

RESEARCH STRATEGY 2018-2020

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1. Vision

Research excellence leads directly to improved patient outcomes, both by attracting high quality employees and embedding a culture of the highest standards of healthcare delivery underpinned by evidence. To this end, the overall aim of the Sheffield Teaching Hospitals NHS Foundation Trust (STH) research strategy continues to be one of increasing the profile, quality and quantity of clinical research, viewed as an essential and valued activity by all members of the organisation and the wider Sheffield community. This research strategy underpins the objectives of the STH Making a Difference Corporate Strategy 2017-2020.

2. Local context and achievements

2.1 Research

The last research strategy covering the period 2015 through 2017 listed the following specific objectives:

- a. Develop, support and monitor Clinical Directorates to ensure that they increase research activity. This included the appointment of research leads in all directorates plus the award of academic status to those directorates whose academic performance was strong. Academic Directorate status was to be awarded (and maintained) by a transparent process based on performance against agreed objectives.
- b. Ensure that the Trust research strategy is aligned to the strategies of the University of Sheffield and Sheffield Hallam University.
- c. Incentivise researchers including:
 - Maintaining financial support for clinical time.
 - Incorporating time for research (i.e. PAs for doctors) as part of the annual job planning round.
 - Creating a Clinical Research Academy (CRA), by providing time for research through the award of 'PAs'/clinical time awarded following open competition.
- d. Ensuring that the Clinical Research Office (CRO) met the need of researchers. This included:
 - Establishing and publishing performance reporting systems to operationalise research and development, and integrate it into the core business of the Trust.
 - Ensuring a framework for continuing good and efficient governance, rapid approval of projects and guaranteeing the Trust met standards of MHRA, FDA and HTA inspections.
 - Providing an efficient Research Finance service to ensure costs of studies are calculated accurately and rapidly and maximum income was recouped.
 - Maintaining a research informatics system to underpin research activities.
 - Promoting and facilitating public and patient involvement in research.
- e. Develop research activity and maximise research income.

- f. Further develop the Clinical Research Facility (CRF) to ensure a balanced profile, sustain and build the CRF experimental medicine portfolio and extend best practice across STH.
- g. Ensure the Trust implemented the key steps to ensure it met the objectives for increasing participation in research as part of the Yorkshire and Humber AHSN.

The strategy was underpinned by the creation of a new metrics based, Performance and Operating Framework (POF) which each STH Directorate adheres to.

On review of these objectives, we can conclude that many have been achieved as described below:

- a. Research Leads have been appointed in all directorates and 15 clinical directorates have successfully applied for academic status. All clinical directorates have submitted an annual report including metrics and key performance indicators and this has allowed the CRO to allocate research funding according to performance. This incentivises directorates to improve their performance. Research funding is allocated transparently according to agreed principles which allow Research Leads and investigators to identify how research monies are spent.
- b. The key metrics which the NIHR CRN Coordinating Centre requires Trusts to report, have improved year on year, such that the Trust ranks within the top ten large Teaching Hospitals for research performance.
- c. Under the management of Dr Dipak Patel, the CRO continues to support researchers whilst ensuring a framework for continuing good and efficient governance, responding to new regulatory requirements and ensuring the Trust is compliant with standards of MHRA, FDA and HTA.
- d. The Clinical Research Academy (CRA) has appointed 6 fellows over the last two years who are being supported by University of Sheffield School of Health and Related Research (SchARR) to develop and submit research proposals.
- e. The Trust Medical Physics Department with the CRO have further developed a research management IT system which facilitates the registration and management of new research proposals and enables the sharing of key data across the Trust, with external sponsors (including commercial) and other bodies.
- f. The Trust's commitment to involving patients and the public in research is illustrated by dedicated staff within the CRO who support a total of 15 patient panels that meet regularly to discuss and inform research proposals. This makes sure that our research is patient focussed, and that we continue to submit high quality grant applications for continued funding to conduct health research.
- g. CRO provides research training opportunities for patients, public and staff informally on a case by case basis, and by hosting regular events, online training and workshops to support staff and the public.

