NHS
The Leeds
Teaching Hospitals
NHS Trust

Delivery against 2020-2025 Research and Innovation Strategy and the 2020-30 Joint Research Strategy with the University of Leeds

Public Board

28 March 2024

Presented for:	Assurance
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Previous Committees:	This progress report has been received annually by the Board to set out assurance against delivery of both the Trust and Joint Research Strategy with the University of Leeds. With the development and refocus of the new Research & Innovation Assurance Committee of the Board, this report was discussed in detail by the Committee.

Our Annual Commitments for 2023/24 are:	
Effectively develop and deploy new assets (buildings, equipment, IT)	✓
Reduce healthcare associated infections	
Improve staff retention	✓
Deliver the financial plan	✓
Reduce average length of stay by 0.5 days per patient	
Achieve the Access Targets for Patients	
Support a culture of research	✓

Risk Appetite Framework				
Level 1 Risk	(✓)	Level 2 Risks	(Risk Appetite Scale)	Impact
Clinical Risk	✓	Research, Innovation & Development Risk - We will deliver agreed minimum research and innovation priorities with health, social care, voluntary, education and private sectors	Open	Moving Towards
External Risk	✓	Partnership Working Risk - We will maintain well-established stakeholder	Open	Moving Towards

		partnerships which will mitigate the threats to the achievement of the organisation's strategic goals.		

Key points	
1. 20 of the Key Performance Indicators set out in the 2020-25 R&I strategy are currently on target to be met and three are classified as red.	Assurance
2. Recruitment to research remains strong with data showing we are ahead of trajectory for both the 2020-25 period and in 2023/24. Data shows that we are recruiting participants from a range of ethnicities and that the proportion of participants from a minority ethnic background aligns with census data for Leeds.	Assurance
3. Data shows that we are on target to exceed our income targets from all our income sources for both the 2020-25 period and in 2023/24.	Assurance
4. The proportion of live studies in the Trust that are meeting Recruitment to Time and Target metrics continues to increase and we are on target to meet our in-year target of 50% of all live NIHR portfolio studies at the Trust recruiting to time and target.	Assurance
5. 234 grant applications have been submitted to funders since April 2020 meaning we are on target to meet our performance target. Of the applications submitted in 2022/23 50% of those we have received outcomes for have been awarded.	Assurance

1. Summary

This paper sets out the performance to date against the key performance indicators (KPI's) set out on pages 23 and 24 of the 2020–25 Research and Innovation strategy. These KPI's set out the target performance that the strategy was to deliver by March 2025. These include metrics on recruitment performance, recruitment to time and target, financial performance and grant applications.

Of the 23 targets set out in the strategy, 20 are ranked as green (on target to be delivered or target already delivered) and three are classified as Red (off target with risk of KPI not being delivered by March 2025). The metrics that are off target are study setup, recruitment to time and target (RTT) and opening a new clinical research facility in the new Leeds Children's Hospital. Action plans are in place to improve our performance in study setup and recruitment to time and target and data presented shows a trajectory of improvement for both study setup and RTT from the actions that have been implemented.

The Board are asked to note that the COVID pandemic had a significant impact in years one and two of the strategy period and that this significantly delayed implementation of improvement workplans (particularly targeted at study setup) and negatively impacted our research portfolio. The impacts can be seen in the data presented.

The focal areas for the delivery of the joint strategy with the University of Leeds have been in Patient and Public Involvement and Engagement (PPIE) and Data. Information on how

those have been progressed are contained within the sections that describe the performance metrics.

During 24/25 the Trust will commence development of a new Strategy for the next five years which will be in alignment with the joint existing University of Leeds Strategy (2020-30). Development will be reported to the R&I Committee prior to seeking approval of the Board. This will also consider future reporting assurance of progress and oversight for assurance by the Board.

2. Performance against KPI's

2.1   100,000 participants involved in research programmes at LTHT   **GREEN**

80,381 participants have been recruited into research at LTHT to date from 1st April 2020 and up to 1st March 2024. Figure 1 shows the recruitment performance against target and shows that we are currently ahead of trajectory to achieve the target of 100,000 participants involved in research at LTHT. The impact of the COVID pandemic on recruitment between April and October 2020 can clearly be seen in the data. Of these participants 4,325 (5.4%) have been recruited into commercially sponsored trials.
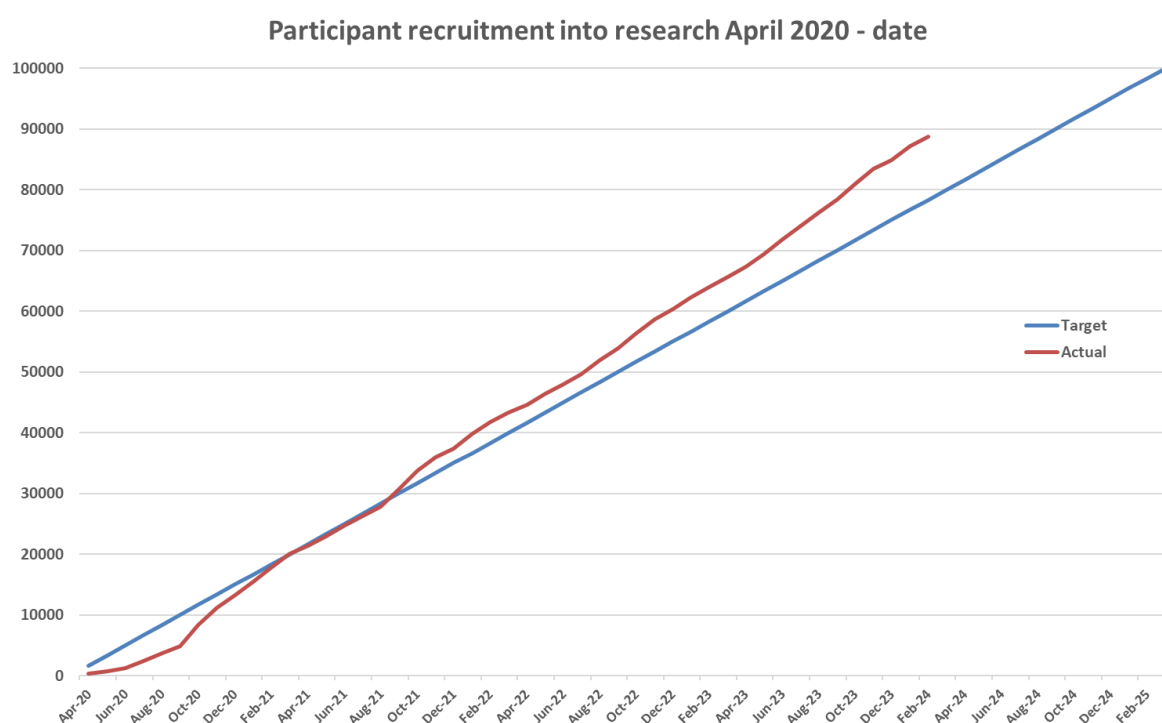

Figure 1: Participant Recruitment into research: April 2020 to February 2024

For the year 2023/24, data to the end of February 2024 shows that we have recruited 19,643 participants into NIHR portfolio studies (target 13,926) and 23,721 participants into research overall at LTHT (target 20,000), meaning we have exceeded our overall recruitment targets for the year. Of these, 783 recruits are into commercially sponsored studies. In addition, 19,740 individuals have been approached about their data being used in the Flatiron project with 790 (4%) declining to participate. Together this takes the total number of individuals participating in research at LTHT during 2023/24 to 38,983.

