CLINICAL RESEARCH EVOLVED

THE FUTURE OF TRIALS IN THE NHS
JONATHAN SHEFFIELD
ON THE IMPACT OF STUDIES

When the NIHR Clinical Research Network was set up in 2006 with the aim of improving the health and wealth of the nation, the landscape for clinical research looked very different. Research delivery was happening but it was difficult to find your way around the NHS to get studies off the ground, and all too often research was considered a nice-to-have optional extra for many trusts. The concept of the network is all about providing the NHS with the support and facilities needed to make it easier for research to happen in England, which will help to drive the UK forward as a world leader in research delivery.

Over the last eight years, the environment for clinical research in the NHS has been transformed – and in 2013-14 the network reported its best year yet. Since the NHS Constitution was modified with a research pledge to patients and staff, over 99 per cent of NHS trusts in England are now conducting research studies annually, showing a real commitment to research activity. And, since 2008-9 more than three million patients have taken part in NHS clinical research, providing evidence that not only do patients think research is important; they also personally commit to the endeavour.

Last year the network conducted more than 4,000 studies – more than double the number of six years ago. The types of studies being delivered are also changing – an increasing number of complex, interventional studies are taking place as the NHS improves its research capacity. There is now a wealth of skill and specialist knowledge that sits at the very heart of NHS trusts, supported by well qualified researchers funded by the NIHR.

Over the last four years the network has made great strides to improve delivery for commercial study contracts. The most recent annual report showing more than 900 commercial studies delivered in the NHS in England. The numbers continue to grow as our reputation increases for delivering high quality studies on time and to target. Commercial studies delivered by the network were set up in an average of 26 days and almost 80 per cent met their patient recruitment targets on time. These figures are internationally competitive and show that our work to improve the environment for commercial pharmaceutical, med-tech and biotech companies is delivering results.

I’m delighted we are showcasing the network’s activities and achievements in this supplement, and I hope you’ll be as inspired as I am by what the NIHR is achieving in the NHS to improve patient care. We all have a role to play but through hard work and by working together, we can ensure clinical research drives the NHS forward with innovative healthcare solutions and make continued progress for our patients.

Jonathan Sheffield, chief executive, NIHR Clinical Research Network.

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CAPACITY

AN EVOLVING RESEARCH LANDSCAPE

Embedding clinical studies within health services is more important than ever. By Jennifer Trueland

When asked what he wants the future to look like, Matt Seymour probably speaks for all senior research directors at NIHR Clinical Research Network. “What I’d like to see happen across all medicine is that research becomes absolutely part of the core business of what the NHS does,” he says.

“People should expect that their doctor or nurse will be involved in research so that at the same time as the patient is being treated, it’s helping patients of the future. Every doctor and nurse should regard research as their job – an integral part of what they do.”

Professor Seymour heads the cancer “theme” in the reorganised NIHR Clinical Research Network, which is now split into 30 clinical specialties from ageing to infectious diseases and microbiology, and works across 15 local clinical research networks.

Although the new system is, to an extent, still bedding in, he is optimistic. “Cancer was a big success story in the old system; it was a really successful network, and its reputation internationally was superb,” he says. “But I think there’s an opportunity now to go up a level, and that’s very exciting.”

A range of breakthroughs

There is, of course, progress in other areas too with great examples from all specialties. To pick out just a couple, the CLOTS (clots in legs or stockings after stroke) studies are already having a real impact on care of people with stroke. The multicentre randomised trials questioned the value of external compression in patients with acute stroke to prevent deep vein thrombosis. More than 2,500 patients were recruited to this trial and, as a result of the findings, NICE revised guidance to no longer recommend thigh length graduated compression stockings for stroke patients – a real outcome with real benefits to the NHS and to patients.

Elsewhere, the N-ALIVE study, a randomised controlled trial – which is still ongoing – tests giving Naloxone kits to people on leaving prison to prevent death from heroin overdose.

This means that family or friends can administer an injection of the drug, which if given promptly after a heroin overdose, can save lives. Scotland has adopted the use of the kits even before the trial has finished.

Recognition for dementia

Another exciting area is dementia. Traditionally a relatively neglected area – now successive governments have made it a priority, culminating in the current Prime Minister’s “Dementia Challenge”. One of the three strands of this challenge centres on improving dementia research.

