



# R&D ANNUAL REPORT

## 2021/22

**Barts Health NHS Trust - Research & Development**

[www.jrmo.org.uk](http://www.jrmo.org.uk)

[www.bartshealth.nhs.net/takepart](http://www.bartshealth.nhs.net/takepart)

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# EXECUTIVE SUMMARY

The Covid-19 pandemic has again affected our research activities this year. Recruitment to many of our clinical trials and research studies was impacted for most of the year by surges in Covid-19 infections and hospitalisations. Although our studies were not formally suspended, recruitment was, as anticipated, less than we have achieved in pre-Pandemic years. Nevertheless, BH recorded the highest number of recruits to NIHR portfolio studies in our Network this year and the total number of patients actively involved in our research studies and trials, whether in treatment modalities or tissue donation and participating in questionnaire studies is around 32,000.

Our financial performance was also good this year and our total income was £27,821K exceeding our forecasts by 9%. Our income from commercial clinical trials was strong, particularly from the vaccine studies we continue to be involved in and our income of £8,332k was 16% above our forecast for the year.

One of the major challenges we have faced this year has been managing the desire of our researchers and external funders to set up new studies that in many cases have been on hold during the last two years because of the pandemic. The number of studies on our portfolio and in set-up is increasing and we anticipate a very positive drive by our researchers to re-start their programs and offer our patients the opportunity to be involved in leading-edge research in 22/23.

Two major applications for funding through the National Institute for Health Research large infrastructure programme were submitted last year. Our bid for Clinical Research Facility support funding was successful and will have a significant impact on achieving our vision of creating a world-class facility at the Royal London Hospital site. Our bid for Biomedical Research Centre funding has reached the final selection round and the results will be published early next year.

Our major research risks are identified in Appendix 3 to this report.

On balance, considering all the unusual difficulties that our researchers had to deal with, 2021/22 turned out to be a good year for research at Barts Health.

# INTRODUCTION

In setting out our objectives for this year we took account of the fact that the continuing Covid-19 pandemic would impact on research and the top line targets we set reflected what we anticipated that impact might be. Throughout the year we navigated several infection surges but continued our input to Covid-19 vaccine and treatment studies and managed a large increase in the number of new trials and studies our research community were eager to participate in, a clear indication of our researcher's commitment to the Trust's drive to grow our research activities.

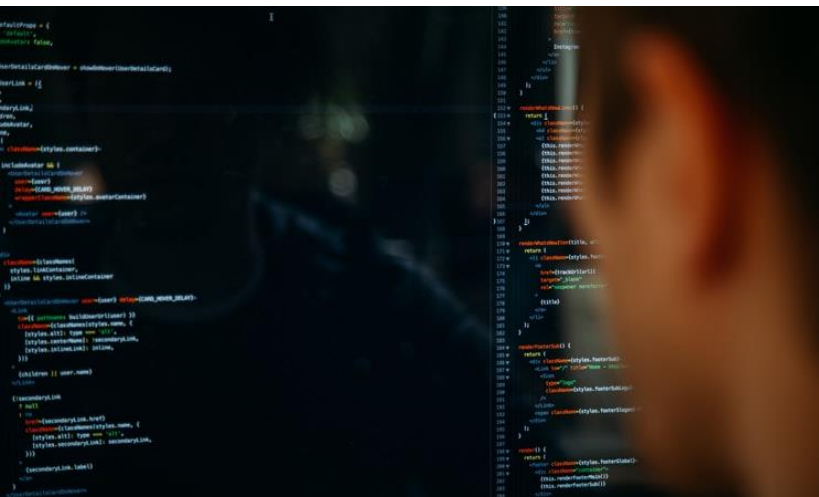
Our report this year includes stories from our research groups that illustrate the real impact that our research can have on the way we deliver healthcare now and, in the future, introducing innovative approaches to the delivery of treatment and therapies to our patients. These are only a small sample of the wide range of research activities, across all our specialities, that our research groups are delivering to our patients.

# RESEARCH IMPACT STORIES

## AI at Barts Life Sciences spares patient's limb amputation

New ground-breaking AI technology has helped [Barts Life Sciences \(BLS\)](#) identify people at risk from diabetic complications. Patient data reviews that would have taken clinicians over 100 years to complete can now be done in weeks using new technology, supplied by [Clinithink](#). The system was used to scan 14m documents to find patients with diabetic foot disease (DFD), a potentially serious, life changing complication. Using

the new software our researchers found 30% more patients with diabetes and 375% more patients with DFD than would normally be expected. In the next phase of work planned by Dr Sophie Williams, the lead research data scientist, the characteristics extracted by the software will be used to determine whether patients most at risk from DFD can be predicted. There are over 3,000 patients with DFD in London alone. This technology and how it's benefitting patients and clinicians was [featured on inews](#).



