NHS
The Leeds
Teaching Hospitals
NHS Trust

Annual Report Research and Innovation Committee

Audit Committee – 5th May 2022

Presented for:	Information and Assurance
Presented by:	Phil Wood, Chief Medical Officer
Author:	Christopher Herbert, Director of Operations: Research and Innovation Rebecca Savage, Research and Innovation Manager (Research Operations)
Previous Committees:	NONE

Trust Goals	
The best for patient safety, quality and experience	✓
The best place to work	✓
A centre for excellence for research, education and innovation	✓
Seamless integrated care across organisational boundaries	✓
Financial sustainability	✓

Risk Appetite Framework				
Level 1 Ris	(✓)	Level 2 Risks	(Risk Appetite Scale)	Risk
Workforce Risk	✓	Workforce Deployment Risk - We will deliver safe and effective patient care through the deployment of resources with the right mix of skills and capacity to do what is required.	Cautious	↔ (same)
Operational Risk	✓	Business Continuity Risk - We will develop and maintain stable and resilient services, operating to consistently high levels of performance.	Cautious	↔ (same)
Clinical Risk	✓	Research, Innovation & Development Risk	Cautious	↔ (same)

		- We will deliver agreed minimum research and innovation priorities with health, social care, voluntary, education and private sectors		
Financial Risk	✓	Financial Management & Waste Reduction Risk - We will deliver sound financial management and reporting for the Trust with no material misstatements or variances to forecast.	Minimal	↔ (same)
External Risk	✓	Partnership Working Risk - We will maintain well-established stakeholder partnerships which will mitigate the threats to the achievement of the organisation's strategic goals.	Open	↔ (same)

Key points	
1. **Terms of Reference** - The Committee Chair, along with the Committee has reviewed the Terms of Reference on a line by line basis, to ensure that the Committee is fit for purpose and carries out its duties as delegated by the Board of Directors. The committee has discharged its duties in line with the ToR subject to the following amendments set out in appendix A (shown in track changes)	Approval

2. **Reporting Requirements** - The Terms of reference for the Research and Innovation Committee state;
The Committee will report annually on the delivery of its work programme which focuses on.
  o Overseeing the development and implementation of strategies to promote LTHT as a global hub for research and innovation and to establish conditions for increasing participation in research, promoting and supporting innovation and continuing development opportunities.
  o Overseeing the establishment of partnerships with higher education institutes, industry, NHS organisations, and charities across the UK and internationally to increase participation in research, the clinical innovation pathway and continuing development opportunities.
  o Keeping under review the performance management for the delivery of the research and innovation strategy.
  o Providing assurance that opportunities to develop the research and clinical innovation portfolio are aligned with the Trust Board's strategy and that high- quality bids are submitted.
  o Providing assurance that the research workforce is developed and replenished in sufficient numbers to meet LTHT's long-term strategic and clinical aspirations.
  o Overseeing the development and implementation of highly-effective controls for research and innovation governance.
	Assurance

3. Work Plans
  I. The Board of Directors approved the Committees Work Plan for 2021/22 (Appendix B), and reports assurance against items received during the year
  II. The Committee sets out its draft Work Plan for the coming year
	Assurance
	
	2

(Appendix C), seeking approval from the Board.	

1. Purpose

The purpose of this paper is to provide assurance to the Audit Committee that the Research and Innovation Committee has discharged its duties in accordance with its Terms of Reference, completed its work plan for 2020/22 and to propose its draft work plan for 2022/23.

The Committee shall review annually the Committee's terms of reference and its own effectiveness and recommend any necessary changes arising therefrom.

To report to the Board on matters set out in its terms of reference and how the Committee has discharges responsibilities.

The Chair of the Committee shall provide an annual letter of assurance to the Chair of the Audit Committee confirming the effectiveness of the Committee and fulfilment of its objectives, and to the effect that the committee has reported to the board financial or operational performance which would adversely affect achievement of corporate objectives.