As NIHR national director for dementia research, Martin Rossor welcomes this emphasis. “It’s a major step forward,” he says. “We’ve got a massive task ahead of us, but getting the focus on dementia means we’re moving away from the notion of the ‘Cinderella’ area of [care for] the elderly demented person.”

There are a number of national initiatives to improve access to dementia research – for example, the ENRICH (Enabling Research in Care Homes) programme and the Join Dementia Research service that gives people the chance to register their interest in taking part in research.

Our understanding of dementia is improving all the time, helped by advances in technologies such as MRI scanning and in systems neuroscience.

Yet Professor Rossor cautions: “We won’t see a simple, dramatic cure for Alzheimer’s, but we will see treatments. And we will reduce stigma and get research funding up.”
Boost for child health

At the other end of the age spectrum, children’s research is also seeing some exciting changes. There are two joint directors for children’s research at the Clinical Research Network. Michael Beresford and William van’t Hoff both have a long pedigree in research and with the Clinical Research Network.

“We support delivery of children’s research across the country,” says Professor Beresford. “We focus particularly on clinical trials and the development of new and safer drugs but it’s not just about clinical trials; it’s also about understanding the impact of disease and outcomes of research on everyone, from pre-term babies to adolescents—it’s important for children and important for the NHS.”

Dr van’t Hoff explains that children are special for various reasons but until recently the development of new medicines didn’t require testing in children. All that changed in 2007, when, as a result of EU regulatory changes, it became mandatory for pharmaceutical companies to test their products in children as well as adults if they were to be used in children and young people.

“What that has meant is that companies that want to bring medicines to Europe have to undertake children’s studies. That’s been a real catalyst for research, and a recognition that children deserve better care and better medicines,” he tells.

Thanks to the network, more than 56,000 children have taken part in almost 300 trials, many concerning novel drugs and treatments. This has an impact on the care that all children receive.

Dr van’t Hoff has noticed a change in the research landscape in recent years with increasing numbers of studies taking place outside specialist children centres. “There are some in general practice and secondary care as well as the major teaching hospitals,” he says. He says that providing support in a variety of settings is a key role of the children’s specialty—and it is paying off: last year studies in the children’s network scored very highly on recruiting the first patient in studies running in different countries, that is, excelling in setting up and recruiting to studies.

Dr van’t Hoff believes tremendous progress has been made. “Over the last eight years we’ve developed a research infrastructure that allows children’s healthcare to be improved. We call upon paediatricians and managers to support this work to seize the opportunity to ensure that research is core to care, not additional. If they want to improve quality of care they should be enabling the workforce to take part in studies.”

The national nature of the Clinical Research Network is particularly valuable in rare diseases, says Professor Beresford. “It means we can focus on delivering excellent research to improve our understanding of the disease wherever the patients are.”

Professor Beresford agrees that research should be embedded in the health service. “Some doctors will be specifically interested in doing research, but it’s integral to the role of all doctors to be involved in improving our understanding and treatment of patients.”

And, says Professor Seymour, it’s hugely satisfying. “It’s having an idea in the clinic, on the bus or even in the shower that could make a tangible difference to people’s lives,” he says. “That’s a real privilege.”

Find out more about other specialities of the Clinical Research Network and their progress in the communities by visiting www.crn.nihr.ac.uk/networks
GENERATIONR – INVOLVING YOUNG PEOPLE IN RESEARCH

Towards the end of last year more than 150 people involved in research attended a high profile event in central London. The speakers – including Professor Dame Sally Davies – were high calibre and the message was clear: children, young people and families are, and should be, at the very heart of clinical research. Dr William van’t Hoff, joint director for children’s research at the Clinical Research Network pioneered the event and advocated that young people organised, designed and hosted the event themselves.

“The GenerationR event was designed to highlight the importance of involving young people and families in the design and delivery of research with children and young people. It was also aimed at dispelling some of the misconceptions and myths around medical research in general. It was an important showcase for what is becoming a key part of the Clinical Research Network activities.

“NIHR believes that patient and public involvement is crucial to the delivery of high quality research,” says Ms Preston. “That’s the case for children and families as well as everyone else.” The current approach was pioneered by Ms Preston and colleagues not long after the network was set up.

The framework

“We felt it was extremely important to adopt a strong participatory approach for involving young people as opposed to placing two young people on a committee or in an adult environment,” she says. “So in 2006 I set up a pilot young person’s advisory group to provide a forum for young people to learn about and comment on various aspects of the research cycle from the identification of research questions to the dissemination of research findings.”

