



St Helens and Knowsley
Teaching Hospitals
NHS Trust

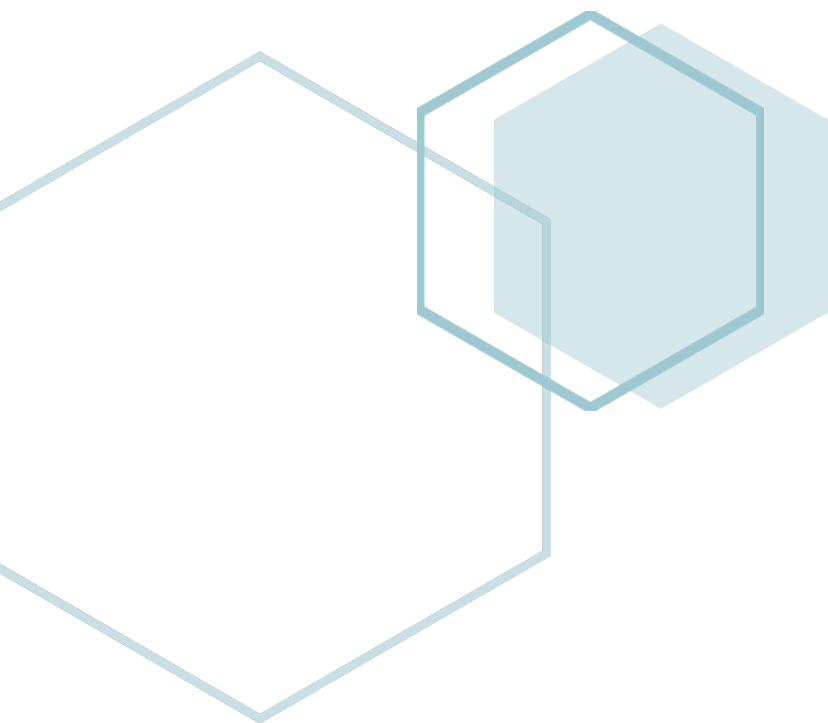


Research Development & Innovation Department

Annual Report 2022/2023

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FOREWORDS

The purpose of this Research, Development and Innovation (RDI) Annual Report is to present information to the Trust Board on the full year RDI activity for 2022/23. The report provides the evidence that St Helens and Knowsley Teaching Hospitals (STHK) maintains and develops their statutory duty to “Promote Research, Innovation and the use of research evidence (Health and Social Care Act, 2012)¹”. It provides an update on the key aspects of progress, performance and financial management. It also includes an overview of achievements in relation to research activity at STHK.

Clinical research is the single most important way in which we improve our healthcare – by identifying the best means to prevent, diagnose and treat conditions². The research conducted at STHK is critical to drive future medical advances, with patients benefitting from prevention of ill-health, earlier diagnosis, more effective treatments, and better outcomes and faster recovery.

As we move forward there are several important factors that will influence our direction of travel for research at STHK the planned merger with Southport and Ormskirk NHS trust, and the merging of Clinical Research Networks. Negotiations have been taking place throughout 2022/23 and we expect further details in 2023/24. These changes should be embraced and seen as an opportunity to grow and develop our services which will ultimately benefit our patients by offering them even more access to cutting edge research.

In February 2023, Lord James O’Shaughnessy was appointed to conduct an independent review into the UK commercial clinical trials landscape. The review will offer recommendations on how commercial clinical trials can help the life sciences sector unlock UK growth and investment opportunities. This will also advise on how to resolve key challenges in conducting commercial clinical trials in the UK. George Freeman, Minister for State at the new Department for Science, Innovation and Technology, said: “Commercial clinical trials are absolutely vital to both our UK life sciences sector and widening NHS patient access to innovative medicines all across the UK.”³ Therefore our vision at STHK will align with the review to allow the growth of our commercial portfolio.

In June 2022 the Department of Health (DOH) released phase 2 of the document: The Future of Clinical Research Delivery: 2022 to 2025 implementation plan. The plan summarises the progress that has been made so far and the actions that will be taken over the next 3 years⁴

The plan is centered around the 5 overarching themes identified in the vision:

1. A sustainable and supported research workforce to ensure that healthcare staff of all backgrounds and roles are given the right support to deliver clinical research as an essential part of care
2. Clinical research embedded in the NHS so that research is increasingly seen as an essential part of healthcare to generate evidence about effective diagnosis, treatment and prevention
3. People-centred research to make it easier for patients, service users and members of the public across the UK to access research and be involved in the design of research, and to have the opportunity to participate
4. Streamlined, efficient and innovative research so that the UK is seen as one of the best places in the world to conduct cutting-edge clinical research, driving innovation in healthcare
5. Research enabled by data and digital tools to ensure the best use of resources, leveraging the strength of UK health data assets to allow for more high-quality research to be delivered

Here at STHK clinical research is of strategic and reputational importance, and our aim is to align with the regional and national agendas to deliver evidence-based medicine. We also know that NHS organisations that participate in research have better performance outcomes, better patient outcomes and higher CQC ratings⁵. The Care Quality Commission (CQC) now requires NHS organisations to play an active part in research and innovation,

assessed through its well-led inspection framework. It recognises that research involves all departments, teams, staff and management functions across an organisation.

Dr Peter Williams, Medical Director

The Research Development & Innovation team have worked tirelessly during 2022/23 and continue to support a diverse range of studies as well as initiating new commercial research projects. As the team continues to grow, we will maximise the impact of our RDI activity by ensuring that we focus on priority areas for new research while expanding our portfolio. I would like to thank everyone involved in research at STHK for their continued support and dedication and ensuring that we offer as many of our patients as possible the opportunity to take part in research.

Dr Ascanio Tridente, Clinical Director of RDI

The year 2022/23 has been extremely successful for research at STHK. The Trust has seen an expansion in portfolio commercial and non-commercial research activity, with several outstanding results (one first recruit in Europe, one in UK, with the Trust being among the top recruiting sites in many studies, and also exceptional performance in the Patient Research Experience Survey). Such results would have not been possible without the hard work, dedication, and commitment of our extremely skilled and devoted workforce. I would like to highlight how important this is for the continued success of the RDI department and the Organisation as a whole, and I would like to thank all involved for their contribution and support.

Mrs. J Anders, RDI Manager

I would like to take this opportunity to express appreciation for the work of all those who have contributed to the Trust research agenda, our Principal Investigators, Research Nurses/Midwives, RDI staff, Nurse Support, and administrative staff, without whose commitment this report would not have been possible. At the heart of all the research undertaken at STHK is our desire to do better for our patients – to develop better understanding, better drugs, better ways of delivering care, better patient experience and better health outcomes.

Table of Contents

FOREWORDS	1
SECTION ONE: BACKGROUND	4
Table 1 - RDI Department Staff	6
SECTION TWO: OVERVIEW / SUMMARY OF RESEARCH ACTIVITY	7
Chart 1 - Trust Comparison	7
Chart 2 - Studies Open to Recruitment by Specialty (N101)	8
Chart 3 - Study Categories (N101)	8
Table 2 - Studies Sponsored by STHK	9
Chart 4 - Active Commercial Studies 2022/2023	10
Table 3 - Studies assessed for Capacity and Capability during 2022/23 at STHK (n30):	10
SECTION THREE: RESEARCH CONDUCT, GOVERNANCE AND FINANCE	12
SECTION FOUR: KEY ACHIEVEMENTS	15
Chart 5 - Participant in Research Experience Survey (PRES)	19
SECTION FIVE: EDUCATION AND TRAINING	20
SECTION SIX: LINKS WITH OTHER GROUPS / PARTNERS	22
SECTION SEVEN: INNOVATION AT STHK	22
SECTION EIGHT: CONCLUSIONS	23
SECTION NINE: RECOMMENDATIONS FOR 2022/2023	25
SECTION TEN: REFERENCES	26
APPENDIX 1 - List of Research Studies with recruitment 22/23	27
APPENDIX 2 - Terms of Reference – RDI Group	29
APPENDIX 3 - Staff Publications – 2022-2023	30

SECTION ONE: BACKGROUND

The UK government has stated its firm commitment to promote research throughout the NHS, which it sees as essential to continually improve effectiveness of health services and patient outcomes. Several current policy documents have placed a strong emphasis on research activity in the NHS:

- 1.1 As referred to earlier, The Future of UK Clinical Research Delivery report 2002 to 2025 implementation plan was updated in June 2022. The phase 2 plan is aligned with funding confirmed through the government spending review for April 2022 to March 2025 and includes up to £150 million of additional funding from the National Institute for Health and Care Research (NIHR) and £25 million additional funding from Recovery, Resilience and Growth (RRG) partners across the UK, complementing up to £200 million in England for the data for research and development programme announced in March 2022 and demonstrating the government's ongoing commitment to delivering on the UK's potential as a global life sciences superpower. This funding will enable RRG partners to:
 - Recover the UK's capacity to deliver research through Department of Health and Social Care (DHSC) and NHS England's Research Reset programme, and aligned work in the devolved administrations, aiming for 80% of all open studies on the NIHR Clinical Research Network (CRN) portfolio to be delivering to time and target by July 2023
 - Ensure we can recognise and support our expert workforce, and develop robust workforce plans, providing the basis for strategic investment in capacity development to support achievement of our vision in full
 - Broaden responsibility and accountability for research across the NHS, and improve measurement, visibility and recognition of those supporting the delivery of clinical research studies
 - Achieve a sector-wide sustained shift in how studies are designed and delivered so that inclusive, practicable and accessible research is delivered with and for the people with the greatest need and in ways that enable us to tackle the greatest challenges facing the NHS
 - Streamline processes, strengthen our regulatory environment and ensure faster approval, set-up and delivery of studies with more predictability and less variation, as well as make it easier to understand and access the UK's clinical research offer, thereby utilising the unique opportunity to develop a more flexible and improved regulatory model for clinical research outside the EU and improving our attractiveness as a leading destination to conduct cutting edge and global multi-centre clinical studies
 - Invest in the infrastructure and tools needed to implement people-centred, innovative data and digitally-enabled methods and increase partnership working across the health data ecosystem to ensure people across the whole of the UK can benefit from these approaches
- 1.2 The Government's budget review (2021) has also recognised the contribution research makes to improving health care outcomes and will invest the "largest ever cash uplift for health R&D" (over the next 5 years). This new funding, of which a minimum of £30m has been committed by the National Institute for Health Research (NIHR) between 2021 and 2026, is targeting infrastructure and capacity building and has a strategic focus on reducing health inequalities and patient-centred research. A large share of this investment will be in underserved areas, particularly in the north of England⁶.
- 1.3 In November 2022, NHS England invested £1.6 million to support integrated care systems (ICSs) and their project partners to increase diversity in research participation across their geographies. The funding will support the development of new or expansion of existing research networks that reach out to local stakeholders, especially the local voluntary, community and social enterprise (VCSE) sector, and engage communities in local research priorities⁷.

