate in diabetes research. This has been achieved by careful liaison with the comprehensive, medicines for children and primary care networks. There is emphasis on patient and carer involvement, providing advice on national and regional research in more than 1500 instances, and we continue to publish our success and findings [13–20]. The public outreach programme has involved over 14,000 people to raise awareness of diabetes research and the role of the diabetes network.

In the non-commercial portfolio there are 213 studies in set up or currently recruiting. In the industry portfolio there are 30 studies in the pre adoption stage, 14 in set up and 20 recruiting. In total, more than 160,000 patients have been recruited in the last five years, and since 2006, there has been a 20-fold increase in patients recruited into portfolio studies. This all makes a difference to patient care. Pharmaceutical companies are using the network to recruit into iconic international trials. One example of such an on-going study is that of the assessment and measurement of major cardiovascular outcomes in those who use a new injectable hormone analogue (GLP-1 analogue) which improves control of diabetes and helps patients to lose weight.

The DRN has emphasized the importance of patient and public involvement and the importance of a wide advocacy for clinical research among patients and professionals. Research involvement of a diverse range of communities, cultures and minority ethnic groups has been a prominent feature [21–26].

**Medicines for Children Research Network**

The MCRN was established alongside the introduction into European law of the EU Regulation on Medicines for Paediatric Use, and now supports delivery of medicines for children research across all of England via its six LRN and in partnership with the Comprehensive Clinical Research Network. The network’s portfolio has grown to over 250 studies, half of which are sponsored by the pharmaceutical industry, and covers a vast range of paediatric conditions and treatments. Recruitment of children to MCRN studies has doubled annually over the past few years, including the notable recruitment of almost 1000 children during a 2-month period to the H1N1 paediatric vaccine study in 2009 [27]. The development of studies for the MCRN portfolio is supported by 13 MCRN Clinical Studies Groups, covering all paediatric specialties, whose remit includes the prioritisation and design of robust, high quality studies identified in collaboration with children and families, clinicians and research funders [28].

Children deserve the same high standards as adults in the assessment of the safety and effectiveness of the medicines that they use. Yet half of the medicines used for children are prescribed without licence or off-label. These inequalities were addressed in the EU Regulation on Medicines for Paediatric Use, which came into force in January 2007, requiring pharmaceutical companies to agree, with the European Medicines Agency (EMA), a Paediatric Investigation Plan (PIP) for all new drugs at a very early stage in the development process. Approximately 90% of commercial studies supported by the MCRN are linked to approved PIPs. As such, the MCRN has a key role to play in addressing the needs of the EU regulation and generating data to support appropriate use of products by children.

Studies supported by MCRN are having a major impact on the health of children and in other ways. Numerous studies have reported results, with publications being available for many. Several products are now licensed/marketed for children as a result of the support that MCRN has provided. A representative sample of studies is presented below.

**Prevenar 13/pneumococcal disease.** The MCRN supported a study of the Prevenar 13 vaccine (sponsored by Wyeth, which was subsequently taken over by Pfizer). The vaccine under investigation was designed to protect against 13 pneumococcal bacteria strains rather than 7 strains covered by an earlier vaccine. The study found that Prevenar 13 is a more effective vaccine [29] and it has now been licensed across the world and adopted as part of the routine vaccination programme for all children across England. Follow up studies are underway in high risk groups of children (e.g. those with sickle cell disease).

**H1N1 vaccine.** This study of H1N1 vaccines was conducted at the height of the swine flu pandemic and determined which vaccine dosing schedule to use with UK children [27]. The study showed how quickly studies can be set up when NIHR processes are followed [30], and depended on MCRN LRN and CLRN teams prioritising this study to achieve the necessary rapid recruitment ahead of the flu season. Approximately 1000 children were recruited to this study over an eight week period.