1. Committee Members and Effectiveness

Dr Phil Wood is the appointed Chair of the Committee. The Committee Members/Attendees are set out below:

Chair:	Phil Wood	Chief Medical Officer
	Helen Christodoulides	Deputy Chief Nurse
	Ai Lyn Tan	Director of R&I
	Christopher Herbert	Director of Operations, R&I
	Julie Evans	Head of Nursing, R&I
	Gordon Cook	Director, NIHR Leeds MIC
	Charlotte Harden	Chief Operating Officer, NIHR Leeds MIC
	David Jayne	Director, NIHR Surgical MIC
	Vee Mapunde	Director of Operations, NIHR Surgical MIC
	Chris Twelves	Director, Leeds CRF
	Helen Radford	Leeds CRF Manager
	Paul Emery	Director, NIHR Leeds BRC
	Medina Inamdar	Operations Manager, NIHR Leeds BRC
	Sinisa Savic	Director, NIHR Bioresource
	Claire Gaunt	Senior Finance Business Partner
	Matthew Callister	CI for Yorkshire Lung Screening Study
	Heidi Siddle	Consultant Podiatrist, NIHR Senior Clinical
	Rory O'Connor	Pro-Dean for Research UoL FMH
	Anne-Maree Keenan	Deputy Pro-Dean for Research UoL FMH
	Peter McWilliam	Chair of the Leeds Cares Research & Innovation Committee
	James Goodyear	Director of Strategy
	David Brettle	Chief Clinical Scientist; Innovation Lead
	Darren Treanor	Consultant Histopathologist (Digital Pathology)

	Geoff Hall	Chief Clinical Information Officer
	Roy Charlton	Head of Commercial
	Nisha Sharma	Director of Breast Screening
	Ceri Williams	Director of Research & Innovation Development (UoL)
Trust Chair (Observer)	Linda Pollard	Trust Chair
Non-Executive Director(s) (Observer)	Chris Schofield	Non-Executive Director
In routine attendance	Rebecca Savage	R&I Manager

The Committee has met 4 times during this financial year, with meetings scheduled quarterly and all have been quorate and well attended. All meetings have taken place using TEAMS due to the ongoing COVID-19 pandemic and the restrictions on face-to-face meetings.

The committee has been effective at discharging its duties.

2. Delivery Against Terms of Reference

The terms of reference were reviewed by the committee in the February 2022 meeting, updated and will be approved at the next meeting on 9th May 2022.

3. Amendments to Terms of Reference

A full ToR is attached as Appendix A and changes made for 2022/23 are shown as track changes.

4. 2021/22 Work Plan

Assurance of delivery of work plan

The workplan for 2021/22 (as set out in Appendix B) allowed scrutiny of the KPI's as set out in the Trust's Research and Innovation Strategy (2020-25) along with a range of other national performance metrics against which the Trust is measured. The committee was assured that, despite the COVID pandemic, KPI's were largely being met. The committee also received reports on the impact of the COVID-19 pandemic on research, with the pause and restart process associated with the established research portfolio as well as the Trust's research response to the COVID pandemic. The annual reports from the NIHR infrastructure programmes (NIHR Biomedical Research Centre, NIHR Clinical Research Facility, NIHR Leeds Medtech and In Vitro Diagnostic Co-operative, NIHR Surgical Medtech and in Vitro Diagnostic Cooperative and NIHR Bioresource) and the associated feedback was shared. In addition, the committee also received regular reports from the National Pathology Imaging Co-operative. Reports on R&I finances were also received as well as a new report focusing on the development of research careers in our nursing, AHP and healthcare scientist staff (collectively Healthcare Professionals). The developing work on Innovation support and business development and the use of routinely collected data for research was reported at each meeting and the committee also received reports and proposals around the development of a major partnership with Flatiron, a company specialising in the curation of routinely collected clinical data in order to help derive more insights from that data.

A summary of the reports received is in Appendices D, E and F.

4

5. Other Issues addressed by the Committee in year

A breach of IRMER regulations associated with a small number of Oncology trials that was reported to the CQC was first reported to the committee in February 2021 and updates on the progress with the task and finish group were provided throughout the year.

The committee was appraised of the potential financial challenges for Research and Innovation associated with the COVID pandemic as a proportion of R&I income is earned based on activity delivered. The pause on non-COVID research and the impact of the COVID pandemic on clinical services (from which patients are recruited) was likely to cause financial pressures both in this year and also in future years due to the impact on the portfolio. Assurance was received that the financial position was being monitored and measures put in place to minimise the impact.

6. Risk Management

The Committee has reviewed and commented on the risk register held by Research and Innovation and has assurance that risks associated with R&I and monitored and mitigated as far as possible. Further work has looked at how R&I risks should be included on the corporate risk register and how R&I risks can be aligned to the Trust's risk framework. R&I now attends the Trust's risk management committee twice-yearly.