- h. The Trust can also reflect on a number of additional research successes in the last 3 years highlighting continued research excellence nationally. In the last 12 months:
- Professor Wendy Tindale led a successful application to the NIHR Medtech and *In vitro* diagnostic Co-operatives Competition (MIC) which renews the Trust's leadership in one of the national programmes of technology research (D4D).
 - Professor Chris Newman led a successful application for the renewal of the experimental component of the CRF.
 - Professor Sarah Danson led a successful application for renewal of the Experimental Medicine Cancer Centre (EMCC) from Cancer Research UK.
- i. A major achievement since publication of our previous research strategy was the recent award of a Biomedical Research Centre (BRC) in Neuroscience led by Professor Dame Pamela Shaw. The non-renewal of our previous two Biomedical Research Units (BRUs) in Cardiovascular Medicine and Metabolic Bone, had dominated the background to our previous research strategy. The next BRC competition is some 4 years away which provides the Trust and University opportunity to learn from the challenges of the previous BRU experience, grow additional areas and not only ensure successful renewal of the BRC but also to extending its reach into other areas.
- j. The Trust continues to receive funding through the NIHR Yorkshire and Humber Clinical Research Network (LCRN) (which it hosts) to support its 'portfolio' research. The proportion we receive is calculated by an activity based funding formula incorporating the number of eligible studies and their complexity together with the number of patients recruited (accruals). Whilst the Trust has successfully increased the number of studies and patients who are participating in clinical research year on year, the last 3 years has witnessed a decline in funding to STH received from the LCRN. This is because clinical research performance has declined across Yorkshire & Humber as a whole, and not kept pace with other LCRNs. This presents a challenge to the Trust's clinical research activity. The appointments of both a new Clinical Director and Chief Operating Officer, provide an opportunity for the Trust to work closely with the new management and to review alternative funding models which incentivise improved performance across Yorkshire & Humber and reflect the Trust's research activity.
- k. The Trust continues to receive additional funding (Research Capability Funding (RCF)) based on successful NIHR research applications, which we have used to build research capacity and support new initiatives (such as the Clinical Research Academy). Our recent success in obtaining NIHR awards may lead to an increase in RCF in future years (although the principles of RCF funding are currently being reviewed nationally). We will need to consider carefully how RCF is best used to meet our strategic objectives.
- l. The Trust already has in place a portfolio of a substantial and growing industry collaboration and is currently working with over 70 different companies. We are 1 of only 10 UK site alliances working with Parexel (an international Commercial Research Organisation) to increase commercial research activity and strengthen partnerships with international commercial companies. Outside of the normal delivery of commercially sponsored trials, STH provides a preferred service arrangement to build

partnerships with industry for example IRMER and ARSAC imaging review for Amgen studies. NIHR metrics demonstrate that we are improving both the volume and efficiency of our commercial studies. Our commercial income from these studies increased from £1.76M in FY15/16 to £2.24M in FY16/17; a 27% increase. Therefore, a key aim of our future strategy is to continue to expand our portfolio of commercially sponsored clinical trials.

- m. Over the last 3 years, we have also benefitted from financial support for research activities from Sheffield Hospital Charities. They have contributed to the Clinical Research Academy and last year, an additional donation allowed us to restart the small grant scheme which permitted both NHS and University clinical academics to use £15k grant awards to undertake pilot and feasibility studies and generate preliminary data for larger grant submissions. We have begun discussions with the Charity about increasing the level of funding as resources permit.

2.2 Innovation

Until recently, the Trust separated its research activities from those related to innovation; there is currently no formalised entry mechanism for industry enquiries and opportunities for collaboration, other than through commercial clinical trials and some pockets of collaborations such as with Devices for Dignity (D4D) and Medipex. Existing industry partnerships are often established through individual clinician connections and the governance arrangements are *ad hoc*. In addition, our partner organisations such as the University of Sheffield, have always integrated their research and innovation activities. To manage and encourage successful innovation within the Trust and ensure corporate awareness of the organisation's activities and capabilities in this area, a considered infrastructure and strategy is crucial.

The importance of combining these activities was recognised by the creation of a Research, Innovation and Education Committee in 2015 involving key members of the Trust and both Universities, which meets quarterly, chaired by Sir Andrew Cash and reports to the Trust Board. Its role is primarily strategic and it has overseen the development of R & D as outlined above and has recognised the need to integrate research and innovation.

The need to extend the responsibilities of the Clinical Research Office to include both research and innovation activities has become urgent in the light of a number of local, regional and national initiatives in which the Trust is already making significant contributions. These activities involve both research and innovation and if the Trust is to play a significant role in these, these activities need to be combined.

In September 2017, Professor Wendy Tindale was appointed as Innovation Director to lead this work within the Clinical Research Office, which will extend its remit and is now known as the Clinical Research and Innovation Office (CRIO). Professor Tindale will lead the development of the Trust Innovation Strategy which thereafter will be incorporated with this Research Strategy into a single strategic document.

3. Future strategy & initiatives

In this document we have highlighted research and innovation initiatives and our intended approach, dividing them into local, regional and national.