Membership of the group was open to any young person aged between eight and 18, who ideally had some experience of taking medication, used hospital services or taken part in a clinical trial. “The age criterion was initially set at 10-18 years but there was an eight year old girl who really wanted to take part, and she was quite amazing,” she says.

It was a learning process for everyone involved but soon the format was expanded to form a national young person’s group with an overall membership of around 100 young people based in four local clinical research networks.

“Over the last eight years the group members have been involved in a significant number of research projects,” says Ms Preston. “Members come from a variety of backgrounds and are different ages – some are still going through treatment, some aren’t but all have an important point of view.”

Using feedback

One of the most important contributions made by the group has been assessing tools such as patient information leaflets, consent forms, questionnaires and interview schedules.

“The group has reviewed around 80 patient information leaflets for publicly funded and industry funded studies, commenting not just on the style of the information but on practical issues such as taking blood samples, length of hospital stays and so on. The contribution has been invaluable in terms of making clinical trials more acceptable to the target group.”

Researchers who present to the young people’s advisory group “expect a hard time” but appreciate the importance of the input at an early stage. For example, Ms Jenny recalls one study where the researchers wanted participants who had cerebral palsy to keep a diary but one young person raised the issue about the practicality of expecting everyone to be able to write.

“Another pointed out that one proposed...
Following the event a key activity has been the development of a GenerationR website (soon to be launched) in collaboration with The Testing Treatments Interactive and Sir Iain Chalmers. A GenerationR magazine is also planned and aimed at promoting and raising awareness about research in children to a wider audience of parents and young people. Feedback from industry suggests that the group’s involvement has boosted recruitment to trials, and helped with the ethics approvals process. “Their impact is amazing and the good work will continue,” says Ms Preston.

**THE VALUE OF BEING A RESEARCH ACTIVE TRUST**

Back in 2007 there were just two members of staff in the research department of the Sussex Partnership Foundation Trust; today there are around 80 people. That growth is testament to the importance that the trust board places on being a research active organisation— and is also a reflection of the high quality of research conducted there. “The trust was aware that becoming a research active organisation would be beneficial to patients,” explains research director Mark Hayward. “And the creation of the National Institute for Health Research opened the door for aspiring trusts with no previous track record.”

**Quick returns**

The research department’s objectives include developing a culture of research, increasing high quality research activity, and increasing income— all of which is reinvested in research.

It has achieved these objectives by building good relationships with pharmaceutical companies and academic partners and getting the message across that Sussex is a great place to conduct research.

Importantly the trust makes it a priority to ensure that research findings are quickly acted upon, improving services for patients.

“We know that being a research-active organisation is better for patients and, for us, it’s very much about quality and improving outcomes,” he says. “What we want to see is high quality, NIHR portfolio studies that are designed, delivered and translated into practice.”

Today the trust is in the top five mental health trusts in the country for recruiting participants into high quality studies. More so, it is the most research active mental health organisation in south England. The trust has made it a priority to research topics that have a particular relevance for the people living in its catchment area.

“We’ve got the oldest population in England so it’s only right that we focus on dementia research,” he explains. Its growing reputation has meant that the trust has been able to recruit some big names. Among them the leader of the Centre for Dementia Studies, Professor Sube Banerjee, who was formerly national clinical lead for dementia strategy in England—a collaboration between Sussex Partnership and Brighton and Sussex Medical School. The trust also has a focus on children and young people’s mental health— being the service provider for a large chunk of the south coast and has recruited Professor David Fowler to lead the development of research into young mental health in collaboration with the University of Sussex.

**Specialised clinics**

The trust has set up emerging research clinics— a collaboration between clinical services and the research department so that research findings can be rapidly translated into practice. One example is the Obsessive Compulsive Disorder clinic which offers evidence based psychological therapy while also recruiting to studies that seek to develop more effective therapies.

“The clinics provide a vehicle for ensuring that advances in treatment are immediately available to our patients. As soon as a more effective therapy is discovered we can offer it within the clinic, enabling our patients to have confidence that their therapy is state of the art.”

“The trust is developing a reputation for dementia drug research with its dementia drug trials unit giving patients early access to promising treatments.”

The trust’s own financial investment in research is “minimal” but gets a definite return. The bulk of research income comes from the NIHR, from running drug trials and from grants. “That’s new money for the trust,” Mr Hayward says. “And the trust board has been fantastic about investing it back in research.”