- 1.4 Health research plays an integral part in how the NHS develops services and continues to provide high quality healthcare for our population. However, National Institute for Health and Care Research (NIHR) data has revealed that UK geographies that experience high rates of disease also have the lowest number of patients taking part in research. The areas where there are the lowest levels of participation also align closely to areas where incomes are lowest, and indices of deprivation are highest. This means that research is often conducted with individuals who are healthier and wealthier and lacks representation from our diverse society.

Treatments need to meet the needs of all groups that make up our society. NHS England has committed to increasing participation in the research it conducts, focusing great effort into engaging those groups and communities who have historically had lower levels of participation, to ensure the needs of all are reflected in the way the NHS develops its services and treatments.

NHS England published 'Increasing Diversity in Research Participation: A good practice guide for engaging with underrepresented groups', which involved six underrepresented communities between March and July 2022 and provides practical insights for researchers on how to engage more diverse participants in health research. More diverse participation will help ensure that the health service continues to serve and be available to all⁸.

- 1.5 The Health Research Authority (HRA) is one of a number of organisations that work together in the UK to regulate different aspects of health and social care research. Their vision is for high-quality health and social care research that improves people's health and wellbeing, and the core purpose is to protect and promote the interests of patients and the public in health and social care research. All research conducted at STHK must have HRA approval, Confirmation of Capacity and Capability (CCC) issued by the RDI Department, and where necessary, Research Ethics approval.

- 1.6 The National Institute for Health Research (NIHR) Clinical Research Network is made up of 15 Local Clinical Research Networks across England. These local Networks coordinate and support the delivery of high quality research taking place in the NHS and across the wider health and social care environment. The local Networks help to increase the opportunities for participants to take part in clinical research, ensure that studies are carried out efficiently, and support the Government's Strategy for UK Life Sciences by improving the environment for commercial contract clinical research. The Clinical Research Network receives funding from the Department of Health and Social Care (DHSC) which it uses to allocate funding to the local Networks. STHK is a member organisation of the Clinical Research Network North West Coast (CRN NWC). From April 2024, the current NIHR Clinical Research Network will be changing to become the NIHR Research Delivery Network. The NIHR Research Delivery Network (RDN) will continue to support the effective and efficient initiation and delivery of funded research across the health and care system in England for the benefit of patients, the health and care system and the economy, with a name that better reflects the scope and purpose of the network to support:

- Clinical trials and other well-designed health and social care research studies (including studies that are delivered outside of an NHS setting);
- Public health studies that require the recruitment of individuals within an NHS setting (i.e. acute, ambulance, mental health, community or primary care) or an episode of care which involves contact with the NHS.

The whole of England will be supported through 12 NIHR Regional Research Delivery Networks (RRDNs). These will work with the National Coordinating Centre to provide a joint RDN leadership function so that the NIHR RDN functions as a single organisation with a shared vision and purpose across England⁹.

- 1.7 The Innovation Agency, North West Coast Academic Health Science Network (AHSNs) is one of 15 AHSNs working together in the AHSN Network and is the innovation arm of the NHS. The AHSNs work

collaboratively, identifying and supporting the successful development of innovations in our local regional healthcare communities, and helping to spread these across our national Network. They support the discovery, development and deployment of innovative solutions through the North West Coast Innovation Pipeline.

- 1.8 The following tables display the research delivery staff funding arrangements during 2022/23.

Table 1 - RDI Department Staff

Funded by STHK		
Title	Area	WTE Funded
Data Manager	RDI	1.00
RDI Manager	RDI	1.00
RDI Co-ordinator	RDI	1.00
Research Nurse	Cross Specialty	1.00
Senior Research Nurse	Cross Specialty	0.80
Project Support Officer	Cross Specialty	0.25
Associate Research Practitioner	Cross Specialty	1.0

Funded by CRN		
Title	Area	WTE Funded
Senior Research Nurse	Cancer	0.8
Research Nurse	Cancer	1.00
Research Nurse	Rheumatology/Cross Specialty	1.00
Research Nurse	Paediatrics	0.60
Research Midwife	Maternity	0.60
Research Nurse	Cross Specialty	4.00
Research Nurse	Gastro	1.00
Data Manager	Cancer	1.50
Project Support Officer	Cross Specialty	1.35
Senior Research Nurse	Cross Specialty	0.20

- 1.9 In January 2022, the Trust employed a dedicated Commercial Research Nurse, for 12 months, to expand and increase the number of new commercial studies. The purpose of the post was to provide Leadership to the Research Nurses and Research Nurse Support staff and to improve the set-up, quality, and integration of commercial research at STHK. This has proved to be extremely successful and in December 2022 the post was made permanent. In addition, we have introduced a new role to our Research Team, the Associate Clinical Research Practitioner, which is an essential post that works alongside Principal Investigators, Research Nurses, and the wider Research Teams to assist in the delivery of high-quality research.
- 1.10 Commercial research is defined as research that is funded and sponsored by a commercial organisation. A study is defined as industry sponsored and funded if a commercial company has developed the study protocol and is fully funding the additional costs of hosting the trial within the NHS. STHK receives income from industry-sponsored research, this income covers all costs for the study as well as overheads and capacity building. At STHK the overheads are distributed in accordance with the Trust approved Income Distribution Plan. All research income is managed centrally within RDI, with support from the Finance Department, to ensure consistency, accountability and transparency of research income and expenditure. As part of the plan to grow research, in November 2022 a review of the Trust's RDI Income Distribution Plan

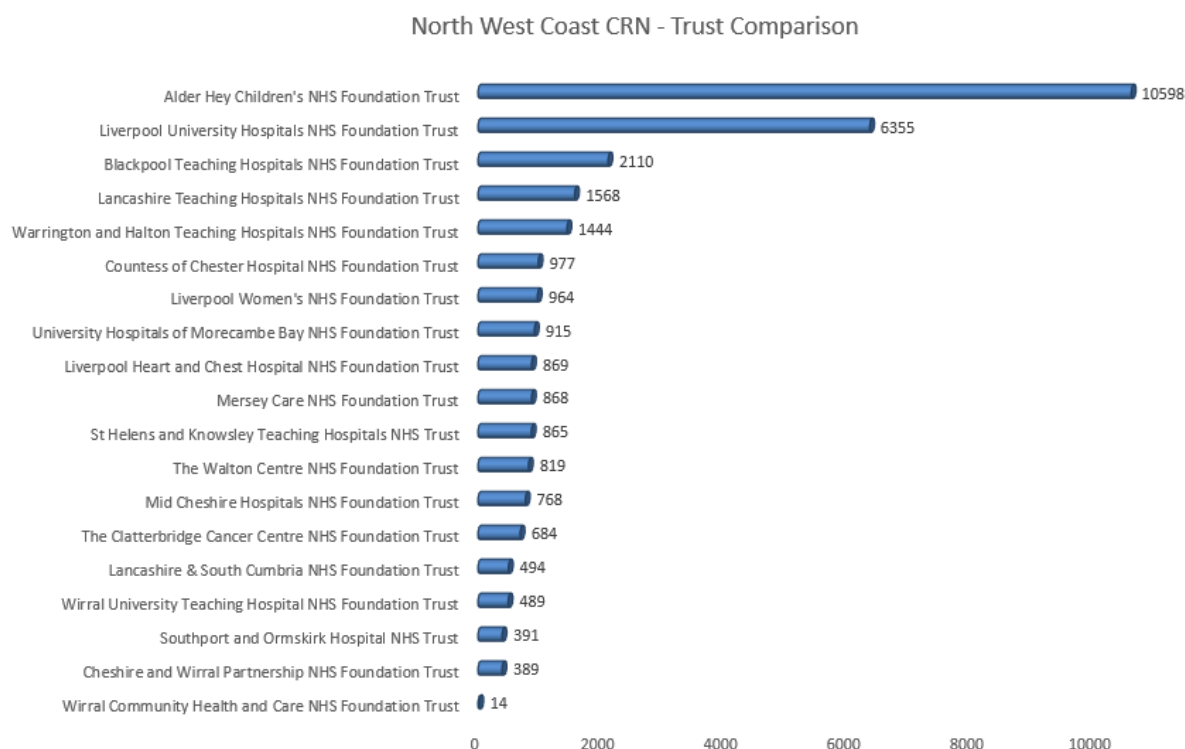
(IDP) was conducted. The IDP was updated to cover both commercial and non-commercial research and included guidance around the spending of funds after a study has closed. It states that any study funds not utilised within 12 months of the study closure or without a set plan for expenditure will be allocated to the RDI Department and reinvested in research. The IDP was produced to provide a transparent and consistent approach to the utilisation of income from research studies. The IDP was updated to allow and encourage the flow of research income to be reinvested back into research in a timely manner, thus enabling growth and expansion.

- 1.11 The RDI 3-year Strategy outlines our vision as a fully research active organisation. The strategy reflects the change in policies and the direction of travel with regards to Research and Innovation at STHK. The RDI Strategy document is due to be reviewed in 2023; however as the merger with Southport and Ormskirk Hospital Trust is pending, the decision was taken to update this once the transaction has completed.

SECTION TWO: OVERVIEW / SUMMARY OF RESEARCH ACTIVITY

- 2.1 STHK recruited a total of 865 participants against a target of 1000, which ranks STHK 11th out of 19 Trusts across the CRN NWC. Although the overall number is lower than last year (1308 in 2021/22) STHK increased the proportion of commercial studies in 2022/23 and therefore the number of patients who have been offered the opportunity to take part in commercially sponsored studies, which generally recruit lower numbers of patients due to the complexity of the condition and tend to be more resource intensive. Also, in 2021/22 STHK conducted the high recruiting COVID 19 study "ISARIC", which contributed 608 to the overall number of recruits (the last patient was recruited to this study in February 2022). As the aim is to increase the amount of commercial research, this may be reflected in a slight reduction in non-commercial research.

Chart 1 - Trust Comparison



2.2 The number of research studies open to recruitment at the Trust during 2022/23 was 101, compared to 99 in 2021/22, of which 15 were non-portfolio and 86 NIHR portfolio studies. Our studies range from observational to complex interventional studies; the following table demonstrates the types of studies conducted at STHK during 2022/23.