Our performance for recruitment into NIHR Portfolio studies vs our peers is illustrated in Figure 2, and shows that since April 2020, the Trust ranks second amongst peers for recruitment into research. When commercial research alone is considered, the Trust is leading amongst peers for recruitment into commercially sponsored research since April 2020.
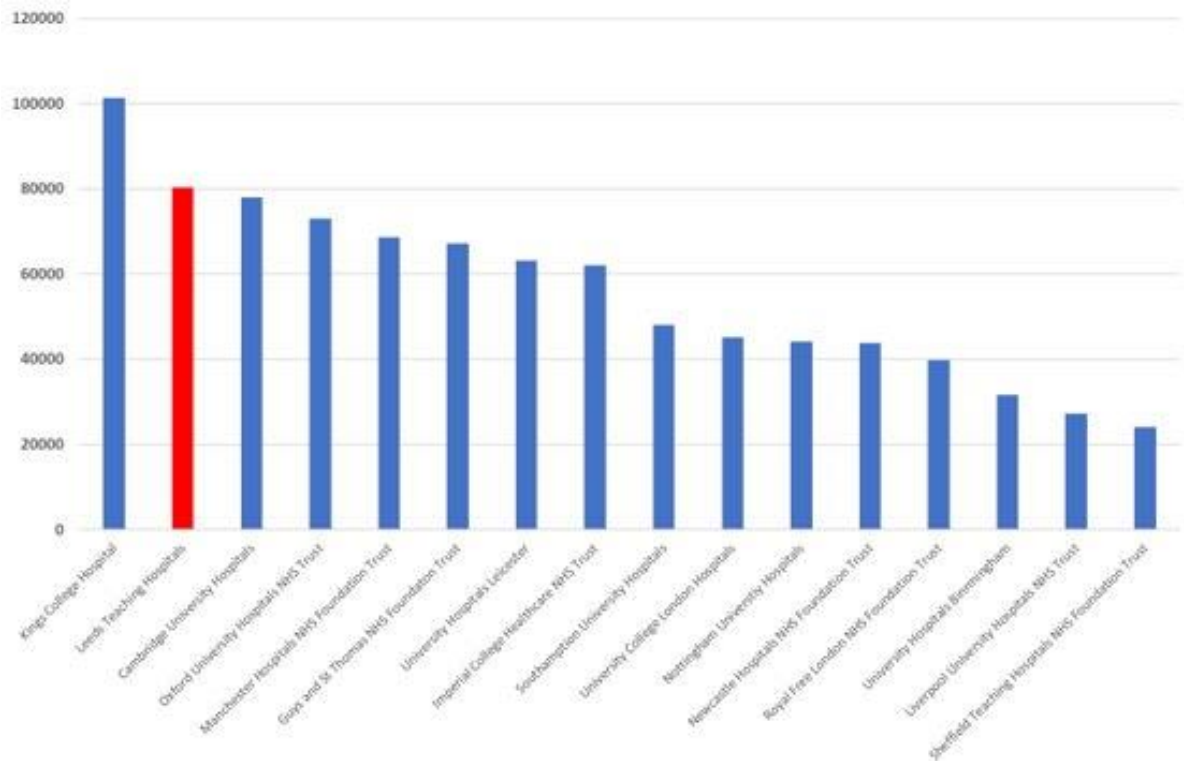

Figure 2: Recruitment into NIHR Portfolio studies (2020 – date)

An analysis of data held on ethnicity of research participants for 22/23 and 23/24 to date (figure 3) shows that we are recruiting into research from a range of ethnic backgrounds. Census data for Leeds states that 18% of the population of Leeds is from a minority ethnic background; in 23/24 19% of our research participants are from these populations.
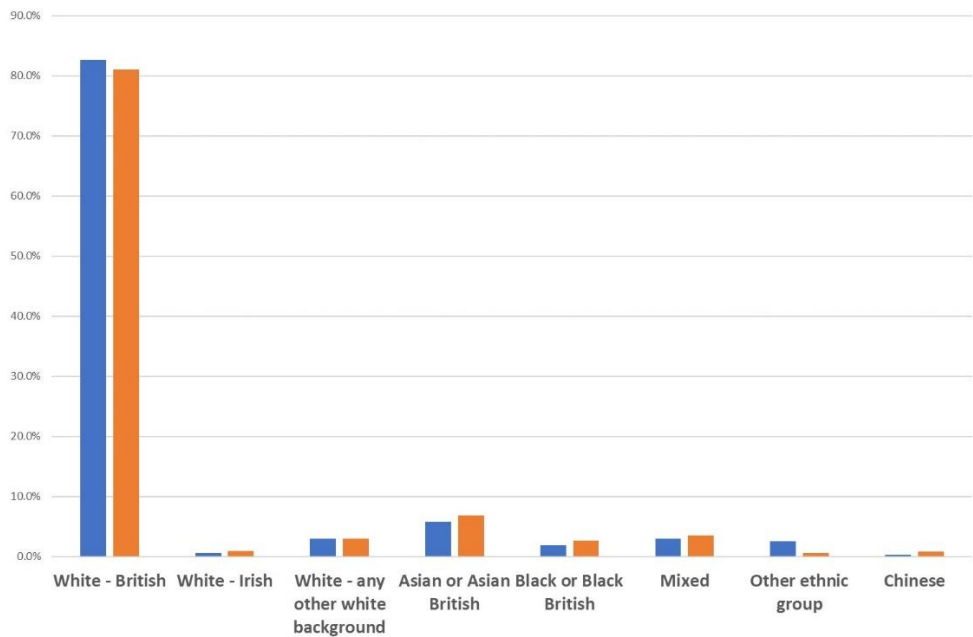

Figure 3: Research participants by ethnicity (sample size 15,531 participants)

Blue = Proportion of research participants
Orange = Proportion of Leeds population (source: Leeds Population 2024 (worldpopulationreview.com))

2.2   **Increase the number of live research and innovation projects at LTHT at any one time to 1,100**   **GREEN**

There are currently 1,353 projects live at LTHT according to data on 1st February 2024. Of these 765 are open to recruitment and 588 are in follow-up. Figure 4 shows the change over time and the impact that the COVID-19 pandemic had on the size of the research portfolio in 21/22.
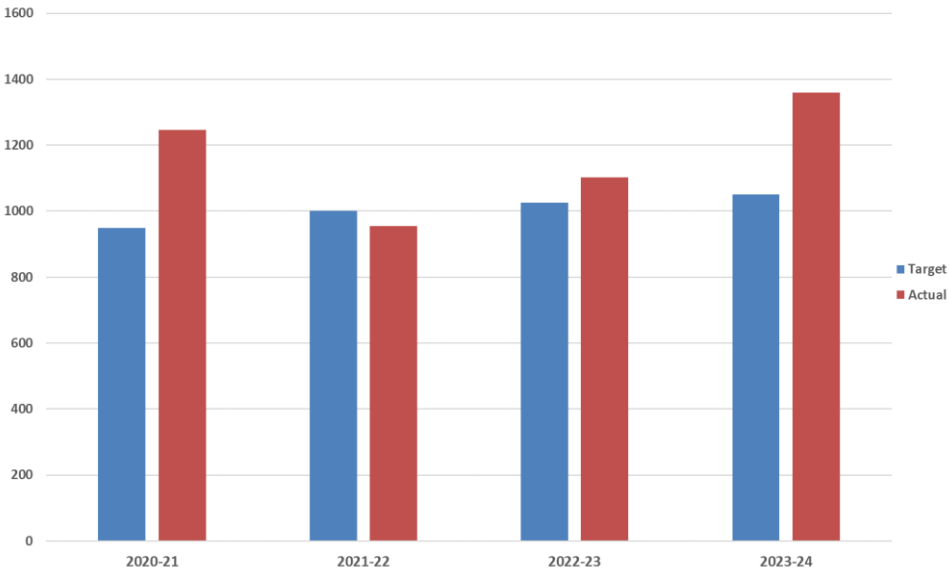

Figure 4: Number of research projects open at LTHT by year

2.3   **Secure £100m external funding to support research and innovation activities at LTHT**   **GREEN**

£108,317,127 has been invoiced for research and innovation activities at LTHT since 1st April 2020, exceeding the 5 year £100m target that was set in the strategy. This is broken down as follows:

- £66,698,088 research and infrastructure grants
- £18,856,146 industry funding
- £22,762,892 NIHR Yorkshire and Humber Clinical Research Network