“Getting the word out to staff in the trust and encouraging people to get involved in research is also important,” he says. Steps have included creating a research network and publishing a magazine outlining what’s going on and making sure that the results of any research activity are robustly disseminated to anyone who took part or who might have an interest.

Members of the research department also work closely with clinical teams to provide expertise and a friendly face. “We have a saying here that if you’re interested in doing research, find a friend to guide your journey,” he says.

“I’m a clinical psychologist and was always an active researcher but my journey was a lonely one in those early days. I want to make sure that anyone who wants to get involved in research is supported to do so— we want a culture of research which is good for staff, good for patients, and good for the health service.”

‘The trust’s own financial investment in research is “minimal” but gets a definite return and is invested back in research’

study involved a lot of [hospital] visits in a week which would have an impact on schoolwork,” she adds.

The groups meet once a month depending on the agenda and over time it has evolved into a format that helps to get the best out of the young people (including warmup exercises and games). Participants are rewarded with a £20 token.

Involving children and families in research remains a priority, according to Ms Preston. Since the GenerationR event, the network has been working on recommendations in the GenR report, which were endorsed by Dame Sally after the conference.

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Health research is vitally important not only for improving health and patient outcomes thereby improving the NHS but also for contributing to the nation’s economic growth via the life sciences industries.

The government established the National Institute for Health Research in April 2006. Since then the NIHR has transformed research in the NHS. It has increased the volume of applied health research for the benefit of patients, the public and the NHS – driven faster translation of basic science discoveries into tangible benefits for patients and the economy and developed and supported the people who conduct and contribute to applied health research.

The NIHR plays a key role in the government’s strategy for economic growth, attracting investment by the life sciences industries through its world class infrastructure in the NHS for health research.

‘The NIHR Clinical Research Network makes this country the “go to” place for the life sciences industries when they’re considering where to place their studies’

Together, the NIHR people, programmes, centres of excellence and systems represent the most integrated health research system in the world.

The NIHR Clinical Research Network is a major element of this world class infrastructure for health research – it is the research delivery arm of the NHS. It is widening opportunities for patients across the country to take part in research studies and it is enabling the vast majority of studies to be delivered to time and target.

This means we get crucial research evidence quicker. It also helps to make this country the ‘go to’ place for the life sciences industries when they are considering where to place their studies of new treatments and diagnostics.

The transformation that the NIHR Clinical Research Network has achieved is truly impressive. I am delighted to see this transformation celebrated in this HSJ supplement. Professor Dame Sally Davies is chief medical officer and chief scientific adviser at the Department of Health.

Technology

SHARE REAL DATA IN REAL TIME

Jennifer Trueland explores new improved information systems that enable speedier access to clinical studies.

Just three years ago it took 122 days to get permission to start a piece of research in the NHS; today that has reduced to 25 days. What’s more the process has become simpler with would be researchers making one online submission to an NHS organisation with a single point of contact.

“Improved information systems have been key to this change,” says the chief information officer with the NIHR Clinical Research Network, Richard Corbridge who adds that the position is getting better all the time.

He tells that last quarter the mean was 21 days. “It’s not just down to technology but it has certainly played an important part.”

The NHS IT projects might not have the best reputation but few would argue that the UK’s health services are actually in a superb position when it comes to data. The real challenge is making good use of it.

That’s something that the Clinical Research Network realises. “Previously if a researcher asked for a report, it could take three days to get it. That wasn’t good enough,” says Mr Corbridge.

How to make research data accessible?

Last year the organisation took the important step of launching its Open Data Platform. This has been a means of bringing together valuable information about research being delivered through the NHS and making it available to researchers and others who need to see it.

The data store is an incredible resource, says Mr Corbridge. Among the information available is how many patients are being recruited to trials at a given hospital, what trials are taking place and where and which specialist centres are doing best in terms of suitable recruitment to trials.

Initially the information was accessible to the Clinical Research Network coordinating centre staff who could use it to get a good overview of what was going on across the UK. Now it can also be accessed by the wider clinical research community including research nurses, research administrators and management teams.

One of the big benefits is that the data is now much closer to real time. “Before the data was six weeks old but some sets are already being updated every 24 hours. We are aiming to have the rest of the data updated at near real time by the end of the year,” informs Mr Corbridge. “That means we know where patients are or aren’t being recruited; we have a very up to date picture.

“It means we can compare two hospitals to see what they’re like at recruitment – unless you’ve got the data, you don’t know what questions to ask. In a way, the information doesn’t answer the question but it prompts you to ask the next question.”