AI scanning underway

## New class of drug leads to 30% reduction in cancer deaths

A new class of drug known as 'antibody-drug conjugates' (ADCs), designed to target chemotherapy directly at bladder cancer cells has increased survival rates by 30%, according to results from a phase III clinical trial led in the UK by Prof Tom Powles at Barts Health. This research found that the risk of death was 30% lower with the new drug than with chemotherapy, with a median survival of approximately 13 months for the new drug. 40% of patients had a complete or partial positive reaction to the ADC therapy, compared to 18% on standard chemotherapy; side effects were manageable and similar to chemotherapy. The results were published in the [New England Journal of Medicine](#) and presented at the 2021 American Society of Clinical Oncology's Genitourinary Cancers Symposium.



Prof Tom Powles

## Heart Centre researcher wins prestigious award

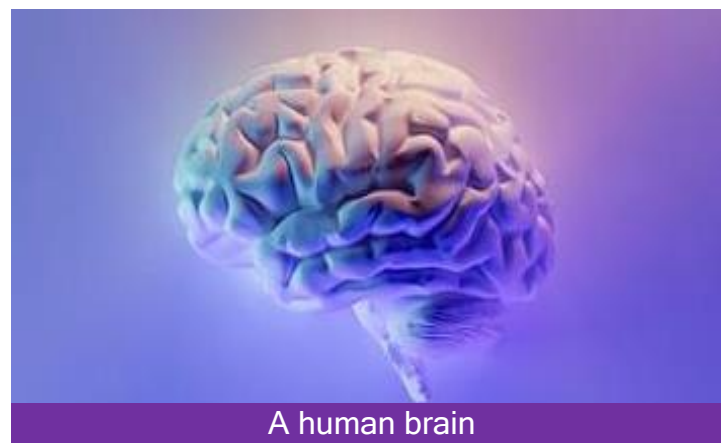
In October Dr Rebecca Hughes of Barts Health won [the British Society of Cardiovascular Magnetic Resonance \(BSCMR\) Annual Young Investigator Award](#). She discovered that all the patients in her study, with apical hypertrophic cardiomyopathy, also had impaired blood flow within small arteries at the tip of the heart. Dr Hughes' research uses the

novel 'perfusion mapping' technique developed at Barts Health to visualise and quantify blood flow. Clinical research fellow Dr Hughes said: "In research, it is very rare for a new finding to be 100% prevalent. This new insight has the potential to change how we understand the development of the disease, how we diagnose it, and suggests avenues to explore for targeted treatment options in future. It is a privilege to be part of the research team at Barts Heart Centre under the supervision of Professor James Moon, and I am delighted to have won such a prestigious award." More information can be found on the [Trust website](#).



## New approach to traumatic brain injuries revolutionises diagnosis and treatment

New research led by Barts Health and Queen Mary, suggests that biochemical analysis of brain tissue could be used for diagnosis and prognosis of severe traumatic brain injury (TBI) to improve patient outcomes and save billions in future clinical trials. The study, led locally by Dr Chris Uff and Dr Ping Yip and published in [Biomedicines Journal](#) in February, is the first to look at what happens to the injured brain at a cellular and molecular level in the acute phase. The study involved 25 adult patients – with brain biopsies obtained shortly after injury undergoing specialised analysis called immunohistochemistry. This analysis revealed previously unknown cellular and biomolecular changes, allowing the researchers to 'score' the severity of injury using their own novel grading system. That information could determine whether patients might benefit from certain treatments. Current neuroimaging techniques such as CT and MRI and based on the Glasgow Coma Scale developed in 1974, lack the resolution to detect cellular and molecular changes, so this adds significantly to the diagnostic tools available.



# PERFORMANCE AGAINST OBJECTIVES

## 2021/ 2022

### Successful bid for major NIHR CRF funding

Barts Health was awarded, for the first time, prestigious funding for a National Institute for Health Research (NIHR) [Clinical Research Facility \(CRF\)](#) at the Royal London Hospital. This is a major enabler and will attract further research investment. NIHR feedback was that the community and patient engagement strategy, led by Dr Vanessa Apea, Neeta Patel and Prof Chloe Orkin, was “exemplary”. Our application to Barts Charity to fund the associated building works and underpinning support costs for the CRF is progressing with the Charity incorporating fundraising for the Facility into its [Barts 900 campaign](#). Our CRF is designed to capture the best elements of current early-phase trial teams, build an inclusive model with equity of access for all our patients and so provide the infrastructure that enables research to grow at Barts Health.