7. Internal control environment

No internal audits were received by the committee.

8. Proposed 2022/23 Work Plan

The proposed 2022/23 work plan (Appendix C) builds on the 2021/22 work plan. Presentations to the committee are planned from the Babi-Leeds team (July 2022), Our Future Health (November 2022) and the Leeds PPIEP team (February 2023)

9. Objectives

The Research & Innovation Committee objectives for 2022/23 will include a particular focus on:
- Patient and Public Involvement and Engagement (PPIEP) activities that support research
- R&I Marketing and Communications
- Strengthened assurance from existing and newly formed joint research centres e.g. The Leeds Cancer Research Centre
- Enhanced assurance and detailed scrutiny into (a) Study setup at the Trust and (b) Research Finances

10. Publication Under Freedom of Information Act

This paper has been made available under the Freedom of Information Act 2000

11. Recommendation

The Research and Innovation Committee has delivered the agreed delegated activities by the Board as set out in its Work Plan and gained assurance as defined by the Committee Terms of Reference. The Terms of Reference have been reviewed and amended for 2022/23 as shown in (Appendix A) and these are presented for approval along with the work plan for 2022/23.

12. Supporting Information

The following papers make up this report:
- Summary of Research reports (Appendix D)
- Summary of Innovation and real world data reports (Appendix E)
- Summary of Finance reports (Appendix F)

Christopher Herbert
Director of Operations: Research and Innovation
April 2022

Appendix A: Terms of Reference

Research & Innovation Committee

1. Main Authority / Limitations

1.1   The Board hereby resolves to establish a management committee to be known as the Research and Innovation Committee ('the Committee'). The Committee is an executive-led management committee accountable to the Trust Board and shall have executive responsibilities, powers, authorities, and discretion as set out in these terms of reference.

1.2   The Committee is authorised by the Board to oversee the development, implementation and performance management of the research and innovation strategy, to foster commercial opportunities that may arise, and to monitor, investigate and address any activity within its terms of reference. It is authorised to seek a range of views, expertise, transparency, and openness in meeting its objective. The Committee is authorised to request the attendance of individuals and advisors with relevant experience and expertise where necessary.

1.3   The Committee Chair provides the Trust Board with a brief summary of the Committee's work at the first available Trust Board meeting opportunity after each Committee meeting. Approved minutes of the Committee are circulated to the Trust Board for information at the first formal meeting of the Trust Board after approval. The minutes are also circulated to those regularly in attendance. The Chair of the Committee will escalate matters in the first instance to the Chief Executive and Executive Management Team, and thereafter to the Trust Board as deemed appropriate.

1.4   Trust Standing Orders and Standing Financial Instructions apply to the operation of this Committee.

2. Objective

2.1   The Committee shall be accountable to the Trust Board and through its work focus on:
(i) positioning LTHT in partnership with the University of Leeds and other academic organisations as a global research and innovation powerhouse and as a catalyst for commercial opportunities that may emerge; or individually, compete for and win research grants or funds that underpin the Board's long-term clinical aspirations; (ii) patient benefit from research participation and utilisation; (iii) linking research participation to quality and service improvement (iv) having oversight of commercial opportunities that arise from research and innovation programmes, as well as related business-engagement activities that seek to exploit Trust-owned resources (v) ensuring good governance and risk management of research and innovation activities in the Trust.

2.2   Primary Duties and Responsibilities
3.1   Oversee the development and implementation of strategies to promote LTHT as a global hub for research and innovation and to establish conditions for increasing participation in research, promoting and supporting innovation and continuing development opportunities.

3.2   Oversee the establishment of partnerships with higher education institutes, industry, NHS organisations, and charities across the UK and internationally to increase participation in research, the clinical innovation pathway and continuing development

opportunities.

3.3   Be alert and encourage the development of commercial opportunities that may arise from research and innovation activities and from the networks that develop with partners and other organisations through the course of that work. When necessary, be prepared to draw upon external advice and expertise to explore and exploit commercial opportunities.

3.4   Keep under review the performance management for the delivery of the research and innovation strategy.

3.5   Provide assurance that opportunities to develop the research and clinical innovation portfolio are aligned with the Trust Board's strategy and that high quality bids are submitted.

3.6   Provide assurance that the research workforce is developed and replenished in sufficient numbers to meet LTHT's long-term strategic and clinical aspirations

3.7   Oversee the development and implementation of highly effective controls for research and innovation governance, including the management of risks, ensuring appropriate controls are in place, reporting to other Board committees as appropriate.