Figure 5 shows the totals invoiced by year against the in-year targets set and figure 6 shows the trends of income secured for each of the different income sources over time. The board are asked to note the increase in commercial income over time and the decrease in financial support received from the Yorkshire and Humber Clinical Research Network.
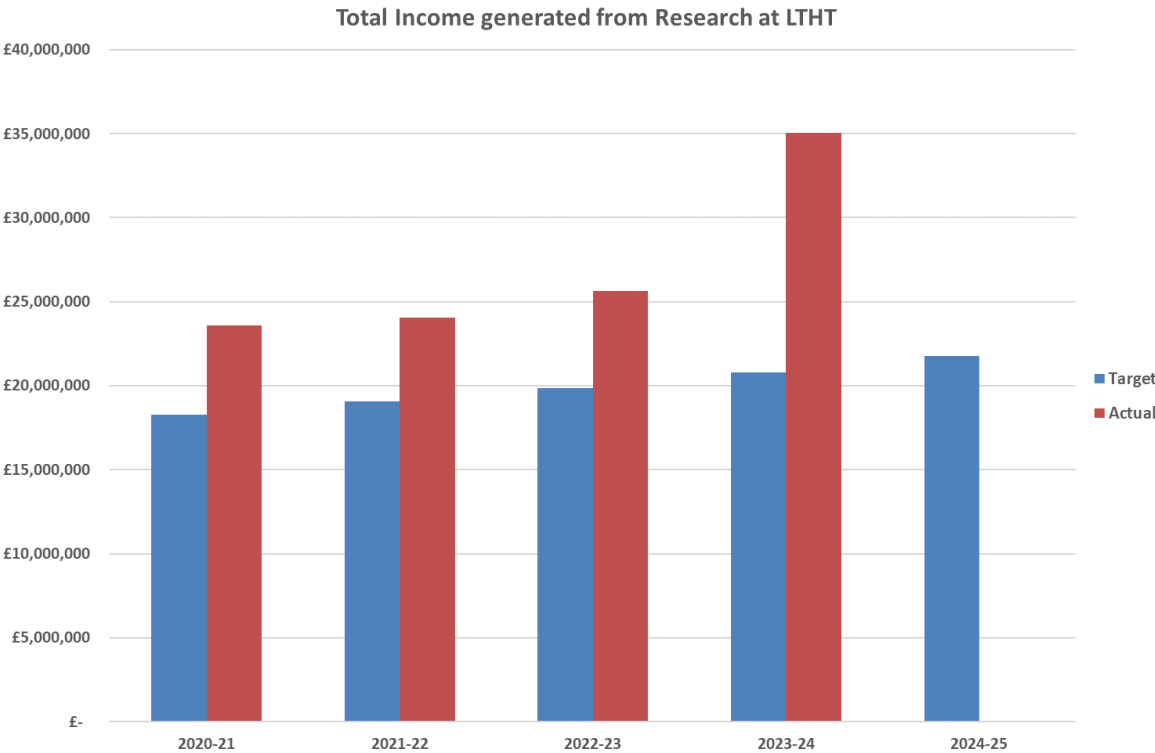
Total Income generated from Research at LTHT

Figure 5: Total income generated from research at LTHT vs in-year targets to date

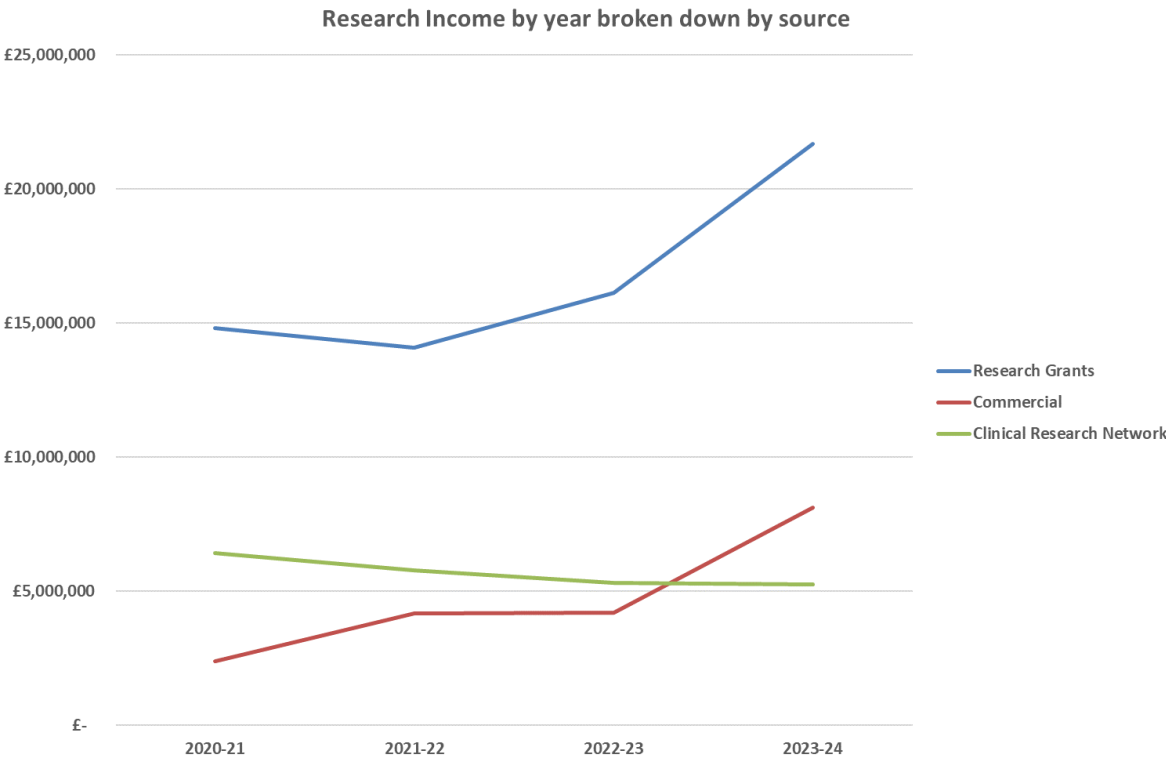**Research Income by year broken down by source**

Figure 6: Research income by year by income source

2.4 **Reduce the median time to local confirmation of capacity and capability to 10 working days**

Performance against this KPI is significantly behind target with median time from date site selected to local confirmation of capacity and capability for the 243 studies approved to date in 23/24 currently standing at 98 days. The data in figure 7 shows our performance since 2021/22 and shows that whilst we are still not at the desired performance level, the trajectory is one of improvement.
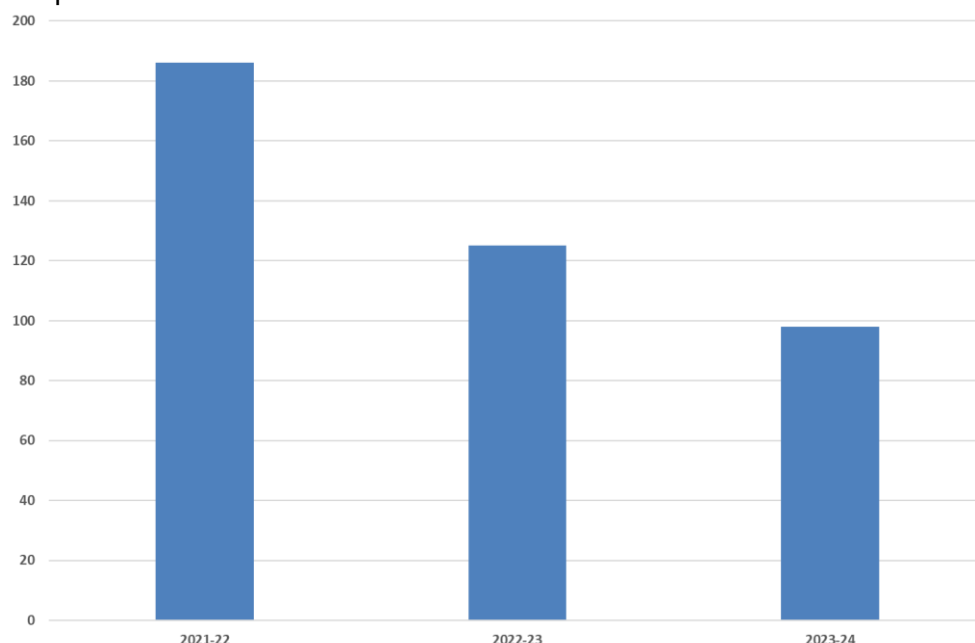

Figure 7: Time to local confirmation of capacity and capability at LTHT (days)*.*

Whilst 938 research studies have been opened to date at LTHT since April 2020, progress in delivering against this KPI was significantly impacted by the COVID-19 pandemic as setup of all non-COVID studies was paused for seven months to allow resource to be freed up to prioritise opening COVID studies, and planned work to look at how the processes could be improved was delayed. This pause created a significant backlog of studies in the setup process.