Integrated approach

Involving the end users, that is, researchers in the process has been important, as has easily accessible and effective training and support.

“Researchers or clinicians are so busy that they’re not always open to new ways of doing things,” he says. “We’ve had to take people on a journey so that they can see the benefits of doing things differently. Our goal was to provide users with systems they want and turn them into ‘fans’ of information.”

The Central Portfolio Management System is a key component of the revitalised network. The CPMS is being built to replace the previous UKCRN database.

It will mean that, for the first time, the information system supporting the research pathway will be truly integrated.

The system has been designed to work with the Open Data Platform and allow users to capture and manage data relating to
The system gives near real time data on research opportunities and allows better management of the research pipeline

The management of studies and research activity. All sites, trusts and the wider research community were able to get involved with this project, meaning that there is an unprecedented level of usable information available.

CPMS will be linked to Local Portfolio Management Systems, giving near real time data on research opportunities and allowing better management of the research pipeline.

According to Mr Corbridge, it will improve the capturing of information on research activity and will facilitate performance management by providing the data very quickly that enables users to identify where support is needed – for example, in recruitment.

“The important thing is making sure that we can use the data – we’re not just collecting for the sake of it,” he adds.

CRN: West of England chief operating officer Mary Perkins says it’s a “challenging, but exciting time” for clinical research in the region. “We’ve got a really vibrant research community with international strengths in population health research and primary care,” she says.

“The ability to link real time local and national data will be game changing for us. It will mean we’ll be able to match resources to activity in a much more agile fashion, further decreasing the time it takes to start study set-up.”

Industry feedback

The industry lead with NIHR Clinical Research Network, Sarah Crawshaw says the system is improving the service that the organisation can offer to commercial researchers such as pharmaceutical, medtech and biotechnology companies.

“By providing a full picture of what’s going on where, and where the expertise and capacity is, the portfolio management systems will give valuable business intelligence on what needs to be done,” she says.

Commercial partners also provide valuable information to the network, for example on where recruitment is working well. “We use it for performance metrics, supporting companies to do research in the NHS,” she adds. “It supports site selection and also means we can review how sites are doing.”

Information such as whether the clinical expertise is available, and whether the patient population is suitable for a given trial is invaluable to prospective researchers, Ms Crawshaw says – and CPMS will be able to support this activity.

“We’re always thinking about improving care and patient benefit – and the technology is really supporting that,” she says. “I think CPMS will revolutionise the way that we work.”

Giving patients direct access to information about trials is close to the heart of Nadine Boczkowski, head of business intelligence at NIHR Clinical Research Network – and she is leading a project to do just that. A search engine called “Find my clinical research study” will allow people to seek out studies using various criteria like disease, postcode and hospital. “The idea for it came about in response to patient need,” she says. “This involves opening up information to a wider audience.”

The search engine has already gone live in order to get public feedback. Her team is now working on the updates to provide a service that can help patients engage directly with research rather than relying on their clinician to raise the possibility or waiting for referral.
CLINICAL WORK

HOW TO BE THE ROLLS ROYCE OF RESEARCH

With a focus on making the UK a hotbed for commercial research, industry experts now focus on early customer feedback to create new pathways to faster clinical trials.

INDUSTRY OVERVIEW

Martin Gibson would be the first to admit that a decade ago the UK didn’t have the greatest reputation for conducting commercial research. A keen researcher himself—his specialty is diabetes—he saw and heard at first hand the experience of industry fellows and others when it came to making choices about where to invest their time and money.

“In the early 2000s, the view was that the UK was not a good place to do research,” he concedes. “We were seen as expensive and slow and as not reacting to the needs of the people wanting to carry out research. Not surprisingly, the work was going elsewhere. “We wanted to change all that, and what we’ve been trying to do is make the country a more favourable environment for research.”

Today Professor Gibson is clinical director at NIHR Clinical Research Network: Greater Manchester. He is also associate director for industry with the network and is a consultant physician with Salford Royal Foundation Trust, where he was previously director of research.

Research, you might say, is in his blood—so not surprisingly he’s as keen to support it as much as possible. That has involved transforming the landscape of 10-12 years ago into a streamlined and dynamic comprehensive system that has, at its heart, the needs of researchers, industry, the NHS and, of course, patients and the public.

“What we had back then was an ad hoc system—there were some good local systems but people didn’t know where they were,” he says. “There was no national vision, no performance management.”