Chart 2 - Studies Open to Recruitment by Specialty (N101)

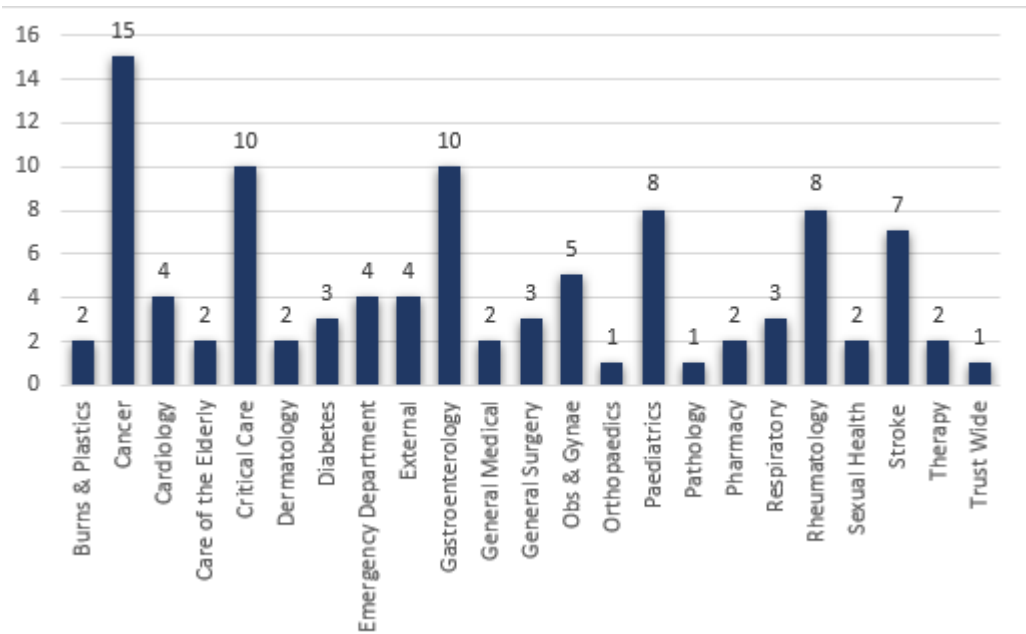
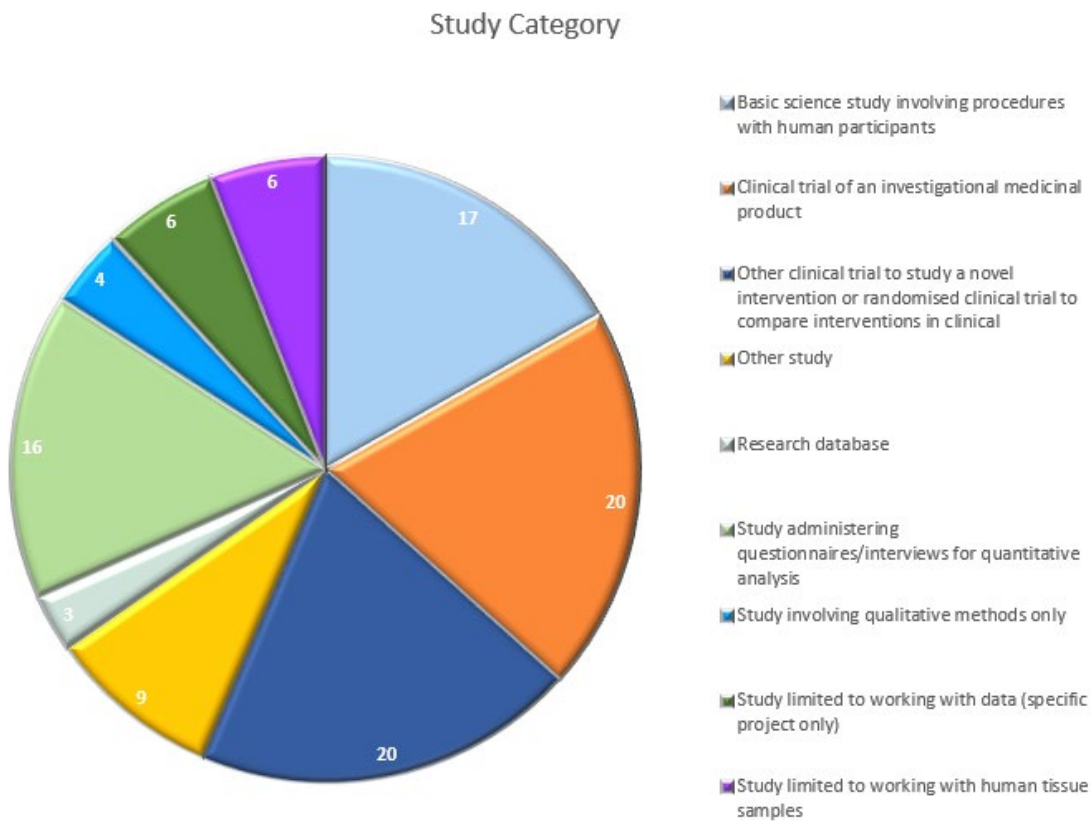


Chart 3 - Study Categories (N101)



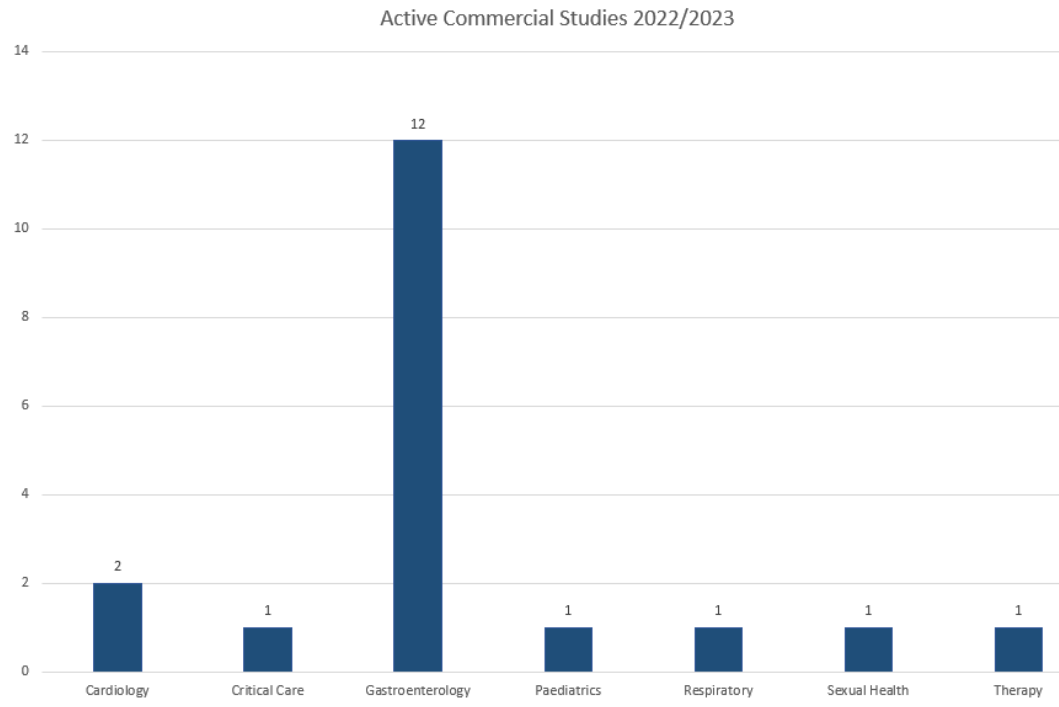
- 2.3 In some cases the Trust takes on the role of Sponsor. The Sponsor is the individual, company, institution or organisation that takes on the ultimate responsibility for the initiation, management (or arranging the initiation and management) and/or financing (or arranging the financing) for that research. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards, and that arrangements are in place to ensure appropriate conduct and reporting.

There was no change to the number of sponsored studies, there were 7 in both 2021/22 and 2022/23, none of these were CTIMPs (Clinical Trial of an Investigational Medicinal Product).

Table 2 - Studies Sponsored by STHK

Name	Type	Specialty
Clyz Cancertain - An observational study to assess the potential of the Clyz CanCertain™ Assay to predict patients' drug response from stage III/IV Lung Carcinoma biopsy samples in vitro	Single Centre Observational study, NIHR Portfolio adopted.	Cancer
Does early burn excision improve outcomes with patients with major burns	Single Centre	Burns
The multi morbidity socioeconomics on health service utilisation during and before the COVID 19 pandemic	Single Centre	Trust wide
Chronologically multi morbidity clustering and its effect on treatment burden - Effects on health service use	Single Centre	Trust wide
Chronologically multi morbidity clustering and its effect on treatment burden - Experiences of patients	Single Centre	Trust wide
The appropriateness of call to an on-call pharmacy service	Single Centre	Pharmacy
COVID-19 prognostic study on ICU	Single Centre	Critical Care

- 2.4 A key priority for the Department of Health is for the Trust and Research Networks to engage with Industry. During 2022/23 we had 19 active commercial studies, compared to 14 during 2021/22. It is recognised that there is a huge potential in the Trust to increase commercial activity, therefore our Clinical Director for Research reached out to highly reputable commercial companies to put STHK on the international and national map. The majority of these were Gastroenterology studies (n12), which demonstrates that the team have built up an excellent reputation and are recognised as a site that exceeds in this speciality.

Chart 4 - Active Commercial Studies 2022/2023

- 2.5 The Trust also leads or collaborates on a range of studies across the health care priorities for research identified by the Department of Health. A total of 30 new studies were assessed for capacity and capability (approval) in 2022/23. This is a decrease since the previous year, when 39 studies were reviewed.