A project was carried out in 22/23 to help understand the issues better and action plans have been supporting steady improvements in setup performance, reducing the number of studies in set up from 220 (22/23) to 131 at time of writing, a 37% decrease. Still, this KPI remains RAG rated red, with a current median time of 98 days (a reduction of 48% compared with 2021/22 performance) for the 243 studies approved in 23/24.

The R&I 2020-2025 strategy KPI to reduce the median time to local CCC to 10 working days was an ambitious target developed in 2019 based on the best documented performance from other NHS Trusts. However, since setting this target it has become clear that the way Trusts define their set-up timelines varies and so the ten day target is not based on a "like" process. Current LTHT processes mean that a study is classed as being "in set-up" as soon as LTHT is site selected, even though the study's feasibility for delivery may not have been thoroughly assessed, which leads to delays in starting the actual set-up process.

We are therefore working to redefine this KPI, using our setup performance in 2020/21 as a baseline. In 2020/21 we only opened 137 studies (vs between 270-280 / year since) as resources were mainly focused on opening COVID-19 trials, although in the latter part of the year setup was restarted for non-COVID trials. The median time for trials that opened in 2020/21 was 107 days. The new target is to be agreed with the R&I Committee but our

proposal is that the median time to approval of studies in 24/25 is set at 83 days, a reduction of 23% over a five year period (despite the impact of the pandemic) against the setup metrics delivered in 2020/21 where there was a lower volume of approvals and a greater focus of work.

2.5	**Reduce the median time to first patient recruited to 50 working days from date of Confirmation of Capacity and Capability**	**GREEN**

We are currently on track to meet the target of first patient recruited within 50 days of local confirmation and capacity to for research. Our data (figure 8) shows that this target was met in 20/21, largely due to the rapid recruitment to a number of COVID-19 trials and is currently being met in this financial year.
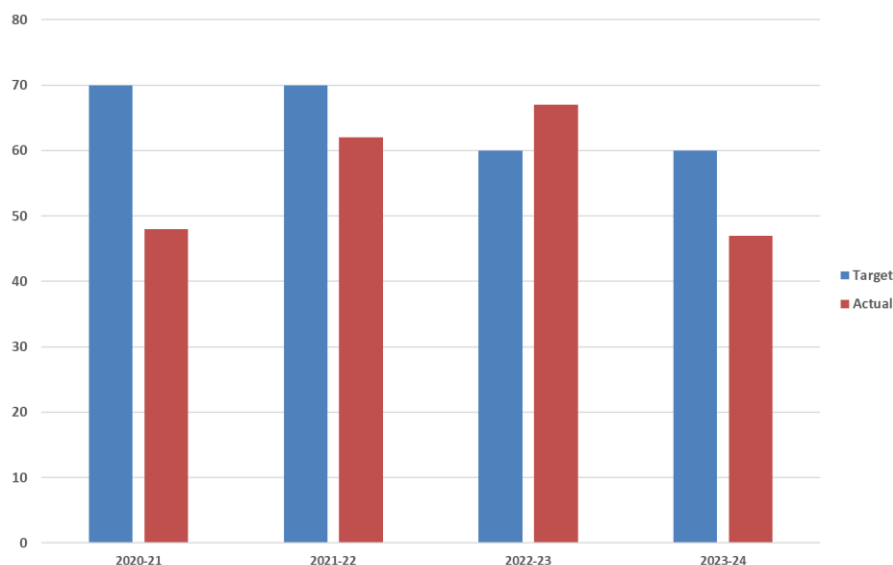

Figure 8: Median time to first patient recruited (days)

2.6	**Complete our modernisation of the Research and Innovation function, delivering a high-quality integrated research and innovation management, support and delivery service to LTHT CSU's, staff and patients.**	**GREEN**

The integration of research delivery teams and research finances into a central R&I department was completed in 2022. New finance processes for monitoring and invoicing income have been implemented and a culture of continuous improvement has been implemented to improve and streamline processes for managing and delivering research.

2.7	**Have 85% of all NIHR commercial and non-commercial studies recruiting to time and target.**	**RED**

In 22/23 our Recruitment to Time and Target (RTT) performance for non-commercial studies upon their closure was 52% and for commercial studies it was 72%. This is short of our target of having 85% of all studies having recruited to time and target when they close to recruitment. Figure 9 shows data on % of closed studies that have met their recruitment to time and target by year between 2020/21 and 22/23.
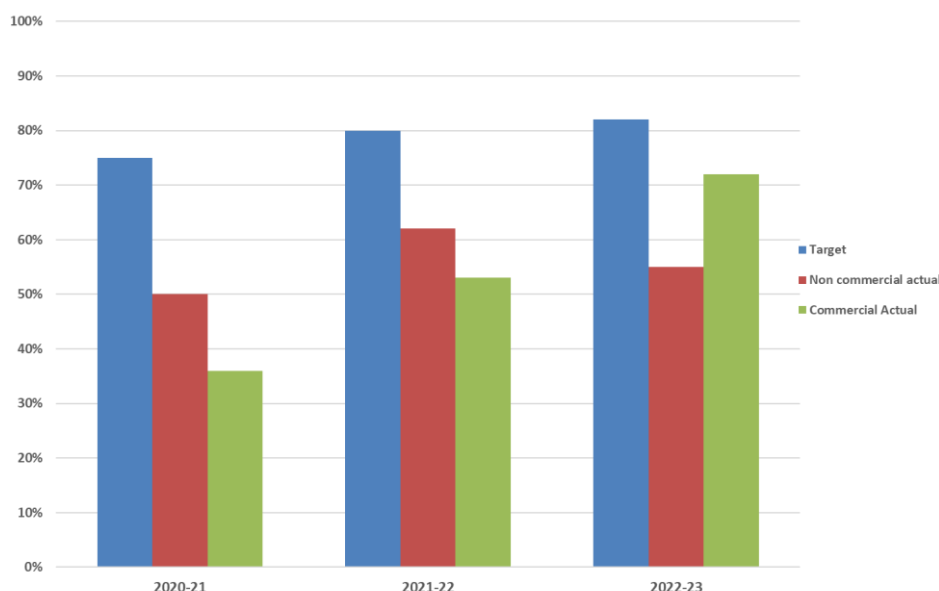
Figure 9: % of studies that have met recruitment to time and target upon closing

To address the identified performance challenges we have implemented an action plan to increase to proportion of studies that are recruiting to time and target and have introduced "live" monitoring of the research portfolio to track RTT performance in real-time to help address the current shortfall in performance. Key actions have included:

- Improving the timeliness and quality of data entered into the EDGE research management system.
- Ensuring that research delivery teams and Principal Investigators (PI's) are aware of studies that are behind target so they can implement corrective actions.