### Re-start programme

For the last two years the number of studies actively recruiting patients has declined as studies and trials were suspended or recruitment halted, due to the pandemic. As the situation eased a managed recovery process was initiated by the NIHR, with the objective of reinvigorating research activity in the NHS, identifying priority studies that trusts should focus on in their re-start programmes. In addition, the number of new studies coming through from pharmaceutical companies and academic institutions significantly increased as organisations released new studies from their development portfolios that have steadily accumulated but couldn't start because of the situation in trusts. The result has been a significant increase in the number of studies seeking start up approval, putting huge pressure on the JRMO Governance and Contracting staff. A managed re-start programme was set up to prioritise projects in accordance with NIHR guidelines. As a result, we had seventeen Covid-19 studies open to recruitment in 21/22 and 157 other studies were 're-started'.

### Covid-19 Research

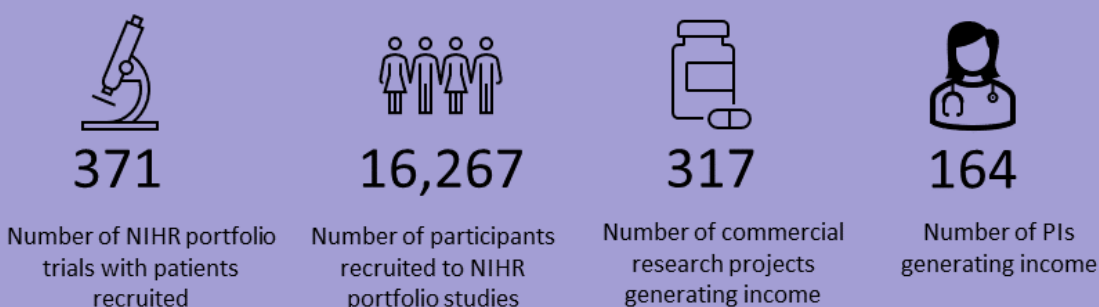
We have continued to follow national guidelines on Covid 19 prioritisation of Urgent Public Health projects this year and supported participation in seventeen Covid-19 vaccine and treatment studies recruiting 5,272 subjects to them. Following the successful delivery of the ENSEMBLE-2 vaccine trial, the centre has delivered an additional four Covid-19 and other vaccine trials. The centre has also moved to a permanent base at Mile End Hospital, where it will continue to have a specific focus on vaccines trials.

# FINANCIAL PERFORMANCE AND INITIATIVES

## Key Performance Indicators - income



## Key Performance Indicators - activity



### Research Finances

In forecasting outturn for 2021/22, the continuing impact of the pandemic was considered and a conservative estimation of total income of £25.5m calculated. In the event actual outturn was £27.8m, 9% above forecast and roughly the same as our 20/21 outturn. Commercial income outturn was £8.3m against a target of £7.2m and although less than our 20/21 outturn, which was boosted from significant income received from our vaccine trials, it does indicate an increase in commercial trials activity due to the positive impact of our research re-start programme. See Table 1 for high level KPI breakdown and Appendix 1 for Clinical Board breakdown.

### Activity Indicators

This year we recruited over 16,000 patients to our NIHR portfolio studies, the highest recruitment rate in our Network region and in the top five in the UK, which was on a par with our outturn projections. The number of trials we recruited to has also risen significantly which reflects the effort put into our research re-start program.



<b>Table 1: Actual Outturn 2021/22</b>	<b>2021/22 Target £000</b>	<b>2020/21 Outturn £000</b>	<b>Inc/ Dec %</b>	<b>2021/22 Outturn £000</b>	<b>RAG</b>
Commercial Research Income	<b>7,180</b>	9,573	-25%	<b>8,332</b>	
NIHR Projects Income	<b>16,000</b>	16,070	0%	<b>16,426</b>	
Charitable and Other Income	<b>2,343</b>	2,232	5%	<b>3,064</b>	
<b>Total Income (NIHR, Commercial and Other)</b>	<b>25,523</b>	<b>27,875</b>	<b>-8%</b>	<b>27,821</b>	
Number of portfolio trials with patients recruited in current FY	<b>230</b>	191	20%	<b>371</b>	
Number of portfolio patients recruited in current FY	<b>16,000</b>	15,965	0%	<b>16,267</b>	
Number of commercial research projects generating income in last 12 months	<b>370</b>	439	-16%	<b>317</b>	
Number of PIs generating income in last 12 months	<b>185</b>	160	16%	<b>164</b>	

### Life Sciences Research

During 2021/22 The Barts Life Sciences research programme of artificial intelligence (AI) and machine learning projects, launched five new projects working with industry partners, ranging from using AI Intelligence to improve the diagnosis of thyroid cancer to establishing digital visual biomarkers indicative of disease progression and disease stability in children with optic pathway glioma using a vision-science video game. The Data Sciences team have Continued the delivery of the Covid-19 Dataset for national requirements in addition to undertaking a range of initiatives with the NIHR Health informatics Collaborative and other partners that use data to address a range of important healthcare issues, developing tools and models in reproducible analytical pipelines to support research across the Trust for example, using patient notes to predict vascular complications of diabetic foot.