3.1 Local

- a. At the start of the 2015, the Trust and the Faculty of Medicine, Dentistry and Health created a Clinical Research Office (CRO) to provide a unified service for the stimulation, involvement, support, training, governance and costing of clinical and applied health research across the two organisations. It was set-up to support the research strategies of both organisations and specifically, clinical researchers in the drive for research excellence.
- b. We believe the creation of the CRIO is central to the improvement in STH's research performance. We will ensure that the CRIO continues to support investigators to prepare competitive grant applications, recruit patients into trials, meet the NIHR 70 day target for first patient recruited and recruitment to time and target metrics.
- c. We will build our research relationship with Sheffield Hallam University (SHU). Sheffield Hallam is already heavily involved in the National Centre for Sport and Exercise Science (a joint project between the Trust, University of Sheffield and Sheffield Hallam), but offers opportunities in other important specialist areas and in the academic development of our workforce. The Trust, working with its academic partners, will offer opportunities for nurses, midwives, allied health professionals, scientists and technicians to engage in research and innovation at all levels. Sheffield Hallam University is a significant partner in training pre-registration and post-registration AHPs and has entered a formal collaborative initiative with STH to pursue joint research opportunities and capacity development supported by a joint Research Development Officer.
- d. The Trust has been working with the Faculties of Engineering and Medicine, Dentistry and Health in the University of Sheffield in supporting the Institute of Insilico Medicine, INSIGNEO. INSIGNEO recently updated its strategy and we will be looking to develop approaches which can increase involvement from Trust researchers in working with bioengineers, mathematicians and computer scientists in addressing clinical problems and developing research proposals.
- e. The Trust has closely aligned its biomedical research strategy with that of the University of Sheffield and this is seen most clearly with the joint work on the BRC, CRF and ECMC applications. The University also continues to give crucial support to STH through ScHARR in the joint work supporting the Clinical Research Academy. The University Clinical Trials Research Unit has been instrumental in the Trust's successful 3 NIHR programme grant awards and two major HTA clinical trials. Looking forward, we will be working with the University to develop a strategy aimed at extending the BRC when the renewal application is made. We have also begun discussions with the Director of INSIGNEO to build more joint projects. While we wait to see how NIHR intends to reconfigure Collaboration for Leadership in Applied Health Research and Care (CLAHRCs) before renewal applications are invited, we intend to start discussions as to how the Trust can work most effectively to ensure that this area of research remains part of our portfolio.

- f. The Trust recently secured NIHR renewal funding to support the Experimental Medicine work of the CRF for a further 5 years. While the successful application reflects the excellent work of the CRF management under the leadership of Professor Chris Newman, the amount awarded (approx. £3.1M), was the same as our previous award. The award of a flat level of funding despite inflation and increased demand, presents a major challenge to the Trust, particularly in the light of reduced funding from the LCRN and our long term aim of ensuring that eventually all clinical trials and interventional trials within the Trust are conducted under the auspices of the CRF. STH has also agreed to the transfer of management of the Cancer Clinical Trials Centre (CCTC) to the Trust from the University of Sheffield. The functions of the CCTC are in many ways comparable to those of the CRF and essentially provide the equivalent of the Weston Park CRF. There is one important exception since the experimental medicine facilities are delivered by the Cancer Research UK funded Experimental Medicine Centre. Nevertheless, the transfer of the CCTC gives the Trust an opportunity to review the management and financial structure of its research infrastructure.
- g. The CRIO, CRF and CCTC have largely operated independently; the accountability between the 3 components is unclear and for historical reasons, the staffing, financial and management processes have evolved separately. Furthermore, the existing financial arrangements between the Trust and University of Sheffield are different between all 3 components. At a time of financial stringency across our organisation, we therefore propose a major review of our research infrastructure to explore economies of scale, greater efficiency while maintaining outstanding research performance. This will include a major review of the memoranda of understanding which guide our financial arrangements with the University of Sheffield.

3.2 Regional

The Sheffield City Region has a range of organisations, which contribute to research and innovation in health and care. The Trust has a key role in contributing to increased collaboration across academia, the NHS and industry to maximise the benefits to the city and region. Current initiatives include:

- a. The NHS England Vanguard site, Working Together Partnership, an innovative partnership between seven hospital Trusts in the region of which the Trust is a key partner.
- b. Sheffield and Bassetlaw Accountable Care System (ACS) consisting of 15 Trusts committed to improving the health and wellbeing of the region. It includes a comprehensive and consultative analysis of the current and future needs of the region's population, identifying key challenges and opportunities for future innovation.
- c. The National Centre for Sport and Exercise Medicine (NCSEM) is a collaboration between universities, healthcare trusts, local authorities and private and voluntary sector organisations, bringing together research, education and clinical services. The NCSEM in Sheffield is focused on the design, implementation and evaluation of whole-system approaches to increasing physical activity across the population.