As a result of the actions taken to date, the number of "green" studies has steadily increased and at the end of January 2024 47% of the open portfolio is classified as currently meeting RTT (Figure 10). This is a significant improvement on our performance in November 2022. Our target for 23/24 is for 50% of our open studies to be recruiting to time and target and whilst we achieved this in November 2023 there has been a slight dip in performance in December and January but are confident of meeting the target by the end of the year. Further actions to help us improve our overall RTT performance include the introduction of a standardised "feasibility" process across the Trust so that the deliverability of studies is considered in a consistent way with realistic recruitment targets set. This builds on processes in place in some areas and will ensure we are only opening studies where we have a high confidence level that the study will recruit to time and target.
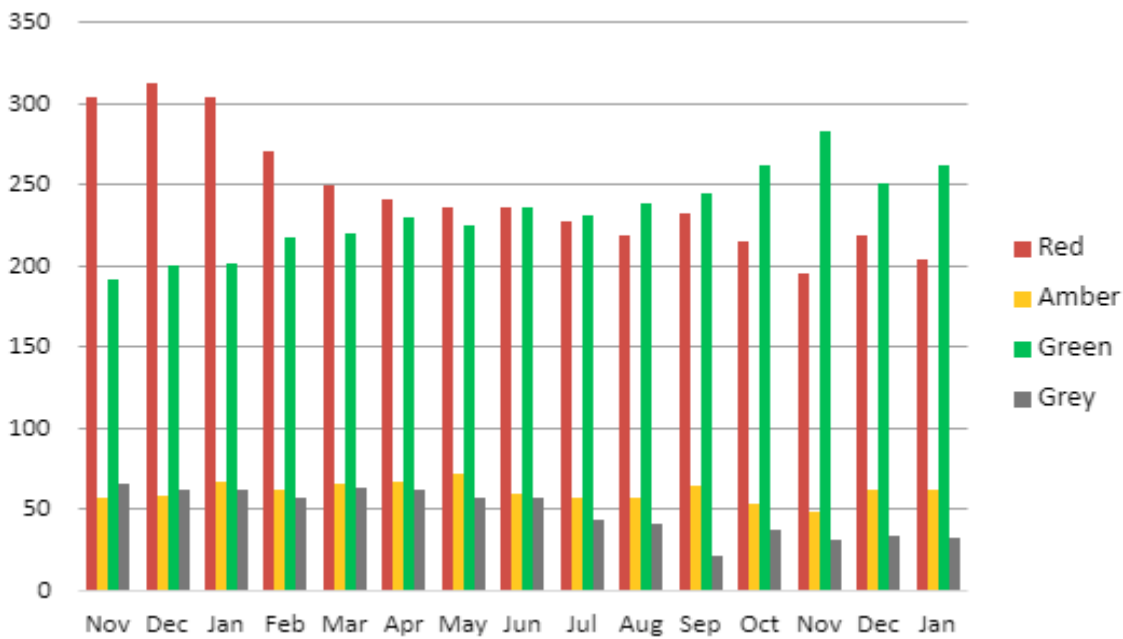
Figure 10: Recruitment to time and target for currently recruiting studies at LTHT

Red: Not on trajectory to achieve RTT and/or planned recruitment end date has been exceeded;
Amber: Not currently on pace to achieve RTT, however Green could yet be achieved;
Green: Currently achieving RTT;
Grey: Excluded due to missing data or other data quality issue;

2.8	**Have 250 patients and members of the public participating in Patient and Public Involvement and Engagement (PPIE) activities annually**.	**GREEN**

Since April 2020 we have invested in PPIE activities across LTHT and our NIHR infrastructure to provide a more professional service working to set standards across all of our research infrastructure. This was enshrined in our own strategy and also within the joint strategy with the University of Leeds. In that time, we have seen a significant increase in the numbers taking part in PPIE activities (Figure 11) with 647 members of the public participating in PPIE activities at LTHT in 22/23 versus 141 in 2020/21. To date in 23/24 800 members of the public have participated in PPIE activities.
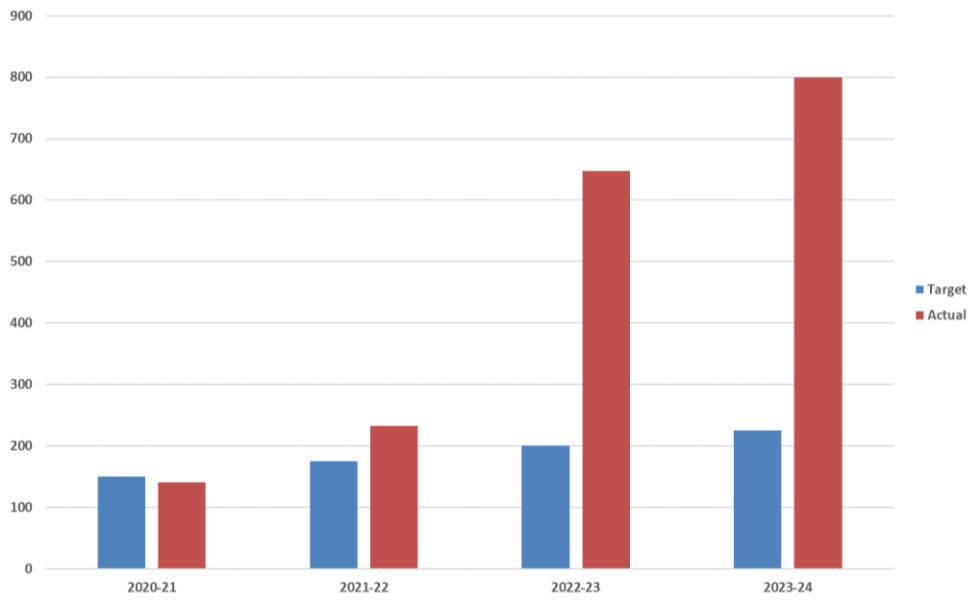
Figure 11: Number of Individuals Participating in Patient and Public Involvement and Engagement work against targets.

Patient and public involvement in research is a core part of the joint strategy with the University of Leeds and is an important focus for the Trust and its partners and that work is being done in a joined-up way across partners and research infrastructure. A workshop was held to consider the activities for PPIEP linked to shared strategic aims. There were Senior Management and PPIEP stakeholders in attendance from across the NIHR@Leeds Partnership, University of Leeds, Leeds Teaching Hospitals Trust and Leeds Hospitals Charities. The main outcome was an agreed approach to enhanced collaboration, and a streamlined framework around PPIEP that brings shared strategic aims to life. In defining what a streamlined PPIEP framework looks like, workshop delegates highlighted the importance of an enhanced profile for PPIEP and increased understanding of its importance; a proactive culture that focuses on outcomes and benefits for patients; and a strategic approach to funding and resourcing.

In defining recommendations, actions were identified around Infrastructure, People and Process -

Infrastructure – A shared hub of information to support the Shared Strategy and the appointment of a member of Senior Management from each organisation to advocate for PPIEP and to support and empower those working in the area.

People - Developing and implementing a bespoke Training Programme on how to conduct PPIEP activity.

Process – Benchmarking best practice and conducting a process review of current arrangements to align with this best practice.

2.9 **Have over 250 staff trained as Principal Investigators in the organisation** **GREEN**

According to our data, there are currently 423 LTHT staff recorded as being Principal Investigators (PI's) on open studies in the Trust. This is a small increase on the numbers identified as being PI's on open studies in 2020/21 (Figure 12). There was a small decrease in the number of PI's in 21/22 due to the closure of studies post COVID pandemic, but the numbers have increased as the portfolio has regrown in 22/23 and 23/24.
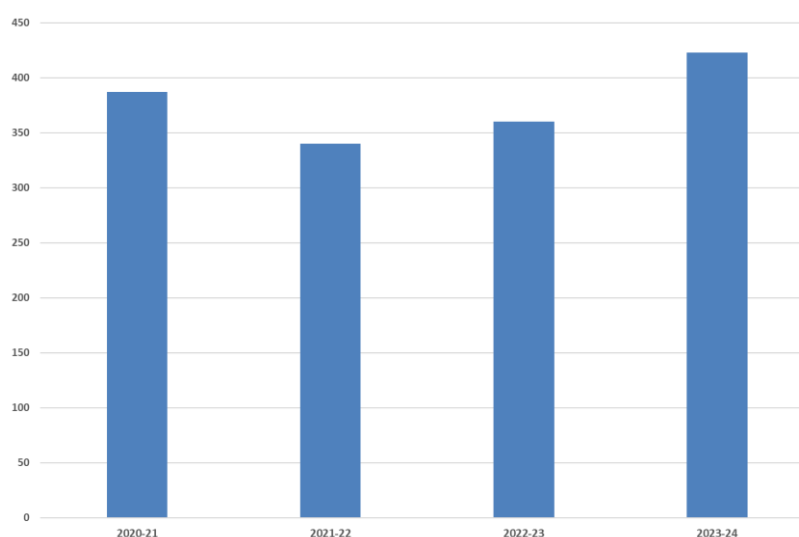

Figure 12: Number of Principal Investigators leading open studies in LTHT

2.10 Have over 625 staff trained in Good Clinical Practice (GCP) in the organisation

<div align="right">**GREEN**</div>

Good Clinical Practice (GCP) is a set of internationally recognised ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people. According to records from EDGE (our research portfolio management system), 738 LTHT staff have been trained in GCP since January 2020.