Table 3 - Studies assessed for Capacity and Capability during 2022/23 at STHK (n30):

Specialty	No. of Studies	CTIMP	Commercial
Burns and Plastics	1		
Cancer Services	4		
Cardiology (Community)	1		
Critical Care	2	1	1
Dermatology	1		
Diabetes	1		
Emergency Dept	1		
External	1		
Gastroenterology	2	1	1
General Surgery	1		
Obs & Gynae	3		
Paediatrics	4	1	1
Pharmacy	2		
Respiratory	2	1	1
Rheumatology	1		
Stroke	2		
Therapy	1	1	1
Total:	30	5	5

- 2.6 The follow up of patients recruited to research studies can be very time consuming for Research Nurses and Nurse Support Admin Staff. This can impact on the resources allocated by the CRN NWC for recruitment to active studies. Follow up of patients includes scheduling research visits according to trial protocols, collecting data for the Case Report Forms (CRFs) and answering data queries. Follow up can range from weeks to years, and in some cases it can be for life. During 2022/23 we have had 74 studies in follow up. Responding to data queries can be time consuming and in some cases the Research Nurse may receive requests from Sponsors of studies that are closed to recruitment.
- 2.7 The NIHR Clinical Research Network (NIHR CRN) provides funding for service infrastructure, including pharmacy, pathology, and radiology services, to support clinical research in the NHS in England. We have a dedicated research pharmacist who supports the delivery of Clinical Trials of Investigational Medicinal Products (CTIMPs).

The Medicines and Healthcare Products Regulatory Agency (MHRA) is required under European law to inspect Clinical Trials of Investigational Medicinal Products (CTIMPs) conducted by both commercial and non-commercial organisations. GCP Inspectors assess compliance with all relevant legislation and guidance. In particular, the MHRA assesses whether organisations sponsoring and/or conducting CTIMPs have systems in place to meet the requirements of the Clinical Trials Regulations (this includes The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019). In order to address the pharmacy requirements of the MHRA a full suite of pharmacy Standard Operating Procedures are in place.

- 2.8 The Trauma Audit and Research Network (TARN) is a national quality accounts audit that collects and processes data on moderately and severely injured patients in England and Wales. STHK is a Trauma Receiving Unit (TU) within the Cheshire & Mersey Major Trauma Network (CMMTN) and submits data on all TARN-reportable patients to TARN. TARN reports and comparison data is used by the Trust and Network to allow for benchmarking and as a driver to facilitate local and regional audit and quality improvement initiatives to continue to improve quality of patient care for trauma patients.
- 2.9 ICNARC (Intensive Care National Research & Audit Centre) was set up in 1994 to provide a national resource for the monitoring and evaluation of intensive care (ICNARC, 1994). ICNARC manages a Case Mix Programme as follows:
- Case Mix Programme (CMP) is an audit of patient outcomes from adult, general critical care units (intensive care and combined intensive care/high dependency units) covering England, Wales and Northern Ireland. The CMP is listed in the Department of Health's 'Quality Accounts' as a recognised national audit by the National Advisory Group on Clinical Audit & Enquiries (NAGCAE) for 'Acute' care.
 - Currently 100% of adult, general critical care units participate in the CMP. Other specialist units, including neurosciences, cardiac and high dependency units, also participate.
 - ICNARC compares the data from these patients with the outcomes from other similar patients, other similar units and all the units in the CMP. Units receive a Quarterly Quality Report which identifies trends over time showing how the unit compares with others and helps us understand more about the care we deliver. It aims to assist in decision-making, resource allocation and local quality improvement.
 - With over 1.8 million patients in the database, the CMP provides the backbone for several important research studies and is a useful resource for many types of data analysis. ICNARC publish the CMP Annual Quality Report. This publicly available report compares the risk-adjusted mortality and key quality indicators at various levels (for critical care units, hospitals and trusts), for the period 1 April to 31 March annually.

SECTION THREE: RESEARCH CONDUCT, GOVERNANCE AND FINANCE

- 3.1 The Trust is committed to the promotion of good research practice, ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards. Research should be undertaken in accordance with commonly agreed standards of good practice. Good Clinical Practice (GCP) is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of humans. An understanding of GCP is a prerequisite for anyone carrying out, or involved in, clinical research and clinical trials. The RDI Department ensures that information and support is available to researchers, and that GCP training is made available to all staff involved in research. The RDI Department has a set of instructions which act as a guide to researchers and assists them in accessing and setting up NIHR online GCP training.
- 3.2 The RDI Manager is a GCP Facilitator, and delivers courses across the North West Coast. In 2022/23 she delivered a new course “Becoming a Principal Investigator”. The aim of the course was to introduce potential PI’S to the role and prepare them for their future duties as PI.
- 3.3 The 19 principles in the UK Policy Framework for Health and Social Care Research (2017) serve as a benchmark for the conduct of research. Adhering to these standards is a must and ensures the health and safety of research staff and participants.
- 3.4 The RDI Department has a suite of Standard Operating Procedures (SOPs). The SOPs cover all aspects of the set up and conduct of a research project. In 2022 the majority of these SOPs were reviewed and amended to reflect changes in the regulations.
- 3.5 In order to maintain the highest standards of rigour and integrity at all times, Principal Investigators are expected to sign an Investigator Declaration form prior to commencing any new research study. The declaration form very clearly outlines the Investigators’ responsibilities when undertaking research at STHK.
- 3.6 An audit of Compliance with Good Clinical Practice re Consent, Record Keeping and Storage of Documents was undertaken on n10 research studies and where possible any identified issues were immediately addressed. The consent forms and patient information leaflets were present in 100% of cases. However, there was slight reduction in the documentation of the consent-taking process, eligibility criteria and the use of the consent checklist. These were very slight decreases and do not raise major concerns.
- 3.7 It is good practice for the PI to be involved with, or at least be aware of all aspects of the research study, particularly regarding Clinical Trials of an Investigational Medicinal Product (CTIMP). The research Nurses meet regularly with the PI to complete a review, which is documented in a specific form, which demonstrates PI oversight of the study.
- 3.8 Anyone connected with research which involves NHS patients, samples, information, facilities, staff or services is expected to conduct research to the appropriate standards. This includes staff with letters of access, students and part-time staff, or those on short term attachments. The RDI Department works with Human Resources department to ensure that the correct employment checks are in place prior to issuing research approval.
- 3.9 The RDI Department is accountable through its Medical Director to the Trust Board sequentially through the Research Development and Innovation Group (RDIG), Clinical Effectiveness Committee and the Quality & Safety Committee. The RDIG meet quarterly; membership includes key local research stakeholders to ensure the Trust meets strategic objectives in relation to Research Development & Innovation. Members

are selected for their specific role or because they are a representative of a professional group/speciality/directorate or division.

- 3.10 The Research Development and Innovation Group promotes, oversees and fosters clinical Research Development and Innovation within St Helens & Knowsley Teaching Hospitals NHS Trust. The RDI Group meets quarterly and is chaired by Dr Ascanio Tridente, Clinical Director for Research. The RDI Group Terms of Reference were reviewed in November 2022 and included changes to the core membership and their authority to oversee the reinvestment (in research) of the commercial and non-commercial funding and the income distribution plan.
- 3.11 The Research Practitioner Group (RPG) at STHK meets twice a year and plays an important role in the delivery of good quality research at STHK. NIHR recruitment is a standing item on the agenda, and updates on performance are discussed and plans put in place to achieve compliance.
- 3.12 The NIHR Clinical Research Network is responsible for the provision of the NHS Support resources to enable studies to be conducted in the local NHS regions they are responsible for. Within many Trusts this funding covers a number of different areas as follows:
- Research Nurses - feasibility support, and to recruit and manage patients in research studies
 - Non clinical research support staff – administrative staff who assist with study feasibility along with record keeping and data collection as part of research studies
 - Service Support departments – Pharmacy, Radiology and Pathology (where this service is provided by organisations as an NHS support activity in the delivery of clinical research).
- 3.13 Core funding is allocated from the CRN NWC to support the RDI Department and Support Services. The total amount of core funding allocated to STHK in 2022/23 was £494860 with an additional £2917 for Dr Prakash Narayanan – CRN Speciality Lead for Metabolic and Endocrine. During 2022/23 STHK submitted 4 applications for non-recurrent additional funding to support Cost Pressures, Capital Funds (equipment), Strategic Funds (staff) and Contingency Funding. 2 of these were successful, and these accounted for an additional £25921. This resulted in an overall funding allocation of £523698. This is a decrease of £59254 compared to the funding allocated in 2021/22.
- 3.14 In 2022-2023 the CRN NWC funding model allocates 80% core funding to all partner organisations and the remaining 20% based on the following criteria:
- 10% Agile working - The overall aim of this approach is to develop a flexible workforce that utilises the skill and experience of research delivery staff to support regional health priorities as a collective and collaborative endeavour across the region.
 - 5% Collaboration – In essence to develop new research partnerships with other NWC organisations including primary care.
 - 5% Conducting studies in strategic disease areas (Cancer, Cardiovascular Disease, COPD and Mental Health).

This model is still subject to change and is being reviewed and discussed with all the CRN NWC partner organisations to determine the final model.

- 3.15 STHK also qualified for £20k Research Capability Funding (RCF), allocated by the Department of Health, for recruiting 500 or more participants to non-commercial research. This will be reinvested back into the department to help with capacity building.

We were notified in March 2023 by the NIHR Central Commissioning Facility (CCF) of a significant change to the RCF funding for 2023/ 2024. Previously organisations have been eligible for recruitment based RCF where they have recruited at least 500 participants to non-commercial studies conducted through the NIHR-Clinical Research Network during the previous reporting period of 1 October - 30 September. Improvements have been made to recruitment based RCF as follows:

- The eligibility target for RCF has been lowered from 500 participants recruited to 100 participants.
- NIHR funding and policies support equal prioritisation of commercial and non-commercial research in the NHS. Therefore, going forward, commercial recruitment will count towards organisations meeting the threshold of 100 participants.
- There has also been an increase in the recruitment-based allocation from £20k to £25k.
- There will be an additional payment for NHS organisations that achieve the target of 80% of commercial contract studies on the NIHR CRN portfolio delivering to time and target (the target for all portfolio studies by June 2023).

- 3.16 All Trusts were encouraged by the CRN to produce an Income Distribution Plan. This provides a transparent and consistent approach to the distribution of income from commercial research studies. Commercial research is defined as research that is sponsored and funded by commercial companies, usually pharmaceutical or device manufacturers, and is directed towards product licensing and commercial development. It is a key strategic goal within the Trust RDI Strategy to increase commercial research contracts. This will only be achieved if clinicians are supported to do this research and are incentivised to do so in the form of income generation for their teams and departments. The money generated from commercially-sponsored studies is a valuable source of income for NHS Trusts. This income can be used to encourage key stakeholders to develop capacity for new research within the Trust and increase the volume, and therefore future income generation.

The principles of commercial income distribution are:

- Departments and individuals are recognised for their contribution to commercial research within the Trust and are incentivised fairly
- All costs incurred by the Trust are fully recovered
- Commercial research continues to afford both investigators and the Trust the opportunity to fund additional research related activities.