3.8   Oversee the rapid resolution of any significant weaknesses found in the Trust's research and innovation endeavours by reviewing decisions to halt research and innovation activity and apply whatever learning is necessary to: (i) ensure safe, high-quality and compliance research and innovation practices at all times; and (ii) the success fulfilment of research obligations to which the Trust is committed. Ensure material concerns are addressed to the satisfaction of all concerned and properly declared to the Trust Board of Directors.

3.9   Provide assurance to the Chair of Audit Committee confirming the effectiveness of the Committee and fulfilment of its objective, and to the effect that the Committee has disclosed to the Audit Chair all significant deficiencies and material weaknesses in the design or operation of internal controls which could adversely affect the Trust's ability to achieve research, innovation, education, or training objectives.

3.10   To undertake or consider on behalf of the Trust Chair or the Trust Board such other related tasks or topics as the Trust Chair or the Board may from to time entrust to the Committee.

3.11   Where there is a perceived overlap of responsibilities between the Committee and Innovation District Committee (IDC), the respective Committee Chair shall have the discretion to agree the most appropriate Committee to fulfil any obligation. To support this, information will be shared (and reported to more than one Committee) to maintain understanding between IDC and the Committee.

4. Duties and Behaviours

4.1   The duties of the Chairperson of the Committee shall be to:

- keep the Board informed regularly of any material matters which have come to the Committee's attention.
- ensure that minutes of the Committee are an accurate reflection of discussion.

- attend or designate another member of the Committee to attend public meetings of the Trust to answer any questions related to the work of the Committee.
- submit an annual report on the work of the Committee to the Audit Committee.
- and ensure that all significant risks are discussed and escalated in line with LTHT's Risk Management Policy.

4.2   The duties of members and attendees shall be to:

- attend and contribute
- have read the papers and materials in advance and be ready to work with them
- actively participate in discussions pertaining to Committee business ensuring that solutions and action plans have multidisciplinary perspectives and have considered the impact Trust-wide.
- disseminate the learning and actions from the meetings; and
- to attend at least 75% of meetings of the R&I Committee.

5. Constitution

5.1   The Committee shall meet as often as required but not less than four times each year.

5.2   The quorum for meetings shall be two Members, one of whom should be the Committee Chair, unless he or she is unable to attend due to exceptional circumstances. In the absence of both the Committee Chair and Vice Chair a decision will be taken in advance of the meeting as to which member of the committee shall Chair that particular meeting.

6. Membership and attendance

6.1   Members of the Committee shall be appointed at the discretion of the Chief Medical Officer. The Trust Chair and Non-Executive Directors shall have the right of attendance but not as members of the Committee. *In extremis*, any member of the Committee who can speak and be heard by each of the other members shall be deemed to be present in person and shall count towards the quorum. The core membership shall be:

(i)   Chief Medical Officer (Chair)
(ii)   Deputy Chief Nurse (Vice Chair)
(iii)   Associate Medical Director for Research & Innovation
(iv)   Head of Nursing for Research & Innovation
(v)   Director of Operations for Research & Innovation
(vi)   University of Leeds representative(s)
(vii)   Assistant Director of Finance
(viii)   Directors of the NIHR funded programmes
(ix)   Operations Directors/Managers of the NIHR funded programmes
(x)   Academic Research Capacity Lead
(xi)   Director of Strategy
(xii)   Chief Clinical Information Officer (R&I)
(xiii)   Chief Scientific Officer
(xiv)   Head of Commercial
(xv)   Representative clinicians with experience of research and the clinical innovation pathway.

In routine attendance:

(i) Non-Executive Director
(ii) Research & Innovation Manager (Serving Officer)
(iii) Minutes Secretary

External partners will be invited to attend the Committee as observers:

(i) A representative from the Academic Health Sciences Network
(ii) A Representative from the NIHR Yorkshire and Humber Local Clinical Research Network
(iii) A representative from Leeds City Council or the West Yorkshire Combined Authority

External partners will not participate in matters confidential to or of a sensitive nature for the Trust

6.2 Wherever possible members must send deputies to represent them in their absence. The Chair may invite specific colleagues to address the Committee where appropriate.