2.11 Submit 225 high quality grant funding applications for research and innovation programmes led by LTHT staff.

<div align="right">**GREEN**</div>

A grant funding development manager within R&I provides support to staff wanting to apply for grants to help signpost them towards appropriate funding schemes, help them understand the requirements that funders have and to ensure grants are properly costed.

234 grant applications have been submitted to funders since April 2020 for a range of research projects, pre-doctoral fellowships, doctoral fellowships and post-doctoral fellowships (Figure 13). Our data shows that 44 (50%) of the grant applications submitted during 22/23 were awarded.
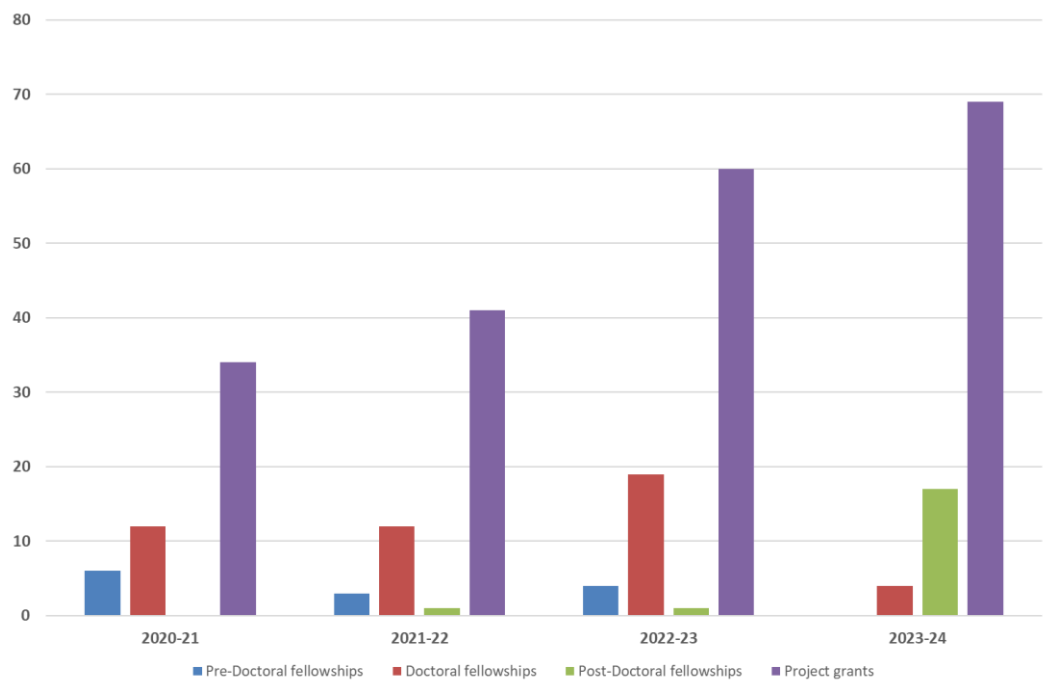
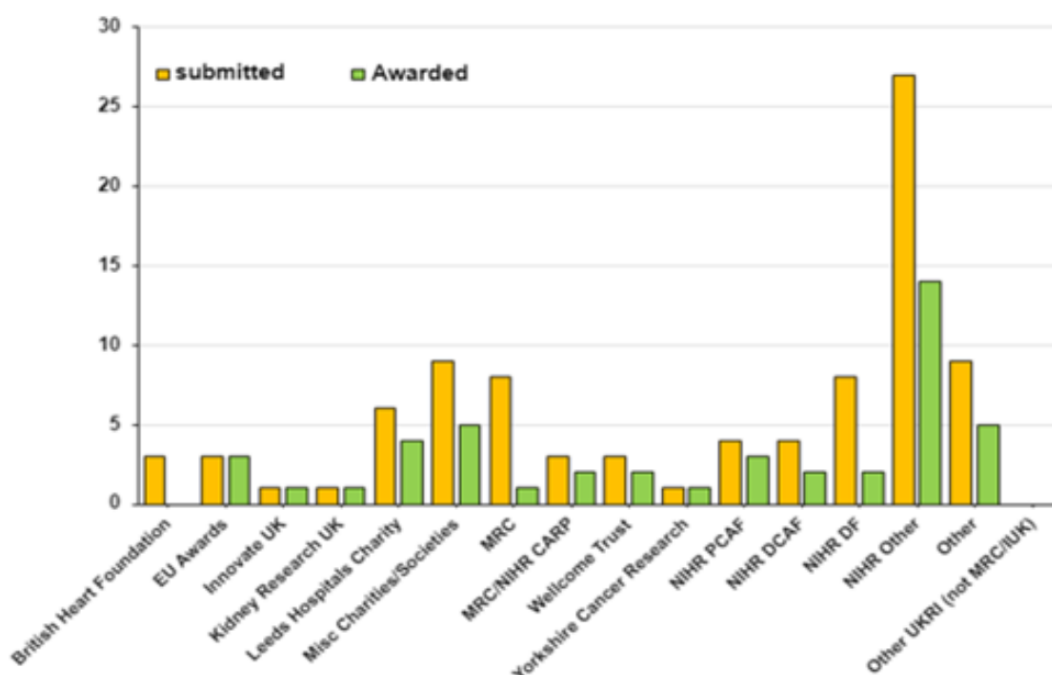**Figure 13: Number of grant applications submitted by year**

Figure 14: Grants submitted and awarded by funder

2.12 Deliver 300 collaborative projects with industry partners.   **GREEN**

Since 1ˢᵗ April we have opened and recruited to 188 commercially sponsored studies at LTHT (across 85 companies). A further 61 commercially sponsored studies are in the local setup process and a further 50 potential projects are in development through the Business Development and Innovation team. Of the 188 commercially sponsored trials recruited to, 14 are sponsored by AstraZeneca, 12 by Roche, 8 by Novartis and 7 by Janssen.

Our relationships with contract research organisations such as IQVIA, Precision Oncology and Parexel are important as these bring a large volume of studies from a diverse range of companies. We currently have 13 IQVIA studies open to recruitment in LTHT with another 14 in set-up.

2.13 Deliver 10 strategic partnerships with industry that deliver mutual benefit   **GREEN**

To date, 7 partnerships have been entered into around research and innovation as follows:

Flatiron
We have entered into a partnership with Flatiron UK to facilitate better insights from the routinely collected data on patients with cancer at LTHT. Under the terms of the Agreements, Flatiron have a licence to process and use data from LTHT for commercial projects with LTHT receiving back a revenue stream and access to the dataset curated by Flatiron. The programme of work gained approval from the Health Research Authority Confidentiality Assessment Group (CAG) on 20th of March 2023 and received a favourable opinion from ethics on the 20th of February 2023. Since then work has focused on engaging with cancer patients to identify those who wish to opt-out of having their data shared with Flatiron.

Fujitsu/Intel:
A partnership has been established with Fujitsu and Intel to create a digital skills training facility within the Innovation pop-up. This is intended to support the development of digital skills in staff to support the deployment of digital technologies in the new hospitals. An investment from Fujitsu and Intel has supported the redevelopment and modernisation of the pop-up facilities.