- 3.17 The RDI Department also supports smaller studies, including individual research undertaken as part of higher qualifications, such as MSc or PhD. This involves guidance through the RDI approval process and ethics review, and the provision of advice and training. As part of their continuing professional development, many staff aim to progress through higher qualifications and/or research work.

SECTION FOUR: KEY ACHIEVEMENTS

The following are examples of how STHK continuously drives to improve the quality of service provided through research:

- 4.1 The past year has seen several exciting changes/additions to our Research Development and Innovation (RDI) Department. In July 2022 we welcomed Dr Peter Williams as the new Medical Director, and at the same time Dr Ascanio Tridente was appointed as our first ever Clinical Director of Research. Their aims for the RDI Department are to build upon and expand our existing clinical research strengths, and to attract, promote and deliver commercial research.
- 4.2 In July 2022, we opened two dedicated Research Clinics, this facility has allowed us to offer more patients a safe and friendly environment to take part in essential research. Participants are seen for screening, randomisation, study procedures and follow-up visits. Altogether, this enhances the patients research journey, ensuring that our participants have the best experience possible, and this is something that we are extremely passionate about.



- 4.3 The North West Coast Research and Innovation awards took place on the 23rd June 2022 at Edge Hill University. Hosted by the Innovation Agency, the NIHR Clinical Research Network North West Coast (CRN NWC) and Applied Research Collaboration North West Coast (ARC NWC), the awards were an opportunity to celebrate success and the excellent work being undertaken in health and care across the region during an unprecedented time. We are extremely proud to announce that the Liverpool School of Tropical Medicine Plus Partners (St Helens and Knowsley Teaching Hospitals Research Team) won the COVID 19 Research and Innovation award. STHK have continued to support the Liverpool School of Tropical Medicine by following up participants on the Oxford Vaccine Study. We are proud to have played our part in this important study as it has led the way in fighting the battle against COVID 19.



- 4.4 In 2022-2023 one of the main priorities for STHK was to increase the amount of commercial research. Dr Ascanio Tridente forged links with commercial companies which has led to an increase in the number commercial studies open to recruitment. The whole research team opened commercial studies swiftly and efficiently and received praise from the sponsors.
- 4.5 We were proud to announce that STHK recruited the first patient in Europe, and the first patient in the UK to the following commercial research studies:
- in January 2023, Dr Jennifer Marlow along with our Research Nurses, recruited the first patient in Europe (out of 34 sites) to the Connect 3 trial. The Connect 3 compares the use of a Digi haler Digital System in getting better control of asthma compared to usual treatment. This is an outstanding achievement and something we are extremely proud of.
 - In February 2023, Dr Ascanio Tridente recruited the first patient in the UK to the TILIA trial. The purpose of this international clinical study is to evaluate the effect of tozorakimab as an add-on to standard of care treatments in patients with viral lung infection requiring supplemental oxygen on the prevention of death or progression to IMV/ECMO.

The following feedback was received from the Sponsors of the TILIA study:

“I want to congratulate you on randomising your first TILIA patient – and the first patient in UK!
The whole TILIA team also wants to thank you for your commitment and preparedness to have potential patients selected”.

Both studies were supported by our outstanding Research Nurses and Support staff. This is a huge achievement for the research staff at STHK and puts us on the map both in the UK and Internationally as a site with an excellent reputation for setting up and delivering commercial research.

- 4.6 We worked especially hard to open the “Aymes Bowie study”. This study is being carried out to test whether a new high energy plant-based style oral nutritional supplement is acceptable to people who need extra help to meet their nutrition needs. Feedback from the sponsor was extremely positive:
- “Working with St Helens and Knowsley Teaching Hospitals NHS Trust has been a breath of fresh air. Since receiving the EOI form, everyone involved. The set-up time has easily been one of the fastest and seamless I have been involved with recently which has made it a pleasure and therefore a site we would approach to do further studies in the future”.
- 4.7 The Endonet study was opened in March 2023 and is looking to determine if the timing and order of breast surgery and hormone treatment affect the quality of life and the amount of surgery required in post-menopausal women with breast cancer. Again we received positive feedback from the sponsors:

“We’ve been really impressed with how quickly you’ve picked up screening and approached patients. We’re looking forward to working with you over the coming months.”

- 4.8 Throughout 2022/23 we have worked hard to open as many studies as possible and are proud to report that STHK were at some point throughout the year the top recruiters for a number of NIHR studies, ie the “Harmonie study”. This was an important commercial vaccine study of nirsevimab (versus no intervention) in preventing hospitalisations due to respiratory syncytial virus in infants.
- 4.9 In 2022/23 87% of research studies (closed to recruitment) met the Recruiting to Time and Target (RTT), compared to 85% in the previous year. RTT and recruiting the first patient to a trial within the specified time frame are priorities for the NIHR: We are expected to meet the following targets:
- First recruit - for Commercial studies, meet the target of 80 days from date site selected (receipt of Information Pack) to first patient recruited
 - First recruit - for Non -Commercial studies, meet the target of 62 days from date site selected (receipt of Information Pack) to first patient recruited
- 4.10 The Cancer Research team is the only Research Team to be Macmillan adopted. Macmillan adoption comes with many benefits, it allows our team to take advantage of learning and development events, networking events, grants for learning and development, free coaching services etc, This is an exceptional achievement and demonstrates our commitment to delivering the best support and treatment for our cancer patients.
- 4.11 Our Burns and Plastics team have successfully recruited to The ELABS Study, this is a study assessing Early Laser for Burn Scars. The team also submitted 23 presentations to the British Burn Association meeting, held in Bristol in early May 2022, and won 2 out of the 3 poster prizes.
- 4.12 The Stroke department have invested in research by funding their own Research Nurse (0.6WTE) who works on both NIHR portfolio and non-portfolio studies. This has led to an increase in the amount of stroke studies being conducted on the stroke unit. They have a diverse portfolio of studies with the aim of offering every stroke patient the opportunity to take part in research. The team have been praised for being the top recruiter to the Huawei study – “Evaluation of Huawei Smartwear for Detection of Atrial Fibrillation in a Post-Stroke Population” There has also been a rise in the amount of academic research being undertaken, including sub-studies of Huawei watch study.
- 4.13 Other areas across the Trust are research active and committed to conducting research, i.e. Intensive Care, Rheumatology, Diabetes, Cardiology, Sexual Health, Dermatology. Without the continued support of the doctors and nurses involved we would not be in the position to offer our patients the opportunity to take part in research. A full list of all the active studies being undertaken at STHK during 2022/23 can be found in Appendix 1.
- 4.14 We have continued to support the Liverpool School of Tropical Medicine by following up participants on the Oxford Vaccine Study; we have also supported recruitment to the Moderna Vaccine Study at the Halton Research Unit. These vaccines have helped to save lives and are the best way to protect people and prevent the emergence of new variant.
- 4.15 In February 2018 the Trust sponsored a non-portfolio study called VOCS. Dr Seamus Coyle a Consultant in Palliative Care, who worked at STHK but subsequently moved to Clatterbridge Cancer Centre, opened the study which included patients from STHK and Willowbrook Hospice. The study looked at predicting when a patient with advanced cancer is dying. There was no prognostic test available, and the study hypothesised that a dying process from cancer is associated with metabolic changes and specifically with changes in Volatile Organic Compounds (VOCs). The study concluded that there are potential biomarkers of dying in

lung cancer that could be used as a tool to provide additional prognostic information to inform expert clinician judgement and subsequent decision making. The study was published in the International Journal of Molecular Sciences¹¹. January 2022 Dr Coyle went on to secure £100K funding from the UoL Innovation fund to commission a Diagnostics R&D company to develop a hospital-based test. This is an incredible breakthrough, helping clinicians to support people and their families in their last few days of life.

- 4.16 The cancer portfolio at STHK has remained stable, with 14 cancer studies open to recruitment and 24 studies in follow up. There was an increase in the number of cancer patients recruited to research studies, from 99 in 2021/22 to 126 in 2022/23. This is an excellent achievement from the team that comprises of 1.8WTE Research Nurses and 1.5WTE Data Managers.

The following graph demonstrates the number of patients recruited to the various tumor groups:

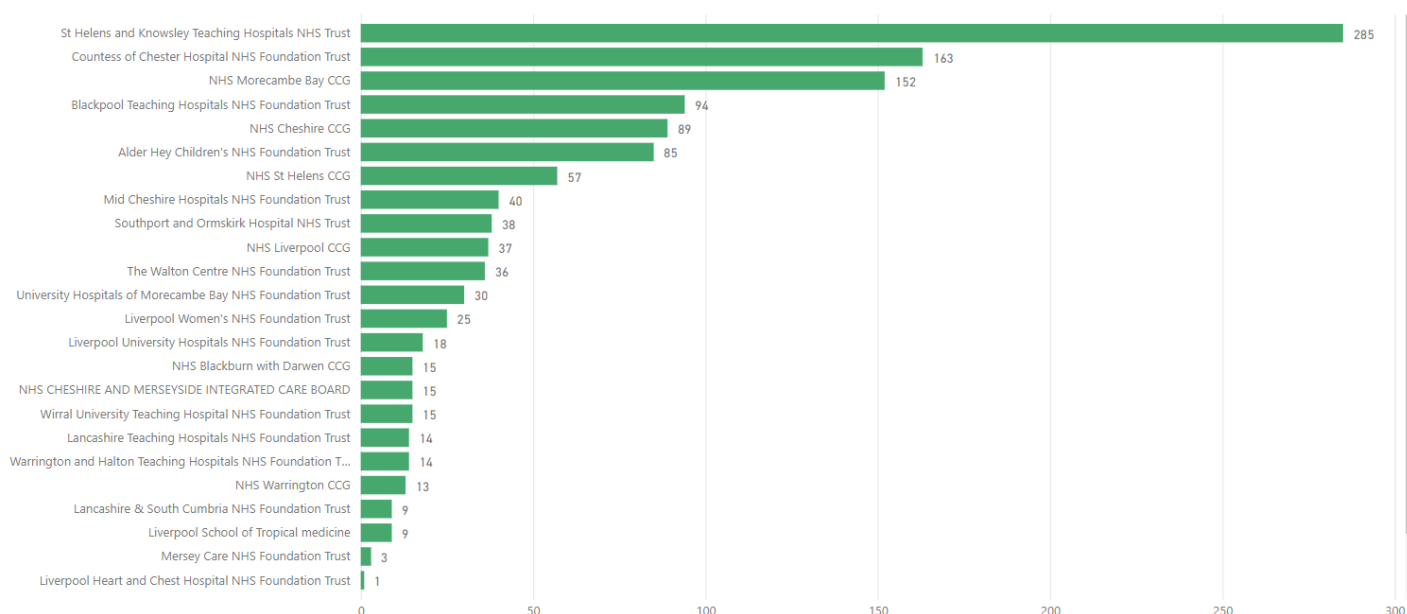
Tumor Group	No. of Recruits
Breast	21
Colorectal	1
Haematology	7
Lung	35
Skin	48
Urology	14
Total:	126