6.3 The Committee is serviced by the Trust's Research & Innovation Manager who shall organise meetings, prepare the annual work plan and record proceedings. Papers shall be available at least five clear days before each meeting. Papers shall not be tabled unless it is essential and only with the Committee Chair's prior agreement.

6.4 Terms of reference are reviewed annually or in the light of changes in practice or national/local guidance. The Board will initiate the mechanism to review performance, which shall include the extent to which the Committee has operated in satisfaction of its terms of reference, and in particular compliance with reporting arrangements to the Board.

Appendix B: 2021/22 Workplan

Agenda Item	1 May 2022	2 Aug 2022	3 Nov 2022	4 Feb 2023
Strategy Update				
• Review of objectives/KPIs	♦	♦	♦	♦
Performance/Metrics				
• Performance in Initiation and Delivery (PID) • Recruitment to time and target (NIHR Clinical Research Network High Level Objective) • Participant portfolio recruitment against target • Number of portfolio studies recruiting participants	♦	♦	♦	♦
Workforce Integration Project				
• Update on programme	♦			
Supporting research delivery in the NHS				
• R&I Operations • Real World Data update	♦ ♦	♦ ♦	♦ ♦	♦ ♦
Research infrastructure update				
• Biomedical Research Centre update	♦	♦	♦	♦
• Clinical Research Facility update	♦	♦	♦	♦
• National Pathology Imaging co-operative update	♦	♦	♦	♦
Supporting innovation in the NHS				
• Innovation update •	♦	♦	♦	♦

• Innovation District update	♦	♦	♦	♦
• NIHR Surgical MIC update	♦		♦	
• NIHR Leeds MIC update		♦		♦
Presentations				
• Research	NIHR Research Grant recipient (Alabama)		Leeds Hospital Charity Research and Innovation Strategy	
• Innovation		Use of AI in Breast Cancer imaging diagnostics (Nisha Sharma)		Innovation Pop-up partner case study: 3D Lifeprints
Finance Report	♦	♦	♦	♦
Risk Review	♦	♦	♦	♦
Chair's Items	♦	♦	♦	♦
Items for Information				
• UoL/LTHT Joint Research Governance Group minutes	♦	♦	♦	♦
• NIHR Annual Reports & Feedback			♦	♦
Board/Assurance Reports				
• Annual Report & Work Plan				♦
• Audit Committee Assurance				♦
• Terms of Reference review				♦
• Committee objectives review				♦

Appendix C: 2022/23 Workplan

Agenda Item	1 May 2022	2 July 2022	3 Nov 2022	4 Feb 2023
Strategy Update				
• Review of objectives/KPIs	♦	♦	♦	♦
Performance/Metrics	♦	♦	♦	♦
• Performance in Initiation and Delivery (PID) • Recruitment to time and target (NIHR Clinical Research Network High Level Objective) • Participant portfolio recruitment against target • Number of portfolio studies recruiting participants				
Supporting research delivery and creating research capacity in the NHS	♦	♦	♦	♦
• R&I Operational update • Research workforce - developing medical and healthcare professional capacity, training and development (Research Academy) • Research Governance update • Patient and Public Involvement and Engagement • Marketing and Communications • Real World Data programmes • Major bids in development				
Major research infrastructure programmes update	♦	♦	♦	♦
• Biomedical Research Centre • Clinical Research Facility • National Pathology Imaging co-operative • Cancer Research Centre				
Supporting innovation in the NHS				
• LTHT Innovation programme update	♦	♦	♦	♦
• NIHR Surgical MIC update	♦		♦	
• NIHR Leeds MIC update		♦		♦
Presentations				
	X	BaBI Leeds	Our Future Health	Patient and Public Involvement and

				Engagement in Research (Amy Rebane and Hanif Ismail)
Finance Report	♦	♦	♦	♦
Deep Dive into Research Finances		♦		
Risk Review	♦	♦	♦	♦
Chair's Items	♦	♦	♦	♦
Items for Information				
• UoL/LTHT Joint Research Governance Group minutes	♦	♦	♦	♦
• NIHR Annual Reports & Feedback		♦		♦
Board/Assurance Reports				
• Annual Report & Work Plan				♦
• Audit Committee Assurance				♦
• Terms of Reference review				♦
• Committee objectives review				♦