### Other Strategic initiatives

Once again, the impact of the pandemic has impacted on some of our planned activities this year. But significant progress has been made in many areas.

### Biomedical Research Centre (BRC)

Our ambitious and strong bid for a much-enlarged BRC was submitted this year reflecting our aim to expand the scope of our research activities to four interrelated themes from the current single funded theme. Success in this bid will enable a step change in the range of research activities that we can engage in with our partner Queen

Mary University of London and enable significantly increased future financial support from the NIHR.

## People Initiatives

Our priorities this year were centred around improving our people capacity in research, reinvigorating those initiatives that were either suspended or stalled as a result of the pandemic and focusing on our research recovery activities. Our consultant leadership programme was reduced this year and we continued to work with QMUL to establish new clinical academic roles in areas where research activity is low. Our Whipps Cross Hospital Academic Centre for Healthy Ageing proposal is progressing with Barts Charity and we are optimistic that this innovative initiative will be funded. This will create at least two senior clinical academic posts in geriatric medicine at WXH. Our drive to engage more of our nursing and allied health professionals in leading research has not made the progress that we had hoped for and this will be an area of focus for the coming year. We also plan to explore options for managing our research delivery staff establishment with a view to developing a more flexible and responsive research workforce.

## Patient and public involvement and engagement

Building on work started in July 2020 to support our community engagement on the topic of vaccines research, our priority has been to support our researchers to engage with groups historically under-represented in research. We have also delivered or participated in several online events, workshops and discussion forums about research, health inequalities and effective community engagement. Outputs include the production of a culturally sensitive [short animation](#), which has been made available to our research workforce as a tool to support community engagement.

There has been a notable increase in the number of requests from researchers seeking PPIE advice and guidance. In particular, the number of queries relating to ‘payment for involvement’. Working with JRMO senior finance manager and others we have introduced [new payments guidance](#) for researchers.

Other work has included, in partnership with Trust, Queen Mary and our CRN comms departments, the production of a number of case studies, press releases and/ or videos about Barts Health research activity, including [Medicago](#), [RECOVERY](#), and the [Barts 900](#) charity bid. By way of example, please see Karen’s story on the next page.

During 2021/22, we also reinstated our PPIE practitioners network, comprised of PPIE leads from across Barts Health, Queen Mary and regional partners (e.g. UCL Partners, CRN:NT); relaunched NIHR Patient Research Experience Survey (PRES) (see Appendix 4 for 21/22 results) and; re-established our [Patient Research Champion](#) programme; activities which were either paused or greatly reduced during the pandemic.

# TRIAL PARTICIPANT EXPERIENCE

## Karen's story - published: 21 May 2021, Clinical Research Network: North Thames

As a nurse herself, Karen was caring for others when she was struck with Covid-19 in November 2020.

She was admitted to Whipps Cross Hospital with double Covid-related pneumonia and moved to the acute respiratory ward, where she was invited to take part in the RECOVERY trial. She immediately grasped the opportunity and feels that her participation may have helped her leave hospital sooner than she might otherwise have done. She says:

"I said yes straight away. I wanted to take every opportunity as even if it didn't benefit me, it might have benefited someone else. Any information was desperately needed then."

Karen received several treatments on the trial, including dexamethasone, which was later shown to assist recovery and reduce deaths in patients who were ventilated or receiving oxygen. She remembers:

"I was very poorly and felt it could have gone either way, but in a short time began to make a fast recovery. It felt really good to be part of the research."

"It was such a scary time. No one really knew what to do about Covid then and I was very scared. It was a horrible feeling to know you are diagnosed with double pneumonia right in the middle of a pandemic but everyone on the trial was so positive. They said 'we've learnt so much already, we'll get you through this'."

"I thought previous trials have been going on to lead to this point and without those, we wouldn't have made progress already. It made a lot of sense to help carry on and contribute more to the knowledge."