- d. Infrastructure hosted by the Trust including the Yorkshire and Humber Clinical Research Network (LCRN), and the NIHR Collaboration for Leadership in Applied Health Research and Care Yorkshire and Humber (CLAHRC).
- e. The Care 2050 initiative is perhaps the best example of the future collaborative process. It aims to provide a world-leading collaborative innovation environment in the region to identify, develop, test, champion and implement the technologies and systems that will deliver affordable and sustainable future health and social care. A Project Plan with clear milestones and governance arrangements has been developed with the overall objective of developing a programme of research and innovation that combines academic excellence with public and private sector health and care partners. Care 2050 will be developed incrementally, enabling it to build around funded projects and programmes, with universities, NHS organisations, other healthcare providers and relevant industrial partners all contributing. Incorporating innovation within the CRIO will ensure we can play a major role in responding to this and other activities. An example is its participation in the 'Perfect Patient Pathway' Test Bed, one of seven national Test Bed innovation centres in a major new drive to modernise how the NHS delivers care. It involves more than 30 partners including the University of Sheffield, the region's NHS, Social Care, Industry and Voluntary organisations.
- f. The Trust also works closely with other public and private sector organisations that contribute to this work in the region:
 - The Yorkshire and Humber Academic Health Science Network (AHSN) is one of 15 innovative health networks set up to create and harness a strong, purposeful partnership between patients, health services, industry, and academia. One of their roles is to facilitate the development and introduction of innovative products and services from their potential to transform lives to become part of routine clinical practice.
 - Medilink Yorkshire and Humber Ltd: the Yorkshire arm of a national initiative which is a membership based representative for health-tech companies.
 - Medipex Yorkshire and Humber Innovation Hub: An organisation with more than 10 years track record of supporting innovation in healthcare technologies.

3.3 National

- a. The UK Life Sciences Industrial Strategy, a report commissioned by the government and led by Sir John Bell was launched in August 2017 by the Secretary of State. The Trust has been closely involved in its development: Dr Peter Sneddon attended all LSIS Board meetings and Sir Andrew Cash made a written submission emphasising the commitment of the Trust Board to research and innovation and the importance of NIHR funding in building our research capacity.

Collaboration with the NHS is identified as one of the key elements of the strategy. Our strong science base, clinical trials infrastructure and expertise in digital technology provides a significant opportunity for the region to engage with and benefit from the Strategy. It proposes a Health Advanced Research Program (HARP) that:

- Charges the NHS and UK based industries to work together to create more efficient ways of delivering sustainable healthcare.

- Shares risk in developing tools and therapies using NHS infrastructure to run evaluative studies and share the benefit from proven technologies.
- Develops partnerships with med tech and diagnostics companies to reshape clinical pathways and improve efficiency.
- Collects real-world data via NHS innovation and assesses clinical and cost effectiveness.
- Modernises clinical trials including digitisation and regulatory innovation.

The Trust has the necessary capacity, infrastructure and expertise to build on our current research and innovation portfolio and our collaboration with industry. Not only are we already developing medical technology through D4D and other projects but we are the only organisation in the region that can both identify the clinical and patient needs and undertake robust research on technology evaluation.

We will engage with the implementation of the Life Sciences Industrial Strategy to ensure that the Trust and our regional partners influence its development and benefit from any opportunities that arise.

- b. The Trust has been an active member of the Northern Health Service Alliance (NHSA), a group consisting of 8 Universities in the North and the 8 major Teaching Trusts, since its inception. The NHSA was actively involved in the development of the UK Life Sciences Industrial Strategy and thus provides an additional way for the Trust to contribute. Potential approaches already being discussed include:
- Identifying regional strengths and supporting the development of life sciences clusters in the northern region.
 - Improving NHS collaboration with industry.
 - Using NHS Data - The NHSA's central project, Health North: Connected Health Cities (CHC), harnesses patient data to diagnose and treat patients quickly and deliver services more effectively and efficiently.

The NHSA is also working closely with Northern Powerhouse Partnership. Its recent report published in September 2017 has made a number of specific recommendations for health research and innovation research that include targeted investment, combining cities and regional capabilities and pan-regional investment recommendations including Connected Health Cities and clinical trials.