Appendix D: Research Summary

Research Operations and Performance

The committee received reports throughout the year from the R&I Triumvirate on the overall LTHT performance in research delivery and its operational management. In August, the committee heard that the integration programme bringing the delivery teams and finances associated with research into the central R&I structures was completed (bar one area which was going to be more challenging). Completion of this programme will allow us to redevelop the Research workforce and cover areas that have previously not received support because they have fallen between historic silos. Completion of this came at the same time as research activity was starting to return to more "business as usual" although with the addition of a portfolio of COVID research. The focus of the COVID research portfolio during the year was around follow-ups for studies recruited to over the past 12 months as well as additional work for the Novavax vaccine study, booster studies (in particular the COV-Boost study which was published in The Lancet in December) and vaccines in pregnant women. It was noted in the May committee meeting that the biggest impacts of the COVID pandemic on research delivery had been in Oncology and Surgical disciplines and that significant work was required to rebuild those. In May 2021, it was reported that the 2020/21 performance for research delivery had been very strong despite the pandemic and overall performance metrics for research delivery presented to the committee during the year were strong

One of the major challenges that the team have been working hard to resolve during the year is the backlog associated with studies in the local setup and approval process. This is the governance process the Trust has to undertake to ensure it has the capacity and capability to deliver research studies both within research delivery teams and in supporting services such as pharmacy and radiology. Where imaging is required it also ensure that imaging doses that participants are receiving are correct. Due to COVID, a large number of studies in this process had been "paused" so that efforts could be focused on studies relating to the COVID pandemic. This had created a significant backlog of studies, meaning that double the number of studies were in the setup process compared to pre-COVID times. Throughout the year, the committee received assurances about the work going on in R&I to manage this backlog, using additional resource secured from the CRN in some areas, and ensure studies were opening. Communications with PI's were being managed through the restarted "R&I Clinical Leadership Committee" which was allowing clinical leaders in research to highlight areas of need and challenge for the R&I management team to work on; setup of studies had been a particular focus at the October meeting of that group.

In May, Julie Evans was introduced as the new Head of Nursing (Research and Innovation) and in August Ai Lyn Tan was introduced as the new Director of Research and Innovation for the Trust.

Health Professional Research Careers

This was a new agenda item introduced after discussion at the May meeting of the committee. A recent consultation had resulted in "non-medical research careers" being changed to "healthcare professional research careers" to help redefine group and make the terminology more inclusive. LTHT has had significant successes to date in securing funding for fellowships (>40 secured to date) but we are now looking at how we build new leadership model to support more widely; his builds on the leadership that Heather Iles-Smith had previously provided. Job descriptions are currently being finalised to create a multi-disciplinary leadership structure across the Trust to push agenda ahead further. The committee also heard how the team are starting to support staff from other NHS Trusts (Harrogate and Mid Yorkshire) and how some "medical" staff were also being supported. The crucial role of the Leeds Hospital Charity in helping staff get started through

funding support to allow them to develop applications for personal fellowships. This is a key part of broadening inclusivity for research at the Trust.

National Institute for Health Research (NIHR) infrastructure:
The Trust hosts a number of major NIHR infrastructure awards:
- Leeds Clinical Research Facility (CRF)
- Leeds Bioresource
- Leeds Musculoskeletal Biomedical Research Centre (BRC)
- Leeds i*n vitro* Diagnostics Co-operative (Leeds MIC)
- Leeds Medical Technology Co-operative (Surgical MIC)

Progress and annual reports for these awards are reported to the R&I Committee and the following reports have been submitted for review and information:

- Annual and finance returns to the NIHR

NIHR Leeds Clinical Research Facility (LCRF)

In February 2021, the NIHR Clinical Research Facility was awarded £8.7m between September 2022 and September 2027 following a funding competition through which a bid for £10.9m was submitted In September 2021. This was the culmination of a number of pieces of work looking at the leadership, governance, portfolio and estate for the CRF. Space for a new 4 bed, 4 chair CRF at Chapel Allerton had been identified and the estates team were prioritising the development of that. A formal process has been undertaken to appoint co-director and delivery spoke leads at each site to allow support for experimental medicine leadership right across the Trust. Governance processes have been improved so that all a consistent approach to oversight of high-risk studies is implemented across the Trust by August 2022.

One of the major pieces of work reported in May 2021 was the work carried out to address NIHR's concern raised in the previous annual report (but none of the ones before that) that LTHT receives little funding but reports more studies than many others. There was a clear steer from that we therefore needed to review portfolio and only report studies where clear input had come from NIHR funding and not from the wider quanta of funding that underpins the work of the CRF. This work meant that the feedback from the 2020/21 Annual report was very positive with all measures ranked as Green. To February 2022, there had been a 6.4% increase in the number of studies on the CRF portfolio.