“Now we have a national managed system that’s supported and driven by national data, which has been a really powerful message to get across to industry.”

Three years ago, the Clinical Research Network started to work with industry in a lean process to work out how it could become more user friendly.

The key, explains Clare Morgan, research delivery director with NIHR Clinical Research Network, was to find out what needed to change from the perspective of those people commissioning and undertaking commercial research in the UK.

Dr Morgan has considerable experience of working in and with industry. Her previous roles include deputy general manager of the Dementia and Neurodegenerative Diseases Research Network where she was responsible for development, strategic planning and performance management of the research portfolio—both commercial and non-commercial. Prior to that she worked in clinical research with the pharmaceutical industry as a scientist and global study leader, and also for a contract research organisation.

“What the industry wants is to have research that is cost effective, timely, high quality and done at speed while being reliable,” she states simply.

Back in 2006, however, the outlook for clinical research in the UK was “bleak”, she says. Although the inception of NIHR Clinical Research Network helped—a step change came five years later. “We knew we shouldn’t rest on our laurels so we had a root and branch review in 2011,” she says. “We asked what it was that our customers needed—the improvement work was driven by customers. We were asking what were the things that worked and what were the things that drove them mad,” she says with a smile.

What came out of this thorough process was a revised system of tools and services for industry—whether for pharmaceutical companies or contract research organisations, through to medical technology and small to medium enterprises.

The new system operates on three levels of feasibility:

- Early feedback (a rapid assessment of feasibility based on the network’s knowledge of the UK research landscape plus advice on study design).
- Site intelligence (if companies have identified sites, this service provides feedback on their capability).
- Site identification (the network can advise on sites that would be suitable for a
In association with nihR clinical Research network

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industry) has been attracted through NIHR's government, charities and the life sciences additional research investment (from recruiting patients into the network studies. Importantly, the time taken to set up commercial trials has now halved (to around 26 days) and UK researchers are winning a reputation for the number of "global firsts" that is, people recruited first to global trials, which adds to the country's attractiveness.

Industry now wants to work in the UK and the benefits to the population are enormous," says Professor Gibson.

Dr Morgan agrees. "As we started people [in industry] perceived that [the NIHR system] felt like an extra layer," she says. "Now it's just the way that we do things in the UK.

"What we have done is to transform our service into something that industry needs."

THE CHARITY/FUNDER EXPERIENCE

From Cancer Research UK's perspective, the clinical research landscape has transformed over the last decade– very much for the better.

The charity's chief clinician, Peter Johnson points out that the number of people taking part in clinical trials has soared, the pharmaceutical industry has invested substantially in UK based research, and most importantly, patients are getting faster access to new treatments.

This has been due, in very large part, to the growth and development of networks of research, now under the aegis of the NIHR. "The partnership between Cancer Research UK and the NIHR has been crucial to our research portfolio," he says.

"Driving up the volume of clinical research has been good for patients with cancer, and has attracted international pharmaceutical companies to partner with us. That's brought hundreds of thousands of pounds of inward investment, which is enormously important."

The enriched research environment has also meant the UK has been able to draw some of the world's best clinical researchers, from the US, Australasia and Europe, he adds. Much of this is down to the focus on collaboration and positive relationships on a national basis.

"The cancer research network has transformed the landscape since it started in 2001. It's increased the number of patients taking part in trials more than six-fold, and has been particularly important for trials in very rare cancers– even national centres would only see one or two cases of some rare cancers per year but the network has been able to bring these together to make trials possible."

Patients are already benefiting from this with concrete examples of trials which are making a difference to people's lives. As an example, Professor Johnson cites research into Olaparib, a drug which the European Medicines Agency has just recommended for approval.

"This has been tested in women with ovarian cancer and has shown that it significantly improves outcomes," he says. "This is clinical research, carried out in the UK, which is really changing the outlook for people with this form of cancer."

He believes that the perception of clinical research– both within the NHS community and among members of the public – is improving all the time in part due to efforts of the NIHR. Government will and backing also helps.

"It's important to highlight the understanding between ourselves, as funders of research, and the Department of Health, that the NHS will cover the treatment costs of people taking part in research [if the charity deems the study suitable and valuable]."

"That means that the UK is in a better position than other countries in Europe when it comes to research: the DH has done that, and, latterly the NIHR has made sure that this has continued."

"Leadership from the NIHR has also been hugely important to ensuring research is seen as core business for the health service rather than an optional extra."