- 4.17 On the theme of collaboration, we have also forged links with the Primary Care sector and are still supporting two PhD students conducting research that cuts across Primary and Secondary Care; this research is exploring valuable questions that will help shape how we manage patients' treatment, journey and experience in the future.
- 4.18 We are extremely pleased that the CRN NWC successfully appointed Dr Prakash Narayanan, one of STHK Diabetes Consultants, as CRN Speciality Lead for Metabolic and Endocrine. This is a key role that works in partnership with the research network locally and nationally (UK) level, providing a forum to share good practice, successes, opportunities, and challenges, and helping influence and shape the clinical research environment.
- 4.19 Two of our research nurses are members of the Trust's Digitalisation Group. We are keen to ensure that our research staff are kept up to date with any new developments and have the opportunity to provide input that will result in more effective data sharing across the health and care system and digital transformation of care pathways.
- 4.20 The Participant in Research Experience Survey (PRES) is conducted annually by the National Institute for Health Research (NIHR) Clinical Research Network (CRN). The PRES is a priority for STHK as participant experience is at the heart of research delivery by providing an opportunity for as many research participants as possible to share their experience of taking part in research. In 2022/23 STHK received the most responses to the PRES across the North West Coast. In 2021/22 one recurring theme that emerged from the findings of the PRES was the uncertainty of clinic appointments, often moved at the last minute due to outpatient capacity and lack of dedicated research clinic space. In response the Trust Board supported a move towards a dedicated research space with 2 clinic rooms/treatment areas. The new unit, opened in

July 2022 and supported by the CRN NWC. The clinic room allows a number of participants to be seen at any one time for screening, randomisation, study visits and procedures and follow-up visits.

The Research Team introduced several methods for obtaining feedback and valued the patients' views on taking part in research, including face to face conversations, implementing QR code and sending out postal questions. Please see below how STHK compared to other sites across the region in obtaining patient feedback. Again, this is a significant achievement and shows our commitment to understanding more about patients' experience of clinical research. We are proud that there were no negative responses, and all the feedback was positive.

Chart 5 - Participant in Research Experience Survey (PRES)



Some examples of the responses include:

"All the staff involved were very positive, friendly, and professional. I really felt I was doing something worthwhile and useful"

"During the initial meeting, I had ample time to ask lots of questions and was never rushed. Answers were provided so that I truly understood. The care and the treatment I received and continue to receive is exceptional. For me personally the thoroughness of the care gave me confidence that I was being looked after and made me less anxious about my cancer diagnosis as I felt any further tumours would have been picked up".

" I am positive about being involved with the research, I have children and want to help them in the future and if this research helps then that's the positive for me".

4.21 In addition, the results from The National Cancer Patient Experience Survey (2021), published in July 2022, placed STHK in first position across all the Cheshire Merseyside Acute Trusts for discussing cancer research opportunities with our patients.

4.22 International Clinical Trials Day (iCTD) is an annual event that takes place on 20th May, where we raise awareness of clinical trials to encourage patients, carers and the public to get involved in research. We also celebrate our achievements and take time to be grateful for the improvements made to public health.

4.23 STHK have continued to promote Research and Innovation to staff and patients via:

- Social media, regularly posting good new stories on the STHK Facebook and Twitter
- Communications Team at both STHK and the CRN NWC
- Library Services
- Training and education

4.24 Staff publications (research and academic) have been recorded by the library and knowledge services at STHK, which shows our commitment to transparency, and our desire to improve patient outcomes and experience across the NHS.

These achievements have only been made possible by the continued support from all staff within the RDI Department, the committed Consultants, who take the role of Chief and Principal Investigators, Research Teams, support services and, most importantly, the patients, who give up their time to take part in clinical trials.

4.25 At the end of March 2023, we opened a large clinical trial in the maternity department “iGBS3” Development of a serocorrelate of protection against invasive Group B Streptococcus disease (the iGBS3 study). The iGBS3 trial is collecting comprehensive information about the amount of antibody that protects babies from GBS infection, so that the researchers can establish what the components of a GBS vaccine need to be to reduce GBS infection in babies. The Research midwife worked hard with staff from the maternity department to ensure the smooth opening and running of the trial. The trial is supported by all the research team at STHK, and by the end of March 117 recruits were recorded. This an exceptional achievement and demonstrates excellent collaboration between the maternity and research department.

SECTION FIVE: EDUCATION AND TRAINING

- 5.1 It is a legal requirement that all staff involved in clinical trials complete Good Clinical Practice (GCP) training, and the Trust has facilitated this for staff by signposting them to the online course. Commercial companies also regularly run refresher GCP courses for staff involved in the clinical trials.
- 5.2 The RDI Manager is a Good Clinical Practice Facilitator and facilitates these courses across the North West Coast Clinical Research Network. She has also delivered the NIHR Principal Investigator (PI) Essentials Course, which covers the understanding of the responsibilities of the PI role in research.
- 5.3 The NIHR offer career development opportunities, including training programmes and fellowships based in the NIHR research infrastructure. Training and career development awards are available at different levels and accessible by different professional backgrounds. These awards are all managed by the NIHR Trainees Coordinating Centre and comprise both personal awards, which can be applied for directly, and institutional awards, which should be applied for through the host institution. They also develop and support the people who conduct and contribute to the NIHR CRN Portfolio of studies. This is done by providing training opportunities via the NIHR Learning Management System, which includes a variety of online and taught courses. The RDI Department also signpost staff to these resources and participation.
- 5.4 In collaboration with Edge Hill University, Professor Rowan Pritchard-Jones is still supervising three PhD students. Two are PhD studentships whose work spans across primary and secondary care. The third is a clinical scientist, who is investigating “The Impact of the COVID-19 Pandemic in the UK on Breast Cancer Patients”. Dr Ascanio Trident is also supervising a PhD student from Manchester Metropolitan University

evaluating trends across multiple markers of inflammation and their influence on organ viability in the context of organ donation and transplantation. The NIHR Doctoral Fellowship is a three-year full-time award that supports individuals to undertake a PhD in an area of NIHR research; these fellowships have been designed to support individuals at various points of their development in becoming leading researchers. We also have Research Fellows based at STHK in Burns and Plastics and Cardiology.

- 5.5 The NIHR introduced an Associate Principal Investigator (PI) Scheme which aims to develop junior doctors, nurses and allied health professionals to become the PIs of the future and provides formal recognition of a trainee's engagement in NIHR portfolio research. The Trust is committed to developing future PIs, therefore we have engaged with this initiative.
- 5.6 We were pleased that in February 2023 one of our Dieticians, Catherine Gallagher was notified that she had been successful in her application for an NIHR Applied Research Collaboration NW Coast (ARC NWC) Research Internship.
- 5.7 The RDI dept supported Trahan Malhotra (Lead Specialist Maxillofacial Prosthetist) with a Pre-doctoral Clinical and Practitioner Academic Fellowship (PCAF) application, which offers nurses, midwives and other allied health professionals a fully funded fellowship during which they can gain the research skills and undertake preliminary work needed to apply for a funded PhD. Trahan was notified by Health Education England of the successful application in June 2022.
- 5.8 In October 2022 our Cancer Research Nurses attended a Regional Champions meeting for the ATNEC study, a randomised trial investigating whether armpit (axilla) treatment and associated side effects can be avoided in patients with no residual cancer in the lymph glands after chemotherapy). The meeting was very productive with topics including, identifying gaps, sharing best practice, and bridging the gap between Sponsor and hospital sites.
- 5.9 One of our Cancer Research Nurses also presented at the Annual Breast Protocol meeting. The meeting took place in June 2023 where all the cancer research studies were presented to the audience in an attempt to raise awareness of the studies and encourage research participation.
- 5.10 In May 2022 our Gastroenterology team were invited to attend an Irritable Bowel Disease (IBD) meeting and given the opportunity to talk about all the IBD research studies that are taking place at STHK.
- 5.11 Our Musculoskeletal (MSK) Research Nurse attended the CRN NWC MSK Community of Practice Meeting on the 18th October 2023 and the Rheumatology Research Meeting on the 19th October. The main focus of the presentations referred to strategies to enhance recruitment to current Rheumatology research studies. An overview of all the studies currently open to recruitment was also included.
- 5.12 Research Design Service - The NIHR Research Design Service provides a very good service in supporting staff in Research for Patient Benefit (RfPB) grant applications on a one-to-one basis. Interested members of staff are signposted to this service when required.
- 5.13 There was evidence that all staff had annual PDRs and appraisals, and evidence that staff had the opportunity to set objectives.
- 5.14 All of the RDI Department staff were issued with the research SOPs. They were asked to sign the training and reading log declaring that they had read and understood all of the SOPs.

- 5.15 RDI Department staff also attended various training sessions, seminars, to maintain knowledge and expertise in order to provide a good service, with appropriate advice and signposting to researchers, as well as ensuring quality data management and timely returns of performance data to the CRN, DOH and Trust Board as required.

SECTION SIX: LINKS WITH OTHER GROUPS / PARTNERS

- 6.1 The Trust has links with key external stakeholders such as the CRN NWC, who provide funding from the National Institute of Health Research (NIHR), the research arm of the Department of Health. Regular business planning meetings with the Delivery Managers enable us to scope the NIHR portfolio and identify any potential new studies.
- 6.2 We have strengthened links with the Primary Care sector, in particular Marshall Cross GP surgery that is based within St Helens Hospital. It is recognised that integrating primary and secondary healthcare has the potential to enhance communication, access to care and sharing of information, thus promoting health, and improving patient satisfaction and participation. We are working collaboratively with them and are supporting them with the management of the study and network finances as well as reviewing studies for capacity and capability. In primary care, funding and infrastructure are often insurmountable barriers to engaging in research¹⁰.
- 6.3 We have developed partnerships with other local academic organisations, including Manchester Metropolitan University (MMU). Our RDI Clinical Director, Dr Ascanio Tridente, has been working on various research projects with MMU, and is named as a co-applicant on a number of grant applications.
- 6.4 The Trust has links with LHP (Liverpool Health Partners). The LHP R&D Directors Group is attended by the Chair of STHK RDI.
- 6.5 The Trust is a partner in the Innovation Agency Northwest Coast Academic Health Science Network (NWC AHSN) which aims to:
- Transform and improve patient outcomes
 - Improve quality and productivity
 - Drive economic growth and wealth creation
- 6.6 Within the organisation, RDI is linked with the Quality Improvement and Clinical Audit Department as part of the Trust governance requirements.
- 6.7 The RDI Manager is a member of the CRN NWC Research and Development Managers' Group. The purposes of the meetings are to share best practice, provide peer to peer support and to keep up to date with current development in the R&D community.
- 6.8 The RDI Department now has links with Library and Knowledge Service and has a specific section on their website where staff can now access information about research services and resources. The Research Twitter account is now well established.