NIHR Leeds Biomedical Research Centre (BRC)

Like the CRF, the BRC submitted a bid for funding for a further 5 years on 20th October 2021. This bid was far broader than the current BRC, bringing in Surgical Technologies, Cardiometabolic Disease, Haematology, Infectious Disease and Pathology alongside the established Musculoskeletal Disease theme. A total of £28.5m was bid for with an outcome expected in May 2022.

The 2020/21 annual report is currently being prepared and the business plan for an 8 month extension has been submitted with approval awaited. The 2020/21 BRC annual report feedback has been received from the NIHR with a "green" rating overall, but with one amber area as an Intellectual Property (IP) meeting had not yet gone ahead with the NIHR. This was resolved in a

February meeting with NIHR. The wider BRC performance has been strong with multiple funding bids for projects secured.

Work on COVID vaccine responses in immunodeficient patients with RA has had impacts on local and national guidance on how these patients should be managed in terms of their booster vaccinations.

National Pathology Imaging Co-operative (NPIC)

NPIC now has 29 partners across the Wave 1 and Wave 2 projects and good progress is being made against programme deliverables. The NPIC Innovation and Training Centre in the Robert Ogden Building was reported as being complete at the May 2021 meeting and an opening event will be held when it is possible to do so. Technology partners for long-term Digital Pathology PACS (SECTRA) and image storage (Exponential-E) were procured during the year and a programme extension to the end of December 2023 has been agreed for Wave 1 funding due to the delays caused by COVID-19. Datasets have been provided for the exemplar AI projects within NPIC, proving that routinely collected Digital Pathology data can be extracted, de-identified and released for research purposes.

An ongoing challenge for the project has been the roll-out of technology due to the COVID-19 pandemic. To mitigate against this, the project as originally conceived has changed so that multiple deployments can happen at once to allow programme to catch up rather than doing one deployment at a time. Work was progressing with WYAAT executives to help them understand any longer term costs and benefits beyond the end of the current funded programme.

More widely, through participation in a European consortium (Big Picture), Leeds is now the European Centre for Quality Assurance and a partnership has been developed with Genomics England to scan all slides associated with the 100k Genomes project. Both of these activities are part of the longer-term sustainability plans for the programme.

Appendix E: Innovation and Real World Data Report Summaries

Innovation

Work has continued to develop "Innovation" activity across LTHT. The aim of the programme is to be an enabler through which staff within the organisation can be supported with Innovation programmes and whereby partner organisations can easily connect with expertise in the organisation by:

(a)   Identifying and understanding unmet needs within LTHT / services

(b)   Identifying opportunities for training to help create and support a culture of Innovation, to support ideation, entrepreneurship and adoption

(c)   Develop collaborative solutions to identified needs where no solutions exist

(d)   Access data (through the R-DIT team) for AI training and other data-related projects

(e)   Carry out product evaluations (using the research infrastructure)

(f)   Support adoption and generate real-world data on clinical impact from use of products in clinical services

Over the past 12 months the committee has heard about the development of the Business Development and Innovation team, the opening of an Innovation facility (the "pop-up") at the Leeds General Infirmary site and a range of projects and initiatives that the team are progressing. Examples of such projects and initiatives included:

i.   The development of innovation training for staff in the Trust (due to launch in May 2022)

ii.   The launch of a monthly "Innovation Club" that any Trust staff member can join

iii.   The development of a wide range of international links to source innovations for the Trust globally and to support wider economic development initiatives in Leeds

iv.   An assessment of "unmet needs" in Motor Neurone Disease services to align with the development of the Rob Burroughs Centre

v.   Radiofrequency monitoring in A&E

vi.   The "Health Entrepreneur Exchange Programme" - a collaboration with colleagues in Barcelona which provided entrepreneurship development opportunities for staff members

Alongside this, the Business Development and Innovation team reported that in the 12 months to August 2021, they had engaged with over 150 companies, were working on >30 potential collaborations between industry and LTHT and had attracted 2 businesses to set-up in the Leeds City Region creating 3 jobs.

The "pop-up" provides a focal point and open door for staff with ideas to access innovation support and serves as a template from which to build our vision for a wider innovation district in 2026 using some of the estate released by the new Hospital developments. The pop-up is also accessible to businesses, allowing them access to hot-desks or space from which to run their operations. Feedback from external partners is that the way the pop-up and the innovation team have been conceptualised and set up is "World Class".