While under no illusion that all in the research world is perfect, Professor Johnson is optimistic. "I do think that the cancer network has meant that we, in the UK, are driving the Rolls Royce of clinical research," he says.

"It might sometimes feel as if we're driving up a muddy track because of all the regulatory hurdles, but at least we're driving a Rolls Royce."

particular study). Given that early feedback is provided within a maximum of 10 days of the application, and site intelligence and identification within 15 working days, the new system is much speedier than previously.

What is more, the feasibility process is much simpler, Dr Morgan says. "It used to be done via faxes," she says ruefully. Now there is online submission and one single contact point. The figures so far are impressive. Since the network started keeping comprehensive records six years ago, the number of patients taking part in clinical trials has reached more than three million.

In 2013-14 more than six million people took part in studies conducted by the network, and 99 per cent of trusts are recruiting patients into the network studies. Additionally, nearly £3.5 billion of additional research investment (from government, charities and the life sciences industry) has been attracted through NIHR's centres and facilities for experimental medicine in the NHS.

Year on year, there has been at least a 40 per cent increase in funding from industry and charities. There have been more than 100 international and national patents granted and nearly 200 licensing deals.

Last year the number of patients recruited to commercial studies rose by 26 per cent to more than 25,000 and the network supported more than 900 commercial contract studies.

Importantly, the time taken to set up commercial trials has now halved (to around 26 days) and UK researchers are winning a reputation for the number of "global firsts" that is, people recruited first to global trials, which adds to the country's attractiveness.

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The enriched research environment has also meant the UK has been able to draw some of the world's best clinical researchers, from the US, Australasia and Europe, he adds. Much of this is down to the focus on collaboration and positive relationships on a national basis.

"The cancer research network has transformed the landscape since it started in 2001. It's increased the number of patients taking part in trials more than six-fold, and has been particularly important for trials in very rare cancers– even national centres would only see one or two cases of some rare cancers per year but the network has been able to bring these together to make trials possible."

Patients are already benefiting from this with concrete examples of trials which are making a difference to people's lives. As an example, Professor Johnson cites research into Olaparib, a drug which the European Medicines Agency has just recommended for approval.

"This has been tested in women with ovarian cancer and has shown that it significantly improves outcomes," he says. "This is clinical research, carried out in the UK, which is really changing the outlook for people with this form of cancer."

He believes that the perception of clinical research– both within the NHS community and among members of the public – is improving all the time in part due to efforts of the NIHR. Government will and backing also helps.

"It's important to highlight the understanding between ourselves, as funders of research, and the Department of Health, that the NHS will cover the treatment costs of people taking part in research [if the charity deems the study suitable and valuable]."

"That means that the UK is in a better position than other countries in Europe when it comes to research: the DH has done that, and, latterly the NIHR has made sure that this has continued."

"Leadership from the NIHR has also been hugely important to ensuring research is seen as core business for the health service rather than an optional extra."

While under no illusion that all in the research world is perfect, Professor Johnson is optimistic. "I do think that the cancer network has meant that we, in the UK, are driving the Rolls Royce of clinical research," he says.

"It might sometimes feel as if we're driving up a muddy track because of all the regulatory hurdles, but at least we're driving a Rolls Royce."
Jennifer Trueland looks at the innovative means being used to manage research staff and teams

If you want to have an NHS organisation that truly has a research culture, then look to the workforce. This is the view of Dr Susan Hamer, organisational and workforce development director at the NIHR Clinical Research Network.

It’s part of her role and that of the group’s workforce development team to support the learning and development of the NIHR funded workforce who deliver clinical research in the NHS.

In recent years, the UK has been driving towards becoming more globally competitive when delivering clinical research; this has a natural knock on effect for the workforce on the frontline.

“The challenge is to have an overview of the workforce and the overall research picture. This bird’s eye view ensures you can provide flexibility in the system.”

The learning and development opportunities offered by the network supports thousands of NHS staff who are involved in clinical research— ensuring they are delivering research studies to the highest possible quality and with care for patients at the heart. One way the network does this is by providing free Good Clinical Practice training to NHS site staff working in all research specialties, which last year saw almost 23,000 people complete the training. This, along with other development programmes such as Fundamentals of Clinical Research Nursing aims to ensure that research healthcare professionals have the knowledge, skills and confidence to deliver the breadth of studies on the portfolio.