Whilst the trial was searching for new treatments, Karen herself was not a stranger to research. Fifteen years ago, she had been diagnosed with a sarcoma (a rare form of cancer). As a result, she had already taken part in several trials into radiotherapy, genomics, and the effect of hormones on sarcomas. She has even been involved as an NIHR CRN patient representative for sarcoma studies, as well as contributing to patient reviews in cancer trial protocols.

Karen was discharged from her Covid-19 admission at the beginning of December but was then affected by 'Long-Covid'. She feels grateful not to have suffered with all possible symptoms, but her muscles were initially badly affected.

As an avid walker, she had plans to stride 50km for charity this year but for some time, was struggling to walk to the door. It took a long time to recover her energy and her thinking and concentration were also affected.

Six months on, she is at last feeling better. Karen is walking again; can soon re-join her walking groups and is looking forward to returning to work. Finally, some good news too, as she is delighted to have been recently discharged after her 15 years of cancer.

With so much behind her now and with so much ahead to look forward to, Karen reflects on the important part that research has played for her.

"It feels so good to be walking again and back in the forest but I'm so glad I could be part of the research. No matter what the field, clinical trials are so essential in developing better patient care and to improving peoples' outcomes."

"I'm just grateful. It feels like everyone is pulling together with research. Even if a trial shows a treatment isn't working, it's still good because we are learning what not to waste time on."

When asked what message she'd give to others who are considering getting involved, she says:

"Don't be scared of research. You could benefit directly yourself and so many other people as well. I would encourage anyone to take part in clinical trials. Without people taking part, we wouldn't know what we know about treatments already."



# FORWARD OBJECTIVES: 2022/23

In setting out our plans for the year ahead we will re-focus on the delivery of our five-year strategy by re-starting our research programmes as our hospitals return to business as usual. We will also re-visit the strategic plan which is due for renewal in 2024 and work with our primary academic partner, QMUL, to construct a new five-year Joint Research Policy.

One feature of the drive to set up new studies is that although we have more active studies on our portfolio, recruitment to these studies is low, raising questions about their viability in terms of recruiting to target or their financial viability, something that has been recognised at national level. It is clear that the NIHR have concerns about this and national measures have been put in place to curb the number of studies on the national portfolio by removing those that, in the opinion of the NIHR, are not viable propositions (see Appendix 2 Letter from Professor Lucy Chappell and Dr Louise Wood). This could impact on our grant funding and possibly commercial trial income. Our objective this year will be to put in place measures to protect our portfolio and work with our investigators to ensure recruitment levels are sustained, directing available resources to supporting those studies that can attain recruitment targets.

Once again other objectives have been impacted by the pandemic and our plans for 2022/23 will include refreshing and re-invigorating our programmes to reflect the new post-pandemic environment in which research will take place.

## Objectives 2022/23

### 1. Re-start programme and study set-up.

- We will review our study start-up procedures, introduce a proportionate review process for low-risk projects to enable us to streamline and speed up our JRMO Capacity and Capability reviews and provide additional training for our researchers and their support staff in how they can work with the JRMO to facilitate a quick turnaround of projects submitted for Trust approval.
- We will continuously review the position as the pandemic progresses, implementing relevant procedures should the UK face another surge in Covid-19 cases.

### 2. Portfolio Review

We will construct a system for continuous portfolio review geared towards ensuring that our studies recruit to time and to target. This will enable us to put in place

measures to protect our portfolio and work with our investigators to ensure recruitment levels are sustained directing available resources to supporting those studies that can attain recruitment targets.

### 3. Covid-19 Research

- We will continue to follow national guidelines on Covid-19 prioritisation of Urgent Public Health projects and
- Support participation in Covid-19 vaccine studies at the Mile End vaccine trials centre.

### 4. Finance and Performance Metrics

The Trust met all of its financial targets in 21/22 and once again this was largely due to a strong performance in recruiting to both commercial Covid-19 treatment and vaccine studies, maintaining activity levels in our cancer research programme and the effects of our re-start activities. This year it is likely that Covid-19 related recruitment will drop substantially. Although our project start-up activity is high, this has not been followed by a significant increase in patient recruitment, although we expect recruitment to accelerate as we move into and through the new year. For this reason, our forecast income has been pitched at a conservative level and will be reviewed and perhaps amended at month 6, as the position on re-start becomes clearer. Table 2 shows 22/23 forecasts.