IQVIA:
IQVIA are a multinational Clinical Research Organisation (CRO) who run clinical trials on behalf of a large number of pharmaceutical and biotechnology companies. We are a key partner in IQVIA's Northern Prime Network and are part of their Early Phase Oncology Network (EPON). We currently have thirteen IQVIA studies open to recruitment in LTHT with another fourteen in set-up.

Fortrea:
Fortrea (formerly Covance) are a CRO with an early phase clinical research facility based in Leeds. We are working closely with Fortrea to increase early phase and experimental research opportunities through close working with the NIHR Leeds Clinical Research Facility team. We are exploring opportunities for staff exchanges and support for training of their staff through the Research Academy.

Precision Oncology:
Precision Oncology are a global CRO specialising in oncology research and we are part of their Precision Site Network (PSN). The PSN is a small number of globally preferred sites for delivery of Oncology trials and LTHT is one of nine such sites in the UK.

Health Innovation Yorkshire and Humber:
We have a partnership with Health Innovation Yorkshire and Humber (formerly the Academic Health Science Network) through which we provide support to their Propel programmes and they help support the development of our international portfolio and innovation pipeline and provide innovation training for our staff.

Johnson and Johnson (DePuy)
The Trust signed an MoU with Johnson and Johnson in November 2023 to bring together the Trust's clinical and health innovation expertise with J&J's innovation capabilities. The partnership will drive lasting improvements to health outcomes in Leeds and across the region and prioritise a focus on addressing health inequalities. Key aims are:

- To drive forward innovation, R&D and new MedTech for the benefit of all patients, with a focus on improving health equality.
- To promote skills, talent and jobs in innovation.
- To deliver increased efficiency within the healthcare supply chain, including climate benefits.

In addition to the above we have established MoU's with the British Embassy in Israel and University Hospitals Oslo / Norway Healthtech through which a pipeline of opportunities for research and innovation collaborations with businesses can be developed. We are also part of the NHS Clinical Entrepreneur InSites programme run by Mid Essex NHS Foundation Trust. This programme brings together 10 NHS sites to work together on developing common practices for streamlining adoption and sharing learnings and processes around innovation. There are also partnerships in place for the innovation pop-up with NEXUS, the Leeds Academic Health Partnership, the University of Leeds Centre for Healthtech Innovation, Medilink North of England and the NIHR Surgical Medtech Co-operative.

We continue to explore opportunities where we can develop more strategic partnerships with businesses based on an alignment of needs and objectives and a number of potential

strategic partnerships are currently in development, including one with Elekta around radiotherapy research.

2.14 **Be working in active research collaborations with >50 academic organisations (national and international).**	**GREEN**

We currently have active research collaborations with 140 academic (NHS and University) organisations across 928 studies. Our major collaborator is the University of Leeds with whom we are partnering on 117 projects (16% of all projects). Other major collaborators are University College London (51 projects), University of Birmingham (49 projects), Cambridge University Hospitals NHS Trust (33 projects), the University of Oxford (26 projects) and the University of Manchester (21 projects). 49% of the academic partners we work with collaborate with us on 10 projects or less.

2.15 **Reform our research governance (regulatory) processes in collaboration with the University of Leeds, creating a comprehensive suite of SOP's, guidance and associated training to provide researchers with a whole project life cycle support service.**	**GREEN**

Work was initially paused on this due to the COVID-19 pandemic and changes in the Research Governance leadership at both the University of Leeds and Leeds Teaching Hospitals in 21/22. Initial discussions have been held regarding better join-up of research governance processes for both trials of drugs and trials of medical devices sponsored by LTHT and the University of Leeds and there is broad agreement around how we can work more closely together. Work is now underway to redevelop the MoU that underpins the relationship which has traditionally focused on regulatory support for drug trials, but expanding this to be more holistic and cover a wider range of activities across the partnership.

2.16 **Ensure that 80% of requests for review and advice on new studies are responded to in full within 10 working days from receipt of minimum data.**	**GREEN**

The purpose of this KPI is to show that we are providing a high-quality service for researchers, particularly around the planning of new research studies led by LTHT staff.   Of the requests received in 2023/24, 3% are off target, 74% have met the target response time set for 23/24 (15 days) and 23% are still in progress but are on target to meet the target time set. Of those that have met the 23/24 target 77% have been done so within 10 working days.

2.17 **Ensure that 100% of LTHT sponsored interventional trials are registered to publicly accessible database within regulatory timelines.**	**GREEN**

Research transparency is central to ethical research practice. When research is carried out openly and transparently, everyone will be able to see what research is happening and the outcomes from finished studies. This means that:

- patients, service users and carers can find opportunities to join studies.
- researchers can build on previous research findings in their efforts to develop new and better treatments, and to identify the best ways for us to stay healthy and well.
- health professionals, commissioners, policy makers, and funders, can use research findings to help make informed decisions.

To ensure that research sponsored by LTHT is transparent, we obligate researchers to ensure that the scope of the research project is available on a public website and our target is for 100% of LTHT's sponsored interventional studies to be accessible in this way. Data shows that this target is being met with LTHT sponsored trials registered publicly on NIHR ODP, ClinicalTrials.gov or EudraCT. The Health Research Authority (HRA) carries out regular audits of trials approved by an NHS Research Ethics Committee to identify which clinical trials have been registered on a publicly accessible database and notifies LTHT if any such approved trials cannot be identified. This provides us with independent assurance that this target is being met.

2.18 Have over 2,000 LTHT staff attend Research Academy courses. **GREEN**

The LTHT Research Academy (https://www.leedsth.nhs.uk/research/research-academy/) was established to provide high quality training to research delivery teams and researchers across LTHT. CPD accredited courses have been developed and evaluated and to date records show that 3,012 staff have participated in Research Academy courses (336 sessions run) since April 2020. The courses are now also offered to other NHS organisations and we have a contract with the Yorkshire and Humber Clinical Research network for 2023/24 that is funding access to courses for all health and social care organisations in the region.

2.19 Create and deliver a digitally-enabled research delivery infrastructure **GREEN**

5 areas were identified where digital enablement will support improved delivery and management of research.

Support for study setup:
The implementation of OneForm in January 2021 replaced a large number of paper forms which were sent to support services to request support for clinical studies, often duplicating information required. It has also facilitated greater oversight of the status of projects in setup, allowing projects which have been in the process a long time to be identified and issues addressed. OneForm is currently in the process of being redeveloped to meet additional needs and functionality that have been identified during its use and to meet the needs of the developing feasibility and setup processes. The target date for completion of the update to OneForm is September 2024.

Electronic Case Report Forms (eCRF's):
Historically, data relating to clinical trials sponsored by LTHT was collected on paper Case Report Forms. Paper-based CRF forms must be transcribed into a computer database before analysis, which introduces the potential for transcription errors and challenges in collecting timely data from participating sites. Collecting data electronically with eCRF eliminates such errors and results in a more efficient data capture process across multiple trial sites and generates better quality data for analysis. After an analysis of systems available on the market, the RedCAP system was chosen for implementation at the Trust. As data from other NHS Trusts who are participating in locally-sponsored trials is held in the system, it is hosted on external servers provided by AIMES, a specialist in setting up research data environments. This implementation work was completed in May 2023 and studies are now utilising the system.

Financial management:
To improve our oversight of research finances and ensure that all income due is invoiced for, financial trackers reflecting activity carried out for individual studies were introduced in 2022. That process is now being digitised within the EDGE Portfolio Management system so that it is directly linked to the recruitment data that researchers and delivery teams enter into that

system. This project is scheduled to be completed by April 2024 and will create improved automation of this process, resulting in operational efficiencies.

Patient Finder:
The screening of patients for inclusion into research is currently a manual process where teams work through patient records to identify those who may meet the criteria for inclusion in a study. To make this process more efficient a digital system (CT-CUE) has been offered to the Trust by IQVIA at no cost. This is a complex project requiring feeds from all systems that capture patient data for it to be truly effective. Work has therefore been exploring options to incorporate CT-CUE within the Leeds Data Platform as this has all the necessary data feeds and an implementation plan has been developed.