The majority of the NIHR funded workforce sits within NHS trusts and so they do not always affiliate themselves directly with the network. That means that developing a sense of belonging and community is a key priority for the organisation. “We’ve worked hard to build a sense of community and belonging with our people by using various communication channels to encourage this,” says Dr Hamer.

“Our research nurses now have a real sense of being part of the bigger picture and that their contribution to nationally identified research priorities is important so we’ve very proud of that.”

“This blueprint to build “communities of practice” as used for the research nurse workforce is now being rolled out to other parts of the community including pharmacists and other research professionals.

“According to Dr Hamer, having a workforce that is trained and research ready is good for the NHS. “High quality clinical research practice leads to good quality care for patients. This has an effect on the wider NHS workforce so overall standards improve.”

Good clinical research staff can also make all the difference to patients, she says, partly by improving the informed consent process but importantly by making the experience of taking part in research a good one. “People talk about it [taking part in a trial] as being

He believes that the future of research will involve making more use of routinely gathered data. And while the randomised controlled trial hasn’t had its day, he believes the way they are conducted needs to improve.

His message to NHS managers is that ensuring their organisations are research active will improve care across the board. “If managers want to raise the quality and efficiency of the service they deliver, they should take research seriously. They need to take a broad view of how research can benefit the whole system— not just their local organisation. But, at the same time, they should recognise that by being research active, they have better quality staff, higher standards of care and patients benefit from being first to get new treatments. That’s definitely worth working for.”
like getting an upgrade,” she says.

Interest is growing in being part of the wider clinical research workforce, she says and “we are working with NIHR Faculty and higher education colleagues to ensure that clinical research competence is embedded in the undergraduate curriculum of the future. It’s really important to raise the profile of this area of clinical care and ensure we have a future workforce that understands the importance of research in the NHS. It will also encourage more nurses and allied health professionals to consider this as a career option once they’ve graduated.”

Working with external partners is of growing importance to the network. “It’s crucial we contribute to the wider nursing and caring strategies being developed by Health Education England,” says Dr Hamer. “These strategies will be the future parameters to which the whole of NHS workforce works to, so it’s vitally important we are part of the process.”

Dr Hamer and the Clinical Research Network are keen to encourage research professionals of all backgrounds to climb the research ladder to become leaders in the field. “Research professionals understand how research is delivered and what this means to patients. This knowledge means they are in a good position to lead studies, or even go down the academic route to drive research.”

A FORCE FOR GOOD TO SUPPORT ORGANISATIONS IN CLINICAL TRIALS

If your research project isn’t going as well as it could – or if you simply need some expert back-up – who are you going to call?

The answer, says Jacqueline Pirmohamed, the chief operating officer with CRN: North West Coast, could well be their taskforce.

This taskforce is a dedicated team of clinical research staff, mostly nurses who provide support to organisations undertaking research. “They’re a bit like a flying squad in that they will enter research sites often at very short notice,” she says. “They provide complementary support to organisations, perhaps to bolster their own expertise or to provide cover for sickness and other absence.”

Sometimes researchers will contact the network to ask for help to get a study off the ground or to drive it forward when recruitment is proving to be challenging. This has the dual effect of helping with that particular piece of research while spreading skills and good practice.

“The taskforce are very good at recruiting to time and to target and in sharing their expertise with the organisation’s own staff,” says Maria Boswell, workforce development lead with Clinical Research Network: North West Coast.

“But it’s also about enhancing the patient experience. By sharing good practice, we can embed a culture of research across the NHS.”

Both acknowledge that more needs to be done to attract nurses into research. “It’s becoming increasingly difficult to recruit nurses – we need to make sure that research nursing is seen as a good career,” says Ms Boswell.

One change driven by the network has been to encourage trusts to put research nurses on permanent contracts. “Traditionally research nurses have been on temporary contracts and that causes a great deal of anxiety,” says Mrs Pirmohamed “These nurses shouldn’t be treated differently to any other members of NHS staff. Most organisations have now put them on permanent NHS contracts in recognition of the fact that they will move from research project to research project if an organisation is research active.”

Meanwhile, the flexible team in the “flying squad” continue to be called on to help bring their research skills to a variety of settings. Mrs Pirmohamed recalls one particular case where a researcher was having difficulties in setting up a new study. “He called us on a Friday afternoon saying he was worried about a study – after the taskforce got involved, he had the highest recruitment from the UK. We hear of that sort of situation all the time. We know the taskforce is making a real difference.”