SECTION SEVEN: INNOVATION AT STHK

- 7.1 All members of staff are encouraged to solve clinical and service problems and to develop new ways of working which benefit patients and improve their care. Many innovations will not be patentable or copyrightable, but nevertheless have enormous potential benefits if successfully implemented. At STHK we are keen to provide staff with opportunities to pursue their ideas. Therefore, the Trust's RDI Department

has responsibility for disseminating information on Intellectual Property (IP) rights, promoting awareness of those rights across the Trust, and offering advice as required to ensure activities are managed appropriately. The IP policy sets out the rules of ownership, protection and exploitation of IP arising from an employee's work. It aims to maintain a balance between the legitimate needs of the Trust to protect its interests and the provision of a creative, innovative working environment. The IP policy was updated in early 2023 following a review by the Trust's external IP advisor.

- 7.2 We received several enquires that have required the services of our independent IP Advisor. However, none of these have yet gone onto the development stage.
- 7.3 UK Research and Innovation works in partnership with universities, research organisations, businesses, charities, and government to create the best possible environment for research and innovation to flourish. We are working collectively with universities to submit grant applications to enable individuals and groups to pursue world-class research and innovation.

SECTION EIGHT: CONCLUSIONS

- 8.1 In conclusion, there have been changes to the RDI Leadership structure, and we welcomed Dr Peter Williams, Medical Director, as our Research Development and Innovation Lead for the Trust, and Dr Ascanio Tridente as the Clinical Director for RDI.
- 8.2 Due to the success and achievements of the research department it was recognised that to expand and develop further addition research space would be required. Therefore, in July 2022 the new Research Hub was opened with 2 clinic rooms dedicated for research purposes. This has been a great success and has made us more attractive to commercial companies who visit the sites research facilities (site selection visit) prior to confirming if the Trust has been chosen to take part in the study.
- 8.3 There has been an increase in the number of commercial studies showing activity at STHK (this includes studies in follow up). We had 19 studies with activity in 2022/23 compared to 14 during 2021/22.
- 8.4 We are extremely proud of being the first Trust in Europe to recruit the first patient the Respiratory trial "Connect 3" and the first in the UK to recruit to the "TILIA" study.
- 8.5 There was a slight increase in the number of research studies open to recruitment at the Trust, 101 in 2022/23 compared to 99 in 2021/22.
- 8.6 Having a varied portfolio of studies is of vital importance to the development of better health and care for our patients at STHK. During 2022/2023 STHK were top recruiters in a number of specialties across the NWC CRN. This demonstrates our commitment and hard work to ensure our patients are offered the opportunity to take part in cutting edge research.
- 8.7 It is reassuring to know that 85% (86) of research studies taking place at STHK are high quality NIHR portfolio studies. These studies have been adopted onto the NIHR portfolio, have a clear value to the NHS and have undergone the rigorous protocol peer review required before they can be considered for NIHR CRN support.
- 8.8 The number of new studies registered and assessed for Capacity and Capability (C&C) decreased from n39 in 2021/22 to n30 in 2022/23. However, this should not be perceived as a negative as the increase in 2021/22 was extremely high at 85% due to the re-opening of studies following COVID. This would be difficult to repeat year on year.

- 8.9 There was no increase in the number of sponsored studies during 2022/23, 7 studies were sponsored by STHK.
- 8.10 This year we have engaged with the Dietetics team who supported the “Aymes Bowie” commercial study, this was a success and recruited to time and target.
- 8.11 The Stroke department have invested in research, which has yielded real benefits for both our patients and the department. They are fully on board with research and plan to grow even more in the future.
- 8.12 Partnerships with Edge Hill and Manchester Metropolitan Universities were strengthened during 2022/23 with Professor Rowan Pritchard Jones, Dr Ascanio Tridente and Professor Kayvan Shokrollahi supporting PhD students on various research projects. We have also supported two Research Fellows from Liverpool University who are working on stroke projects as part of their PhDs.
- 8.13 A major achievement was being ranked first on the CRN NWC dashboard for the number of responses to the Patient Research Experience Survey. Again, this shows our commitment to gaining important feedback that will allow us to improve our service and make taking part in research a positive experience
- 8.14 During 2022/23 STHK secured an additional £25,921.00 of on-recurrent strategic NIHR funding. However, the amount of NIHR funding decreased in 2022/23 and we received £59,254.00 less funding than the previous year. The funding from the NIHR CRN NWC doesn’t take into account the incremental pay rises or any cost-of-living rises, therefore the funding envelope doesn’t allow for growth. The solution to this is to increase the amount of commercial research that we conduct which will allow us to generate more income to reinvest back into the RDI department and promote growth.
- 8.15 The Trust’s Income Distribution Plan was updated and includes guidance on the spending of both non-commercial and commercial income within a specified time period or having a definitive spending plan in place.
- 8.16 The RDI Group Terms of Reference were also reviewed in November 2022 and included changes to the core membership. It was felt that it was important to have finance representation as the core membership of the group oversee the reinvestment of funds (in research) for both the commercial and non-commercial research. They also have input into the income distribution plan and any amendments to this have to be approved by the core members.
- 8.17 We also qualified for STHK also qualified for £20k Research Capability Funding, allocated by the Department of Health, for recruiting 500 or more participants to non-commercial research.
- 8.18 Negotiations through a series of workshops took place with the CRN NWC and its partner organisation to discuss a new funding model. The start of the transition will take place from April 2022 with full implementation by March 2024.
- 8.19 Regular business planning meetings have taken place with the CRN to discuss our performance and to identify new studies in the pipeline.
- 8.20 To ensure best practice most of the Research Standard Operating Procedures were reviewed and updated in 2022.

SECTION NINE: RECOMMENDATIONS FOR 2022/2023

Our aims for 2023-2024 are to:

- 9.1 Work towards a merger with Southport and Ormskirk NHS Hospital Trust (SOHT). It is expected that this will take place in July 2023. We aim to work together to reduce duplication, share good practice, and increase our ability to deliver more research opportunities to our patients. STHK have previously managed the research department at SOHT, under a service level agreement, and feel that the transition for the research departments will be smoother than with some other department within the organisation.
- 9.2 Update the Research Development and Innovation (RDI) Strategy. This will take place once the merger with SOHT has taken place. The strategy will set clear goals and objectives that will enable us to promote a culture where RDI drives better patient care and improves the Trust's capacity, capability and delivery of clinical research. This will include an ambitious vision to expand our existing facilities and staff.
- 9.3 Increase the number of commercially sponsored studies as these are a valuable source of support for NHS trusts. This income can be used to encourage key stakeholders to develop capacity for new research within the Trust and increase the volume, and, therefore, future income generation. In the long term we aim to increase the amount of Commercial Research conducted at STHK (50% of portfolio studies will be commercial – over the next 3-5 years). This is in line with Government mandate, and the recommendations from the independent review into UK clinical trials led by Lord O'Shaughnessy.
- 9.4 Work with the Integrated Care Systems (ICSs). In England, the Integrated Care Systems (ICSs) are partnerships between organisations to coordinate services and deliver healthcare in a way that improves population health and reduces inequalities between different groups within their region. Research and innovation should be considered as key contributors to this planning and coordination of services, ensuring equal access to research across an ICS footprint. In preparation for this we will update the Strategy in line with ICS and CRN NWC strategies.
- 9.5 Ensure that we have robust monitoring systems in place to facilitate our ability to meet our NIHR RTT obligations. The CD of Research and the RDI Manager will meet regularly (twice a year) with the research workforce to allow us to be responsive to the organisation and NIHR objectives. This will be in a supportive manner, allowing the staff to discuss any challenges, and an opportunity to look at how we can improve our service.
- 9.6 Continue to strive to qualify for £25K Department of Health Research Capability Funding (recruiting 100 or more participants to non-commercial research). This number has been reduced to 100 participants for 2023/24, the aim of this is to allow smaller organisations an opportunity to access funding.
- 9.7 Encourage engagement with the NIHR in accordance with the Department of Health strategic direction for Research, Development & Innovation.
- 9.8 Raise the clinical and academic profile of the Trust, by encouraging collaborations with other NHS organisations and Universities.
- 9.9 Develop our social media and website platforms to help promote research and reach out to people in an increasingly virtual world. In addition to this we will explore new ways of promoting and increasing engagement in Trust research.
- 9.10 Ensure that the NIHR PRES is embedded into patients' research journeys and that both positive and negative feedback is considered.

- 9.11 Ensure that research becomes a routine consideration by clinicians, so that any patient is offered the opportunity to participate and benefit from the research conducted at the Trust.