Table 2: Forecasts 22/23	2022/23	2021/22	Inc/Decr %
	Forecast £000	Outturn £000	
Commercial Research Income	9,165	8,332	10%
NIHR Projects Income	16,000	16,426	0%
Charitable and Other Income	3,370	3,064	10%
<b>Total Income (NIHR, Commercial and Other)</b>	<b>28,535</b>	<b>27,821</b>	<b>3%</b>
Number of portfolio trials with patients recruited in current FY	390	371	5%
Number of portfolio patients recruited in current FY	17,894	16,267	10%
Number of commercial research projects generating income in last 12 months	350	317	10%
Number of PIs generating income in last 12 months	170	164	4%

### 5. Consultant leadership: Support ten consultants to become research active within two years.

Although this initiative was suspended during the pandemic it will be re-visited and revitalised next year. Consideration will be given to opening the initiative for new applicants in 2022.

## 6. Clinical academic leadership

The initial objective was to establish two new clinical academic roles in partnership with Queen Mary University of London, in departments with little or no current research activity and a post in Orthopaedics was filled in 2020. Work on this is on-going and our Whipps Cross Hospital Academic Centre for Healthy Ageing proposal is progressing with Barts Charity. We are optimistic that this innovative initiative will be funded. This will create at least two senior clinical academic posts in geriatric medicine at WXH with several avenues being explored for developing similar roles in partnership with QMUL.

## 7. Widening our Partnerships

Our new partnership with Barking, Havering & Redbridge University NHS Trust will further increase the population that our trusts jointly serve, and this provides us, as partners, with an opportunity to expand our research offer to communities in both organisations. Through partnership working we will share expertise, best practice in delivering research, collaborative opportunities and academic knowledge and know-how. We are actively talking with our opposite numbers at BHRUT about how we can support and work with them and are looking forward to engaging with colleagues from the Homerton as our collaboration expands.

## 8. Nursing and allied health professionals

This will be an area of focus this year and we will work with leaders within the Trust for nursing, midwifery and allied health professionals to promote multi-professional research activities in the Trust as part of the review of the current strategy.

## 9. Infrastructure funding

The following major projects are underway. We will review the bid outcomes as they are announced and work with our research teams to help manage their programmes.

- **Biomedical Research Centre:** The bid was submitted in 2020 and we will be informed of the outcome later this year. Our objective will be to work with the BRC senior leadership team to implement the new five-year award if the application is, as expected, successful.
- **Clinical trials infrastructure, NIHR bid:** Our application was successful for the first time and we will work with the NIHR to revise our delivery programme in line with the available funding. We will also ensure that a holistic funding plan is presented in our Outline business case to the Trust Board that incorporates NIHR, Barts Charity and commercial income sources.

## **Post Hoc Note**

We have recently been informed that our BRC bid has been successful and The Trust, in partnership with QMUL, has been awarded a five year grant of close to £21m. This compares to a current award value of approximately £6.5m and is a significant achievement by the team led by Professor Sir Mark Caulfield. We will now work to implement the new BRC programme which will start in December 2022.

## **10. Bioinformatics and information governance**

The initiative led by our Life Sciences colleagues to develop a secure data facility with robust information governance procedures to support research using NHS patient data will be continued next year. The shared objective will be to establish a service which enables our internal research community and external partners to conduct research using our patient data. The Lifesciences teams' ambitious programme of work for 2022/23 will include research and development projects in the early detection and prevention of disease, stratified medicine, patient outcome predictions and improvements in the management of patients in a variety of hospital environments.

## **11. Barts Health Research Strategy Review**

Our original plan was to re-visit the Trust's five-year strategy in preparation for the development of a new five-year strategy in 2023 but work on this was put on hold whilst the R&D leadership team dealt with contingent issues that arose as a result of the pandemic, changes to the Trust's Clinical Leadership team and the appointment of Professor Sir Mark Caulfield as QMUL's Vice Principal for Health. It has been agreed that work on a new Joint Research Strategy will begin this year to synchronise the future for research that our organisations will jointly and severally engage in.

## **12. Patient & Public Involvement and Engagement (PPIE)**

We will continue to work to ensure that we maximise the opportunities for Patient and Public Involvement and Engagement in our research. We will:

- Actively support inclusion, diversity and equity in our research endeavours.
- We will support the involvement of patient groups who are often excluded from participation in research.
- We will embed standards, reporting and a culture of feedback and evaluation to demonstrate and evidence the impact of PPIE on our research programmes.
- We will champion reward, recognition and payment for those involved in our PPIE activities.
- We will strengthen and build upon existing work by the NIHR and others and learn and share knowledge and experience of PPIE throughout our organisation.