**Cozaar/proteinuria.** This study sponsored by Merck, Sharp and Dohme demonstrated the efficacy and safety of Cozaar (losartan) in children with chronic kidney disease (CKD) associated with proteinuria [31]. The causes of childhood CKD (predominantly congenital disorders) are very different to those of adult CKD (acquired kidney disease) and this was the first commercial study of any intervention to reduce the progression of CKD in children. A PIP was approved and the SmPC changed on the basis of the data generated.
Stroke Research Network

The SRN Coordinating Centre was established in 2005 comprising academic Directors from several UK institutions and an administrative team based in Newcastle. In 2006, eight LRN were established which support stroke research across all of England in partnership with Comprehensive Research Network LRN. A similar network was established in Scotland. Recruitment of stroke patients into SRN studies has more than trebled from 2612 in 2006–2007 to 8769 in 2009–2010 with over two-thirds of patients entering randomized controlled trials. In the last 4 years, the number of portfolio studies open to recruitment increased from 26 to 71. In England patient access to stroke research has improved as stroke services recruiting patients into SRN studies also more than trebled in number from 57 in the first quarter of 2006–2007 to 189 by the last quarter of 2009–2010, with over 90% of hospital stroke services now involved in stroke research. In 2010–2011 investment was made in eight hyperacute stroke research centres across England to develop round-the-clock research support and access to research imaging and neurointerventional procedures to enable the evaluation of new emerging hyperacute stroke therapies.

SRN’s portfolio includes trials and studies across the care pathway with evaluation of therapies to prevent stroke, reduce acute damage, improve recovery and reduce the impact of long term disability. Many patients lack capacity to consent due to cognitive or language problems. The ECASS III trial was an international multi-centre study assessing whether the time window for intravenous thrombolysis for acute ischaemic stroke could be extended from 3 hours assessing the effects of intravenous alteplase against placebo in the 3- to 4.5-hour window. The narrow time-window made recruitment challenging. Support from SRN increased UK recruitment to the trial. The trial demonstrated significant benefit from thrombolysis in this time window leading to guidelines extending the time-window from 3 to 4.5 hours [32].

Acute stroke patients are at high risk of developing deep vein thrombosis (DVT) and pulmonary embolism which produce significant morbidity and mortality. The CLOTS 1 trial was a multicentre randomized controlled trial testing whether thigh length external compression stockings reduced the risk of post-stroke above-knee deep venous thrombosis. Recruitment to the trial from UK centres increased 4-fold with support from SRN enabling the trial to substantially increase overall recruitment. No significant effect of compression stockings was found on the occurrence of DVT but stockings produce more skin ulcers, blisters and necrosis [33]. On the basis of these results NICE revised their guidelines in early 2010 to no longer recommend thigh length GCS for stroke patients (ref http://www.nice.org.uk/nicemedia/live/12695/47197/47197.pdf).

The PERFORM trial was an international, randomized, double-blind study, sponsored by Servier, comparing a novel anti-platelet agent with aspirin, with a 3-year mean duration and requires 18 000 patients to be recruited in 46 countries. It opened in 2006 and became an SRN study in July 2006 which led to LRN involvement, 10 new sites, active management by SRN all resulting in a significant increase in recruitment rate, especially in SRN supported sites.

SRN have examined in detail the association between stroke service organization and research activity. Preliminary findings show a significant correlation between quality of organisation of stroke care and research activity which suggests that well-organized stroke care facilitates stroke patient participation in research and/or that participation of stroke services in research facilitates improved services.

Primary Care Research Network

The PCRN [34], consisting of eight LRN covering the whole of England and with strong collaborations with PCRN in the Devolved Nations of the UK, and with a central management team, was developed from 2006 onwards. By the end of 2010, approximately one in seven of the 8200 general practices in England had been consistently research active through PCRN, with a total of some 4000 practices having been involved in at least one study. The number of new PCRN studies opening annually rose from 20 in 2005/06 to 149 in 2009/10, and the number of NHS patients recruited per year increased from 23 000 to 142 000 over the same period. In 2009/2010, approximately 30% of all CRN recruitment took place from primary care settings. As of October 2010, the cumulative total of PCRN portfolio studies was 520, of which 355 were co-adopted with other networks.