PPM+:
The MHRA inspection carried out in November 2018 identified that PPM+ did not meet the requirements of the MHRA's guidance on electronic health records for research. These included not having an audit trail within PPM+ of who had made changes to records and when. Working with colleagues in DIT, solutions to these issues have been implemented and following an assessment of PPM+ by the MHRA as part of their inspection carried out in December 2022 there were no findings in relation to the compliance of PPM+ with their guidance. Alongside this development work, a service has been developed to provide external monitors with "gated" access to PPM+ which allows them to only see the records of participants in the trials that are being monitored. This service saves research teams significant time in preparation for monitoring visits as they no longer need to print out records from PPM+ for monitors.

2.20	**Fulfil 90% of all research requests for real world data within 8 weeks of sign-off**	**GREEN**

A service to support researchers access to de-identified datasets for research was established in 2019 following the identification of a risk around knowing what routinely collected clinical data was being used for research (a secondary purpose) and who was accessing it for those purposes. Working with information governance and the Caldicott Guardian, a data access process was established alongside the service to ensure that there was oversight of what data was being requested and that appropriate datasets were being requested for projects.

The service has developed capabilities to provide not just de-identified textual content from LTHT systems but also images (e.g. Radiology). The complexity of the projects that the team are being asked to complete are increasing with an increasing focus on multimodal datasets being requested for research. The performance of the service (Figure 15) is now ahead of its target performance target, having been behind target in 21/22 and 22/23.
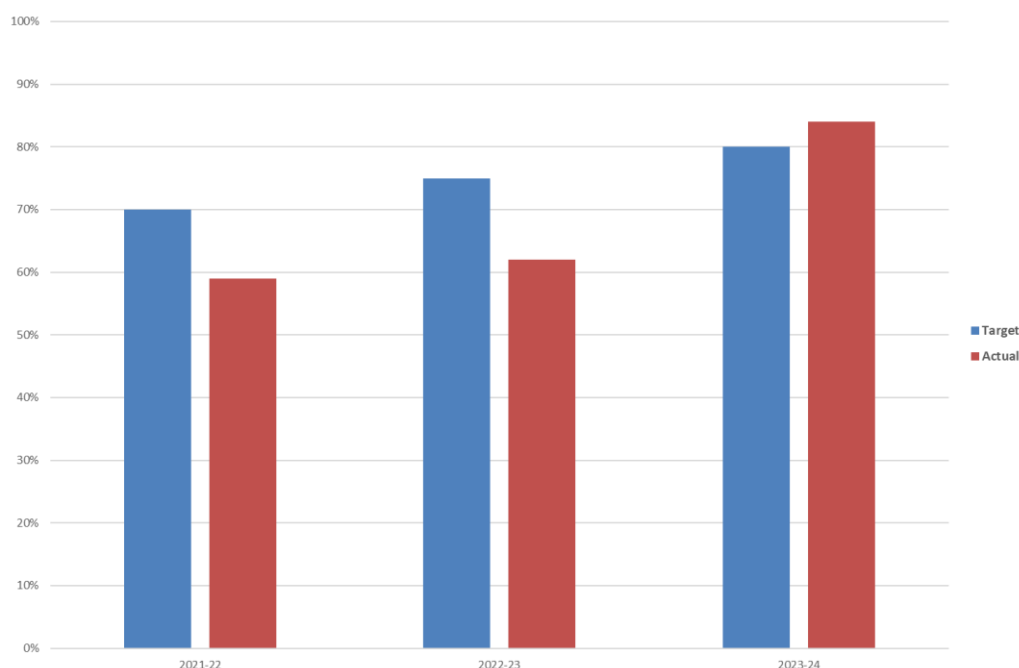
Figure 15: Fulfilment of Real World Data requests (% within 90 days)

Once the Leeds Data Platform is fully operational, this will support further improvements in performance as this will provide a single source where the team can access data from, rather than the back ends of individual systems.

Work to improve sharing of data with the University of Leeds has been part of the focus in delivering the joint strategy. Both organisations met to discuss typical use cases, which enabled mutual appreciation of the processes involved, and to agree on steps in managing and costing such cases. A Memorandum of Understanding for the Data Sharing Framework between LTHT and the University of Leeds has been finalised, which underpins guidance and ways of working.

2.21	**Open our new Clinical Research Facility at St. James's University Hospital**	**GREEN**

The St. James's Clinical Research Facility (SJUH CRF) opened in 2020 and is now fully operational. The SJUH CRF provides dedicated state of the art facilities to deliver safely first in human studies, early phase drug development trials and experimental research. The facility provides 17 treatment beds/chairs, a multi-functional treatment room, a suite of outpatient rooms and two dedicated laboratories. The CRF currently has a portfolio of 117 NIHR reportable studies, of which 57 trials (49%) are open to recruitment, 34 trials (29%) are closed to recruitment but remain in follow up and 16 (14%) are in active set-up. The remainder trials have either been withdrawn or suspend by the sponsor (8; 7%) or fully closed (5; 4%). The portfolio contains 82 (70%) Early Phase trials (Phase I-IIa) and 35 (30%) later phase trials (Phase IIb-III), with 97% of the portfolio being medium-high risk and/or intensity. The CRF also supports a further 76 studies which require delivery space for later phased trials that do not require the specialist facilities of a CRF but have no other available space.

2.22 Open a Digital Pathology Innovation Centre   **GREEN**

The National Pathology Imaging Co-operative Innovation Centre is open and operational in the Sir Robert Ogden Building. The £1m refurbishment was funded by the Wave 2 funding from InnovateUK / Office of Life Sciences for the AI Centres of Excellence. As well as dedicated facilities for training and validation of pathologists for using digital pathology, the facility contains a quality assurance lab and an "AI Forge". The AI Forge allows for scanning of research samples for training AI at scale and also uniquely allows the same images to be generated on a wide range of digital pathology scanners so that AI can be trained on datasets representative of what it might encounter in the real world and variations in images created by different scanners are accounted for as AI is developed.

2.23 Open a new Clinical Research Facility within the new Leeds Children's Hospital   **RED**

Delivery against this KPI has been impacted by the delays to the new hospitals programme and so will not be achieved within the lifetime of this strategy.

3. Risk

The content of this report fall under 2 level 2 risks as defined by the Trust's risk framework.

- Research, Innovation & Development Risk - We will deliver agreed minimum research and innovation priorities with health, social care, voluntary, education and private sectors (risk appetite: cautious).

- Partnership Working Risk - We will maintain well-established stakeholder partnerships which will mitigate the threats to the achievement of the organisation's strategic goals (risk appetite: open).

Risks have been assessed as being within the Trust's risk appetite and therefore do not need inclusion on the wider corporate risk register.

4. Publication Under Freedom of Information Act
This paper has been made available under the Freedom of Information Act 2000.

5. Recommendation

The Trust Board are asked, note the scrutiny of assurance by the R&I Committee and to receive this paper for assurance that:

a) We are on target to deliver the majority of the objectives set out in the R&I strategy for 2020-25 despite the impact of the COVID-19 pandemic and that where we are off target plans are in place to move us towards the target performance level.
b) Recruitment to research remains strong with data showing we are ahead of trajectory to meet our targets and that participants recruited are representative of the ethnic diversity in Leeds.
c) We have exceeded our income targets from all our income sources for 2020-2025 and the trajectory is one of growth.

d) The proportion of live studies in the Trust that are meeting Recruitment to Time and Target metrics continues to increase and we are on target to meet our in-year target of 50% of all live NIHR portfolio studies at the Trust recruiting to time and target.

e) Our grant funding support is effective with a high proportion of applications submitted being awarded.

The Board are asked to consider future reporting requirements of the annual progress report against this Strategy, noting the new R&I Assurance Committee in place, and to prevent duplication of discussion by both the Committee and the Board.

Ai Lyn Tan
Christopher Herbert

6th March 2024