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7. Embedding Research in the NHS
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8. NHS England published 'Increasing Diversity in Research Participation'
<https://www.england.nhs.uk/aac/publication/increasing-diversity-in-research-participation/>
9. NIHR Regional Networks
<https://www.nihr.ac.uk/news/organisations-invited-to-host-the-nihr-regional-research-delivery-network/31445>
10. Understanding the Primary Care Research Landscape
<https://www.nhsconfed.org/publications/understanding-primary-care-research-landscape-directory>
11. Journal of Molecular Sciences
[IJMS | Free Full-Text | GC-MS Techniques Investigating Potential Biomarkers of Dying in the Last Weeks with Lung Cancer \(mdpi.com\)](https://www.mdpi.com/1422-0067/23/1/1)

APPENDIX 1 - List of Research Studies with recruitment 22/23

Short Title	Managing Specialty	Recruitment 22-23
Huawei Stroke Study	Stroke	143
iGBS3	Obs & Gynae	117
Molecular Genetics of Adverse Drug Reactions (MOLGEN)	Cancer	50
IBD Bioresource	Gastroenterology	49
UKIVAS	Rheumatology	41
UK-ROX	Critical Care	40
Melanoma Wide Excision Trial - MelMarT-II	Cancer	38
ORION-4	Diabetes	36
HARMONIE	Paediatrics	36
Toxicity from biologic therapy (BSRBR)	Rheumatology	31
IMID BioResource	Rheumatology	24
GCA Consortium	Rheumatology	23
CHOSEN	Stroke	21
SHED - Subarachnoid Haemorrhage in the Emergency Department	Emergency Department	19
ROSSINI 2 - Reduction Of Surgical Site Infection using several Novel Interventions	General Surgery	14
UK Genetic Prostate Cancer Study	Cancer	12
The ROSETA Pilot Trial	Cancer	11
IBD-BOOST: SURVEY	Gastroenterology	11
Hand-2: RCT of treatments for Dupuytren's contractures	Orthopaedics	11
NAFLD BioResource	Gastroenterology	10
SHOCC study	Cardiology	9
IBD-BOOST OPTIMISE	Gastroenterology	9
Early Laser for Burn Scars (EL4BS)	Burns & Plastics	8
GenOMICC	Critical Care	8
Febrile Infants - Diagnostic assessment and Outcome (FIDO)	Paediatrics	8
BSR-PsA	Rheumatology	8
Cardiovascular and Renal Treatment Implementation in Heart Failure	Cardiology	7
OPTIMAS Trial	Stroke	7
ATNEC	Cancer	4
GONDOMAR Version 1.0, Dated 18.05.2021	Gastroenterology	4
IBD-BOOST TRIAL	Gastroenterology	4
TTTS Registry	Obs & Gynae	4
Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) Trial	Stroke	4
Myeloma XIV (FITNEss)	Cancer	3
RADAR (UK-MRA Myeloma XV)	Cancer	3
The ANTHEM Feasibility Study	Cancer	3

Short Title	Managing Specialty	Recruitment 22-23
Evaluation of the Organ Donation	Critical Care	3
HYST	Dermatology	3
SINEPOST study	Paediatrics	3
Positive Voices - Development and validation of a national survey of people with HIV	Sexual Health	3
SEARCH - Visual scanning training for hemianopia	Stroke	3
PATHWAY Beacons	Cardiology	2
BLING III	Critical Care	2
SIGNET	Critical Care	2
Tozorakimab in patients hospitalized for pneumonia with hypoxemia at risk of respiratory failure	Critical Care	2
CONNECT 3	Respiratory	2
IVIS II - Impact of Visual Impairment after Stroke II	Stroke	2
Acceptability and Tolerance of AYMES Bowie	Therapy	2
PREPARE: imPROving End of life care Practice in stroke cARE.	Therapy	2
EndoNET	Cancer	1
Myeloma XII (ACCoRd trial) Version 1.0	Cancer	1
CAPYBARA Galapagos NV – GLPG0634	Gastroenterology	1
Fluids Exclusively Enteral from Day 1 (FEED1)	Paediatrics	1

APPENDIX 2 - Terms of Reference – RDI Group

Core Membership

No	Title	Named Deputy (if app)
1	Clinical Director of Research	Chair
2	RDI Manager (Vice Chair)	Vice Chair
3	Medical Director or Nominated Responsible Person	
4	Deputy Director of Finance	
5	Senior Research Nurse	
6	RDI Co-ordinator	

Non-core membership

No	Title
1	Research Pharmacist
2	Lay Member
3.	Cancer Services Manager
4	Education Facilitator
5.	Radiologist
6.	Management Accountant
7.	Stroke Consultant
8.	Anaesthetics Consultant
9.	General Surgery Consultant
10.	Obstetrics & Gynaecology Consultant
11.	Paediatrics Consultant
12.	Plastic Surgery Consultant
13.	Rheumatology Consultant
14.	Sexual Health Consultant
15.	Librarian
16.	Clinical Research Network – Northwest Coast
17.	R&D Manager – Merseycare

In addition to the above, the group shall be able to require the attendance of any staff as required (Co-opted).

Objectives

- Review and approval of the RDI strategy consistent and compliant with contemporary (inter)national guidance.
- Review and approval of the Annual RDI Report (written by the RDI Manager)
- Review and approval of the Research Capacity and Capability Statement
- Review and approval of the Research Standard Operating Procedures.
- Oversee operational delivery of the RDI strategy via updates received from the RDI Manager.
- Review of research studies. Any deemed high risk or with identified issues/concerns will be referred to RDIG for consideration (by the RDI Manager).
- Any risk or safety issues relating to research activity will be reported to the RDI Group for discussion and action Plan

APPENDIX 3 - Staff Publications – 2022-2023

Aarvold, A; Perry, DC; Mavrotas, J; Theologis, T; Katchburian, M. (2023). The management of developmental dysplasia of the hip in children aged under three months : a consensus study from the British Society for Children's Orthopaedic Surgery. <i>The Bone & Joint Journal</i> . 105-B(2), pp.209-214. [Online]. Available at: https://doi.org/10.1302/0301-620X.105B2.BJJ-2022-0893.R1 [Accessed 23 February 2023]
Adams, ST; Harrington M. (2022). Subspecialist abdominal wall reconstruction services in Canada. <i>Canadian Journal of Surgery</i> . 65 (2), E264-265
Adams, ST; Scott, M; West, C; Walsh, CJ. (2022). Separating the components of an abdominal wall fellowship. <i>Annals of the Royal College of Surgeons England</i> . epub 14 Nov(.), p... [Online]. Available at: https://doi.org/10.1308/rcsann.2022.0058 [Accessed 3 February 2023]
Agarwal, K; McCabe, J. (2022). P10-9 Correlation of Hounsfield units and stone volume with LASER time in stone surgery. <i>Journal of Clinical Urology</i> . 15(Suppl 1), pp.59-60
Ahmad, A; Hamed, Z; Vataha, K; Abdelaziz, M. (2022). 945 Usefulness of Skull X-Ray in diagnosis and management of craniosynostosis and suspected NAI in children less than 4 years, results of three years retrospective observational study. <i>Archives of Disease in Childhood</i> . 107(Suppl 2), pp.A465-A466. [Online]. Available at: https://adc.bmj.com/content/107/Suppl_2/A465 [Accessed 22 December 2022]
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Akgul, AK; Adali, E et al. (2022). Do preoperative leukocyte and neutrophil levels have a predictive value on the complications of hypospadias repair in children. <i>Archivio Italiano di Urologia e Andrologia</i> . 94(4), pp.459-463. [Online]. Available at: https://doi.org/10.4081/aiua.2022.4.459 [Accessed 21 February 2023]
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Alfred, J; Santoro, G; Beggs, R; Brookes, J; Rajaganeshan, R. (2022). P014 Video assisted anal fistula treatment (VAAFT): A 5 year review. <i>Colorectal Disease</i> . 24(Suppl 3), p.53. [Online]. Available at: https://onlinelibrary.wiley.com/doi/10.1111/codi.16276 [Accessed 6 January 2023]
Alobaida, M; Hill, A et al. (2022). Outcomes in patients with ischaemic stroke undergoing endovascular thrombectomy: Impact of atrial fibrillation. <i>Journal of Stroke and Cerebrovascular Diseases</i> . 32(2), 106917. [Online]. Available at: https://www.sciencedirect.com/science/article/pii/S1052305722006097 [Accessed 5 December 2022].

<p>Alobaida, M; Hill, A et al. (2023). Endovascular treatment for ischemic stroke patients with and without atrial fibrillation, and the effects of adjunctive pharmacotherapy: a narrative review. <i>Expert Opinion on Pharmacotherapy</i>. epub 1 Jan. [Online]. Available at: https://doi.org/10.1080/14656566.2022.2161362 [Accessed 20 February 2023]</p>
<p>Archer, N; Westall, SJ; Cardwell, J; McNulty, S; Furlong, N; Narayanan, RP; Bujawansa, S; Balafshan, T; Hardy, KJ. (2022). P124 Covid-19 pandemic associated with three-fold increase in demand for diabetes specialist advice. <i>Diabetic Medicine</i>. 39 (Suppl 1), 78</p>
<p>Baillie, S; Bassi, A et al. (2022). P0490 Opioid exposure in IBD and associated factors: a UK prospective multicentre audit of 1362 patients. <i>United European Gastroenterology Journal</i>. 10(Suppl 8), pp.788-789. [Online]. Available at: https://onlinelibrary.wiley.com/doi/10.1002/ueg2.12295 [Accessed 3 February 2023]</p>
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<p>Botzenhardt E; Clifford, R; Rajaganeshan, R. (2022). P066 Incisional hernia rate following laparoscopic anterior resection. Does extraction site matter?. <i>Colorectal Disease</i>. 24(Suppl 3), p.75. [Online]. Available at: https://onlinelibrary.wiley.com/doi/10.1111/codi.16276 [Accessed 6 January 2023]</p>
<p>Bruce, C; Lipscombe, S et al. (2022). The British Orthopaedic Surgery Surveillance study: Perthes' disease: the epidemiology and two-year outcomes from a prospective cohort in Great Britain. <i>The Bone & Joint Journal</i>. 104-B (4), 510-518</p>
<p>Cairns, JA; Lee, C; Pendlebury, H; Sullivan, H; Furlong, NJ. (2022). P181 Diabetes nurse specialist-led glucose balance telephone support clinic associated with improved HbA1c in insulin-treated patients with diabetic foot ulceration. <i>Diabetic Medicine</i>. 39 (Supp 1), p101</p>
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<p>Cappuyns, L; Gurusinghe, D; Bell, D; Shokrollahi, K. (2022). The Peroneus Brevis muscle flap for distal third tibia reconstruction in burns and trauma – a non-microsurgical and expeditious technique offering rapid wound healing of a complex wound. <i>Conference poster from British Burns Association Annual Meeting, 4th-6th May 2022.</i></p>

Cappuyns, L; Holme, H; McCrossan, S; Booth, S; Nicole Lee, Mandal, A; Gurusinghe, D; O'Boyle, C; Ralston, D; Anwar, M; Nugent, N; Dheansa, B; Shokrollahi, K. (2022). Developing a burn-specific peri-operative checklist: Version zero, a starting point. <i>Conference poster from British Burns Association Annual Meeting, 4th-6th May 2022.</i>
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Chit Su, HM; Putchakayala, K. (2022). A Mystery of Joint Pain: Is It Rheumatoid Arthritis (RA) or Hereditary Hemochromatosis (HH)? . <i>Cureus</i> . 14(12), p.e33037. [Online]. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9881094/ [Accessed 23 February 2023]
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