4. Research objectives

Reflecting on the rapidly changing research and innovation landscape as detailed above, we believe that a review of the relationship between the Trust and Universities is required. If the Sheffield region is to exploit successfully, the opportunities in both research and innovation, particularly at a time of financial stringency and uncertainty, then there is need to find better ways of working together which benefits both academic institutions, the Trust and the people of Sheffield. We therefore propose a major strategic review of current relationships and the development of a joint research and innovation strategy.

The specific objectives for the next 3 years are to:

- a. Continue to support and monitor Clinical Directorates to ensure that they increase research activity. The Academic Directorates model is deemed a success and we will continue to look to these directorates to lead the Trust in:
 - Meeting NIHR metrics.
 - Increasing research capacity and output.
 - Generating NIHR grant and other income to conduct research which is nationally leading and internationally competitive.
 - Academic Directorate status will be awarded (and maintained) by a process based on performance against agreed objectives and remains open to other Clinical Directorates ([Performance & Operating Framework](#)).
- b. Ensure that the Trust Research and Innovation Strategy is aligned to those of the University of Sheffield and Sheffield Hallam University. STH investigators need be able to access support both in areas identified as key themes by the Universities and to the cross-cutting platforms as they emerge. Equally, the Trust can provide clinical input and the testbed to evaluate both research and innovation. We will form task and finish group to develop a joint STH/Universities research strategy. This will require a wide-ranging review of existing relationships, including financial and the development of innovative solutions which will benefit all 3 organisations.
- c. Incentivise researchers by:
 - Incorporating time for research (i.e. PAs for doctors) as part of the annual job planning round allied to delivery of key targets within 2-3 years.
 - Maintaining and extending the Clinical Research Academy (CRA) competition, by providing time for research through the award of 'PAs'/clinical time awarded following open competition, including for the first time a 'ring-fenced' award for nurses and/or professions allied to medicine. The CRA Fellows in receipt of awards will use that time to work in SchARR or other University schools to develop research grants with input from the Sheffield Clinical Trials Research Unit and Yorkshire & Humber Research Design Service, with appropriate institutional support available.
 - Encouraging applications to the Health Education England (HEE) and National Institute for Health Research (NIHR) Integrated Clinical Academic (ICA) Programme. It provides personal research training awards for healthcare professionals (excluding doctors and dentists) who wish to develop careers that combine clinical research and research leadership with continued clinical practice and clinical development. Applicants must belong to one of the eligible professions.
- d. Institute regular meetings of a joint working group including members of the Trust and University of Sheffield to identify potential research areas which could be part of an extended BRC and plan the key steps to ensure these areas are competitive at the time of the next BRC competition.
- e. Encourage partnerships between Trust clinicians and bioengineers from the University of Sheffield, working in INSIGNEO, to develop research projects to solve clinical problems, particularly which utilise innovative technology.

- f. Ensure that all three components of our research infrastructure (CRIO, CRF and CCTC) meet the needs of researchers. We will reorganise our structures such that the Executives of both the CRF and CCTC report to CRIO Executive. Our performance reporting systems will extend to all 3 components of our infrastructure to ensure that these are working in a coordinated way to support researchers. These key activities will extend beyond the CRIO to both the CRF and CCTC.
- g. Develop research activity and maximise research income. Over the last 3 years the Trust has increased the number of patients participating in portfolio research by 47%. We aim to sustain this level of activity over the next 3 years. We will give equal priority to ensuring that the Trust reaches and meets its targets of ensuring that patients reach the two NIHR targets of first patient recruited within 70 days of site selected and recruiting patients to time and target.
- h. Despite having a comprehensive infrastructure of patient panels and training packages already in place, there are additional areas where we could do more to involve patients in all parts of the research process, and to involve individuals that are harder to reach. To address this we will:
- Involve patients/public in the development of a Trust Research Patient & Public Involvement (PPI) Strategy.
 - Adopt the principles of co-production in research involving patients in the development of research priorities and ideas, all the way through to study delivery and dissemination of findings.
 - Continue to grow our existing patient panel base, with CRIO staff offering bespoke advice to investigators involving patients/public in their research.
 - During the first 12 months we will:
 - Create a task and finish group with representatives from the Trust and both Universities to develop a joint research and innovation strategy.
 - Conduct a review of the 3 components of our research infrastructure and work with the senior management of both the CRF and CCTC to implement an overall structure and governance framework to ensure STH provides an efficient and financially viable service, ensuring excellent support for our researchers.
 - Extend the CRA to support aspiring researchers from disciplines other than doctors to develop their academic careers.
 - Work with the incoming Innovation Director, Professor Wendy Tindale to integrate innovation activities within the Clinical Research & Innovation Office.

Professor Simon Heller, Director of R&D