Real World Data

Within Research and Innovation at LTHT is a team (R-DIT) dedicated to the extraction, de-identification and release of routinely collected clinical data where it is required for research projects, and is the route through which all such requests are handled and processed. These projects can include big data analysis or AI training and capabilities and infrastructure developed by the team support the use of a wide range of data types including images (digital pathology, radiology) and structured data collected in a wide variety of systems across the Trust. The work of the team is overseen by the LTHT Data Access Committee which reviews and approves requests for datasets being made by research teams and alongside set processes ensures that there is strong governance around the work of the team which mirrors processes of NHS Digital and other bodies. The team also provides infrastructure and capabilities to support the work of NPIC, NCIMI (National Centre for Innovative Medical Imaging), DATA-CAN (Health Data Research UK (HDR-UK) Hub for Cancer) and Gut Reaction (HDR-UK hub for IBD), all of which the Trust are partners. The team also supports the interface with the NIHR Health Informatics Collaborative (HIC) which is closely aligned to the NIHR Biomedical Research Centres.

The committee has heard about 2 established and 1 developing strategic projects around use of LTHT's routinely collected clinical data in the last 12 months:

1. **OMOP Common Data Model**
   In early 2021 €100k was awarded to LTHT to support the transformation of its data assets into a common data model called OMOP, allowing de-identified LTHT data to be analysed alongside data from other sites that is in the same model format. This is potentially very powerful for research. Whilst initially intended that this data model would be used for research only, there has been significant interest in it being adopted more widely in LTHT as part of the new Data Platform. We have had personnel from the Data Platform team as well as the Information and Insight team involved in the programme and the benefit of this will be that all routinely collected data in the Trust will be transformed into this model for all purposes, not just for research purposes.

2. **IQVIA Partnership**
   The Trust has an established partnership with IQVIA for the last 6 years around the use of routinely collected clinical data and in the August meeting, Geoff Hall gave a detailed update on what the partnership has delivered over that time. The partnership with IQVIA is yielding a number of major projects with a focus currently in small cell lung cancer, non-small cell lung cancer and bone metastases. The partnership with IQVIA supported the creation of DATACAN and has also meant that Leeds has been included in an EoI for a £20m CRUK Grand Challenge application led by IQVIA looking at Cancer Cachexia.

3. **Flatiron Partnership**
   Throughout the year, the committee were appraised of a partnership with a company called Flatiron Health that the Trust were exploring. The purpose of the partnership would be around the use of data to improve cancer outcomes for LTHT patients and generate

new insights through secondary use of data for research, with both direct and indirect long-term benefits to LTHT and its patients. The attractiveness of Flatiron as a partner is their ability to "curate" data to a very high quality and create unique datasets sourced from patients across the world through which researchers can identify features that may benefit cancer patients. Flatiron have an existing data practice in the USA however this partnership would be the first of its kind in the UK. The work with Flatiron has required significant work developing a data sharing model that complies with current data laws, patient and public involvement to test acceptability of the partnership, clinical engagement to ensure clinical colleagues can see the benefits of the partnership for their clinical practice and the negotiation of various partnership and data processing contracts to cover the partnership. External support and assurance has been received for the Trust from NHSx and DLA Piper.

Appendix F: Finance Report Summary

Significant work has taken place during the year to assess the ongoing impacts of COVID on research finances at LTHT and the medium-term impacts on individual teams within R&I. The finance team has worked closely with the BRC and CRF teams on the bids that were submitted and have supported the NPIC team with the complex financial requirements of that programme. Throughout the year the impacts of COVID across all the research teams has had to be assessed and arrangements for managing (often complex) COVID trials / financial arrangements implemented.

The R&I Business Management and finance teams have been working together to look at how issues are resolved and to spread the financial management workload so that the right skills are being used to support teams. This is part of the "lean working" programme that is being implemented to support R&I activities and improve the experience of stakeholders involved in research in the Trust. Teams have linked out to other NHS Trusts (Nottingham, Sheffield, Newcastle) to learn more about their processes and understand how they work to see if there is "best practice" we can learn from elsewhere. Costing logs have been implemented and new financial information reports have been developed. Finance training has been delivered as part of the "Research Academy" programme and an approval process for managing Excess Treatment Costs implemented.