**Rupert Pearce**  
**Clinical Director of Research**  
**29<sup>th</sup> July 2022**

**Gerry Leonard**  
**Director of Research Development**

# APPENDIX 1: KEY PERFORMANCE INDICATORS: OUTTURN BY CLINICAL

## BOARDS 2021/22

Actual Outturn 2021/22	2021/22 Target	2020/21 Outturn	Inc/Dec	AHS	Cancer	Cardiovascular	Childrens Health	CSS	Medicine	Surgery	Womens Health	Other	Total
	£000	£000	%	£000	£000	£000	£000	£000	£000	£000	£000	£000	£000
Commercial Research Income	<b>7,180</b>	9,573	-25%		2,227	1,010	124	706	4,029	235	0	1	<b>8,332</b>
NIHR Projects Income	<b>16,000</b>	16,070	0%	5,497	969	2,231	535	766	2,802	505	448	2,672	<b>16,426</b>
Charitable and Other Income	<b>2,343</b>	2,232	5%		86	1,406	108	128	797	422	82	36	<b>3,064</b>
<b>Total Income (NIHR, Commercial and Other)</b>	<b>25,523</b>	<b>27,875</b>	<b>-8%</b>	<b>5,497</b>	<b>3,282</b>	<b>4,646</b>	<b>767</b>	<b>1,600</b>	<b>7,628</b>	<b>1,162</b>	<b>529</b>	<b>2,709</b>	<b>27,821</b>
<i>Number of portfolio trials with patients recruited in current FY</i>	<b>230</b>	191	20%	0	71	45	19	14	134	67	11	10	<b>371</b>
<i>Number of portfolio patients recruited in current FY</i>	<b>16,000</b>	15,965	0%	0	566	2,207	1,550	80	9,589	1,467	529	279	<b>16,267</b>
<i>Number of commercial research projects generating income in last 12 months</i>	<b>370</b>	439	-16%	0	69	52	15	22	134	24	0	1	<b>317</b>
<i>Number of PIs generating income in last 12 months</i>	<b>185</b>	160	16%	0	18	29	12	11	63	23	4	4	<b>164</b>

Notes: 1) Combined Emergency Care & Trauma with Medicine; 2) Combined Inactive Project with CSS



# APPENDIX 2: NIHR LETTER: URGENT ACTION TO ADDRESS THE CURRENT RESEARCH DELIVERY CHALLENGES IN THE NHS



Department  
of Health &  
Social Care

**NIHR** | National Institute  
for Health Research

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39 Victoria Street  
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E: [Louise.Wood@dhsc.gov.uk](mailto:Louise.Wood@dhsc.gov.uk)  
[Lucy.Chappell@dhsc.gov.uk](mailto:Lucy.Chappell@dhsc.gov.uk)

Sent via email

17 February 2022

Dear colleagues

## URGENT ACTION TO ADDRESS THE CURRENT RESEARCH DELIVERY CHALLENGES IN THE NHS

We are writing to update you on continued efforts to support the delivery of research and our commitment to support a diverse and balanced portfolio of studies.

We remain committed to delivering on the ambitions set out in [Saving and Improving Lives: the future of UK clinical research delivery](#), and to supporting the recovery of UK clinical research delivery system needed to enable this. However, clinical research delivery is facing unprecedented challenges at present, and we believe there is now an urgent need and an opportunity to reset to build a stronger future.

The [Managed Recovery](#) process was implemented in spring 2021 and has had a degree of success. Studies selected by research funders and sponsors for inclusion in the Managed Recovery cohort have recruited more quickly than those on our wider portfolio. However, this has not had the effect of clearing the path for other studies paused or delayed in the early stages of the pandemic to return to the levels of recruitment that would normally be expected.

The Clinical Research Network currently supports studies from a wide range of non-commercial and commercial funders, with around 20% being directly NIHR-funded. The number of studies in the portfolio is currently higher than ever before. This is accounted for by the additional COVID-19 studies; other research that has remained on the portfolio from before the pandemic that has been paused or delayed by pandemic-related challenges; together with new studies being funded and coming into the system. In addition, the number of studies in set up is now much higher than prior to the pandemic, further increasing the workload for NHS R&D offices and research delivery teams. This is taking place in the context of the recovery of NHS services and the ongoing pandemic, with the most recent omicron wave significantly impacting staffing levels across the system. Throughout this the resilience of the workforce has been remarkable.

We have consulted with stakeholders across the research system and the NHS and have heard consistently that we now need to take radical action to address the situation. Data available through the NIHR portfolio management systems has confirmed this and emphasises the need for an expedited approach. We have therefore initiated work at pace

to develop options for a revised approach. It is likely that this will include closing some studies that are struggling in the current context. Subject to agreement from Ministers, we will share plans with partners and stakeholders in the first weeks of March 2022.