Comprehensive Clinical Research Network

The Comprehensive CRN (CCRN), was developed based on the identification of existing NHS clinical referral patterns and healthcare economies to enable all patients to participate in and benefit from clinical research. It was initiated in April 2007 and was fully established by April 2009. In 2009/10, the NHS in England, gave Strategic Health Authorities explicit responsibilities for research, including creating a requirement for NHS organisations in England to work with the CCRN to improve clinical research and setting out a national ambition to double the number of patients taking part in clinical trials and other well-designed studies within 5 years. The CCRN comprises 25 Comprehensive LRN and includes all NHS organizations (Trusts) in England, 97% of which are now actively involved in research. CCRN provides funding for the NHS costs required to support research funded by the NIHR and more than 200 other national research funders. The CCRN also manages the regulatory approvals process for research studies. The total budget for the network was £243m in 2010/11. A total of 1662 studies were open in the CCRN portfolio in 2010/11, recruiting a total of 321 858 patients.

Twenty-six national Speciality Groups were also established, covering all of healthcare outside the Topic CRNs and these operate as national groups of clinical experts (more than 450 in total) addressing national and local barriers to the delivery of clinical research. Through having a comprehensive overview of their portfolios and detailed monthly reports, Speciality Groups actively manage the CCRN portfolio, which represents around half of the total NIHR CRN portfolio. Speciality Groups have also played a leading role in improving both the quality and comprehensiveness of the study information on the portfolio database. Examples of impact include:
• Critical Care: Swine flu triage study was set up across entire UK with Speciality Group support, and active engagement with CLRNs and pandemic planning group ensured adequate resource in most ICUs. A recent report showed the success of the project [35].

• Dermatology: Despite overwhelming support from patients, recruitment to the Softened Water Eczema Trial (SWET) had been slower than anticipated. Through provision of additional research nurses, use of GP databases to identify suitable patients and opening two new recruiting centres, target recruitment was reached by June 2009. The trial was delivered on budget (after a short no-cost extension for analysis and write-up), and a proposed funding extension of £100 000 was not required.

• Infectious diseases and microbiology: In the Carriage Study, 3000 volunteers had to be recruited for a vaccine study in 2 months. The Speciality Group achieved this by circulating details to members of the network and found an additional four sites. The study subsequently recruited to target.

The success of the CCRN is dependent on the engagement of NHS health care providers and commissioners. This in turn means that the Comprehensive network must ensure that healthcare managers are fully involved as ‘co-producers’ in the management of research; not as an ‘add on’ but rather using core NHS business processes and provision of detailed research study performance data, including numbers of patients in open studies, study status, number of studies and research approval times, to the managers in each NHS organization on a regular basis. This has proved increasingly effective in improving delivery of studies.

industry-sponsored research

A high priority for the CRN has been to provide effective support for research funded and sponsored by pharmaceutical, biotechnology and medical device companies. The key purpose is to improve speed, cost and delivery of Industry studies in the NHS. Substantial progress has been made. The CRN Coordinating Centre has engaged with over 300 companies to promote the CRN, and has introduced a range of standardized systems to improve NHS delivery for Industry, including a national Industry Costing Template. The CRN Portfolio now includes some 460 industry studies, with 38% of all UK commercial clinical trials being included in the portfolio in 2009. The number of active studies per year has increased from 18 in 2006/07 to 205 in 2009/10, and participant recruitment has increased from about 570 in 2006/07 to about 14 150 in 2009/10.

The focus of the NIHR CRN on the initiation and delivery of commercially sponsored studies is beginning to bear fruit, perhaps most clearly in the MCRN where the number of network-supported studies and number of children taking part have increased even more rapidly than predicted. The introduction of the CCRN has given greater scope for actively supporting the life science industries, with evidence of improvements in both trial initiation and recruitment being demonstrated across all CRN.