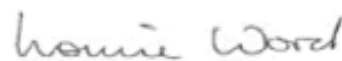
In developing options, we will consider the open portfolio, new studies coming into the system, supporting sites to make transparent and realistic assessments of capacity and capability, and potential implications of any changes on the future portfolio and UK ecosystem.

The aim of this work is to ensure that the research ecosystem can continue to flourish. We are committed to undertaking this essential work in a transparent and informed way so that together we are able to deliver on the potential of clinical research to tackle health inequalities, improve the lives of people across the UK and to boost economic recovery.

Yours sincerely



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Chief Scientific Advisor



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National Institute for Health Research – Department for Health and Social Care

# APPENDIX 3: IDENTIFIED RESEARCH RISKS

There are currently two corporate R&D risks:

## (i) Inaccuracies with research invoicing leading to a reduction in income

Not all research income is being invoiced accurately or on time possibly leading to income loss. Inaccuracies often caused by communication issues between research teams, JRMO and commercial sponsors. Sponsors then dispute or refuse to pay invoices.

There is an SOP in place that directs staff through the invoicing process and staff are fully trained in the procedure. However, the process for collecting patient activity data from research groups, pricing that information and constructing invoices via credit control is complex and there can be considerable interactions with companies that refuse to pay invoices that are marginally in error because somewhere in the information exchange chain an error has occurred. Controls are still in the process of being worked through. Additional investment in training or systems is being established and changes being made. However, there remain concerns, particularly as commercial research increases in importance due to the reduction in NIHR/ Govt funding, and a new paper has been called for by the Trust's Research Board. A review of internal arrangements has concluded now, and a staff consultation on consequential changes to work practices, team restructuring, and Job Descriptions is proceeding.

The risk rating has already reduced, due to changes to date, and it is hoped can be significantly mitigated (leading hopefully to risk closure) by Autumn 2022. It is currently deemed moderate consequence, might happen or recur occasionally (score 9).

## (ii) Reduction in UK Government research funding to Barts Health

Reduced infrastructure and support funding from NIHR, and other Government funding bodies, for Barts Health research.

NIHR and other Government funding bodies are reducing funds to support research for NHS Trusts. Influencing NIHR funding decisions is almost entirely outside of our control and the only way to address reductions in funding is to focus on generating income from other funding streams, commercial, charities and non-Government funding in general. This continues to be an issue and impact remains uncertain during this post-pandemic period with other sources of research funding restricted. The situation is now stabilising, and a substantive review of income-related risks can be undertaken in FY 22/23.

This risk is currently deemed moderate consequence, might happen or recur occasionally (score 9).

# APPENDIX 4: NIHR PATIENT RESEARCH EXPERIENCE

## SURVEY 2021/22

*“I have been well looked after with tests, appointments, follow ups etc. The team of doctors and nurses kept me updated and always came up with solutions to my problems”. Cancer study participant, aged 65-74*

In 2021/22, we again took part in the NIHR Patient Research Experience Survey (PRES), a key means of gathering feedback from patients who take part in our studies and to learn what works best for them. The feedback we gather from the survey enables us to make targeted changes in the way we undertake our research in the future. This a key part of PRES, where we can make improvements as a result of the survey. This highlights our commitment to continuously monitor our performance and adjust the way we deliver research.

We were pleased to discover the overwhelmingly positive feedback of our participants' research experiences. Here are some key figures from our 21/22 PRES campaign:

- 92% of participants felt prepared for the study before it took place
- 92% of participants knew who to contact during the study
- Throughout the trial, 95% of participants reported feeling respected by researchers

Due to recovery from the Covid-19 pandemic, we received significantly fewer responses during this year compared to previous years. Nonetheless, we collected 137 responses, equal to a second-place finish within the NIHR CRN: North Thames network. Providing us with a significant amount of patient feedback to help us better understand what is important to patients taking part in our studies, we use this feedback make improvements, where they are likely to have the greatest impact.

### **Changes made in response to PRES**

- Contacting patients by phone/in clinics and giving them the option to receive study information via their mode of conversation.
- Consider offering virtual follow-ups for patients who must travel further, as, and where possible dependent on study protocol.
- Improving ways to share study results with trial participants – currently, each study has its own dissemination SOP; the local plan is to streamline this process and create an SOP to be applied to all studies.
- Improve the dissemination of research results using infographics and other formats (such as videos), ensuring we share study results with staff and patients in a more streamlined process across all studies.
- Improve visibility of research by ensuring that current information about relevant research (for example, current trials or updates) is featured on the Barts Health website and made available in our clinics and waiting areas.

For more information about NIHR PRES at Barts Health, contact Neeta Patel, Associate Director, Research Engagement [neeta.patel6@nhs.net](mailto:neeta.patel6@nhs.net)