A specific project in the north west of England, which involved all three Comprehensive LRN and all of the Topic LRN has resulted in reductions in study set up times and improved recruitment into studies. The North West Exemplar Programme reported in January 2011 and significantly supported seven studies to recruit their first global patient in the UK. The Exemplar Programme has created a new way of working which has enabled biopharmaceutical companies to articulate the challenges facing the industry in the UK and to work in partnership with the NHS and the NIHR CRN to identify and implement novel solutions (www.crncc.nihr.ac.uk/Life+sciences+industry+nwe).

research management and governance

The CRN Coordinating Centre has developed and delivered a range of research management and governance initiatives to streamline and speed up the conduct of clinical research in partnership with NHS Trusts. In November 2008, the CRN introduced the first-ever national online system – the NIHR Coordinated System for gaining NHS Permission (CSP) – with the aim of standardizing the process to gain permission for research to be undertaken in NHS organizations, reduce bureaucracy, and reduce the time required to set up studies in the CRN Portfolio. In the initial phase, CSP effectiveness has been limited by a range of factors, including information systems, and substantial improvements to the information system and underlying processes are in progress. The sharing of performance data, to support Trusts in their management of the approval process, is a core element of the drive to eliminate inefficiencies in the process. Another key initiative has been the implementation of the Research Passport system in the NHS and higher education institutions (HEI) across England, which aims to simplify NHS access processes for non-NHS researchers across different NHS organisations. This has been successful: 98% of NHS organizations now accept Research Passports, and 96% of HEI now issue Passports.

workforce development

The development of a skilled and expert NHS workforce to support CRN study delivery has been a high priority. The CRN workforce consists of approximately 7800 NHS staff, including clinicians of all professions, support services staff, and research management and governance staff. The CRN delivers an extensive programme of free online and taught training opportunities. The programme has been accessed by over 14 000 NHS staff and others involved in clinical research within the CRN.

Clinical Trials Unit activities

In its first 5 years, the CRN Coordinating Centre was funded to enhance collaboration and coordination between Clinical Trials Units (CTU), to link Research Networks with high-quality CTU, and to develop stronger strategic links between CTU and research funders. A major achievement was the development and delivery of the UKCRC CTU Registration Scheme, with some 30 CTU registered by 2009, and the creation of an online directory of Registered CTU. The CRN Coordinating Centre
also hosted the UK office of the European Clinical Research Infrastructure Network (ECRIN) (Chapter 7 [36]), which aims to facilitate conduct of multi-national clinical trials in Europe, and hosted the coordination function for the UK Trial Managers Network.

conclusions

The development of CRN is a key element in implementing health research policy and strategy in England and other UK nations. Its scope, size and scale has increased rapidly between the initiation of the first network in cancer, in 2001, and 2011. A great deal of progress has been made and the CRN is already delivering benefits for both researchers and clinicians of all professions and for patients and the public. Across all eight NIHR CRN Networks in England, over 1.1 million NHS patients have taken part in CRN studies in the past 5 years. Annual recruitment has increased dramatically and study delivery to time and target is improving. There is compelling evidence that:

1. Patients and healthcare professionals from all parts of the country are able to participate in and to benefit from clinical research and that health research and patient care are being integrated.
2. The quality, speed and coordination of clinical research are being improved by the removal/reduction of barriers to research in the NHS.
3. Research collaboration with industry has been strengthened through collaborative working at all levels and the creation of systems to support the work of industry and evidence of the impact is now being demonstrated.
4. The speed of research has increased and more trials complete their accrual to time and target since the introduction of CRNs. This evidence is only mature for NCRN but active management processes established already by the other TCRNs, the PCRN and the Comprehensive CRN should continue to be reflected in improved speed in both commercially and non-commercially sponsored studies.
5. Research and Development and Innovation are now convincingly central in the work of the NHS.

The Review Panel report for the CRN Coordinating Centre in 2009 concluded:

The Review Panel congratulated the CRN Coordinating Centre on its impressive achievements to date. The challenge had been immense in terms of the pace and scale of change. Nothing like this has ever been attempted anywhere else in the world, and thus there are no benchmarks on which to draw. Progress had been admirable.

However, there remains a great deal to be done. Such rapid growth against such a challenging background inevitably means that many tasks remain unfinished, and many operating and information systems are not yet optimal. The CRN is now beginning its third 5-year programme, having begun with the National Cancer Research Network 10 years ago, which is focusing on increasing NHS engagement, managing and improving performance, and further developing the CRN processes and workforce, with the aim of delivering research to the highest standards of efficiency and effectiveness for the benefit of NHS patients.

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References