

UNIVERSITY HOSPITAL BIRMINGHAM NHS FOUNDATION TRUST
BOARD OF DIRECTORS
THURSDAY 25 JULY 2013

Title:	RESEARCH ANNUAL REPORT 2012/13	
Responsible Director:	Tim Jones, Executive Director for Delivery	
Contact:	Hilary Fanning, Deputy Director of Delivery, Ext 13697	
Purpose:	The purpose of this paper is to provide the Board of Directors with an account of Trust research activity for 2012/13	
Confidentiality Level & Reason:	Not applicable	
Annual Plan Ref:	To ensure UHB is a leader of research and innovation	
Key Issues Summary:	This document details key achievements for research in 2012/13 and details future plans for 2013/14	
Recommendations:	The Board of Directors is requested to: 1. ACCEPT this research activity annual report for 2012/13	
Signed:	Mr. Tim Jones	Date: 16/07/2013

UNIVERSITY HOSPITAL BIRMINGHAM NHS FOUNDATION TRUST

BOARD OF DIRECTORS THURSDAY 25 JULY 2013

RESEARCH ANNUAL REPORT 2012/13

PRESENTED BY EXECUTIVE DIRECTOR OF DELIVERY

1. Introduction

The purpose of this paper is to provide the Board of Directors with an account of Trust research activity during the financial year 2012/13.

2. Strategic Context

2.1 Partnerships

University Hospitals Birmingham NHS Foundation Trust (UHBFT) has in place a number of key relationships which allow the Trust to build and strengthen its research activity, attract funding and develop a portfolio of high quality research.

Birmingham Health Partners, a strategic collaboration between UHBFT and the University of Birmingham (UoB) was established in January 2012. Following the BHP Board meeting in December 2012, Birmingham Children's Hospital formally joined BHP as a member. BHP will substantiate and build on the existing working relationship between UHBFT, BCH and UoB, and will also create a mechanism to develop and deliver a shared strategy, specifically in relation to research, translational medicine, commercialisation, workforce development and capital planning.

The tripartite collaboration will strategically place the institutions in a strong position to attract inward investment, to generate growth within the region, to be seen as the partner of choice for translational medicine and to gain national and international recognition for clinical and academic strength.

2.2 Associate Directors of Research

To support the work of BHP and facilitate the development and delivery of collaborative research strategy, the Trust has appointed three senior clinical academic staff to the role of Associate Director of Research (ADR). The ADRs have, individually, responsibility for clinical academic groups (CAGs) within the Trust. These are: Dr Paul Cockwell (ADR for Chronic Disease and Informatics & Personalised Medicine CAGs): Dr

John Townend (ADR for Surgery, Interventions & Diagnostics): Prof. Nick James (ADR for Cancer).

2.3 Collaborative Research Hosted at UHBFT

The Trust continued to host and support a number of key collaborative research partnerships during 2012/13, including:

Cancer Research UK Centre
NIHR Experimental Cancer Medical Centre
NIHR Wellcome Trust Clinical Research Facility
NIHR Liver Biomedical Research Unit
NIHR Surgical Reconstruction and Microbiology Centre
Centre for Clinical Haematology
NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) programme
Birmingham & Black Country Comprehensive Local Research Network (BBC CLRN)
Pan Birmingham Cancer Research Network
NIHR National Office for Clinical Infrastructure (NOCRI) Translational Research Partnerships Joint and Inflammation cluster
Healing Foundation Burns Research Centre

In 2012/13 the Trust successfully led a research infrastructure bid for designation as a NIHR Healthcare Technology Co-Operative: Trauma (NIHR HTC-Trauma). The NIHR HTC-Trauma commenced operation in January 2013.

3. **Research Activity**

3.1 UKCRN Portfolio Clinical Trials

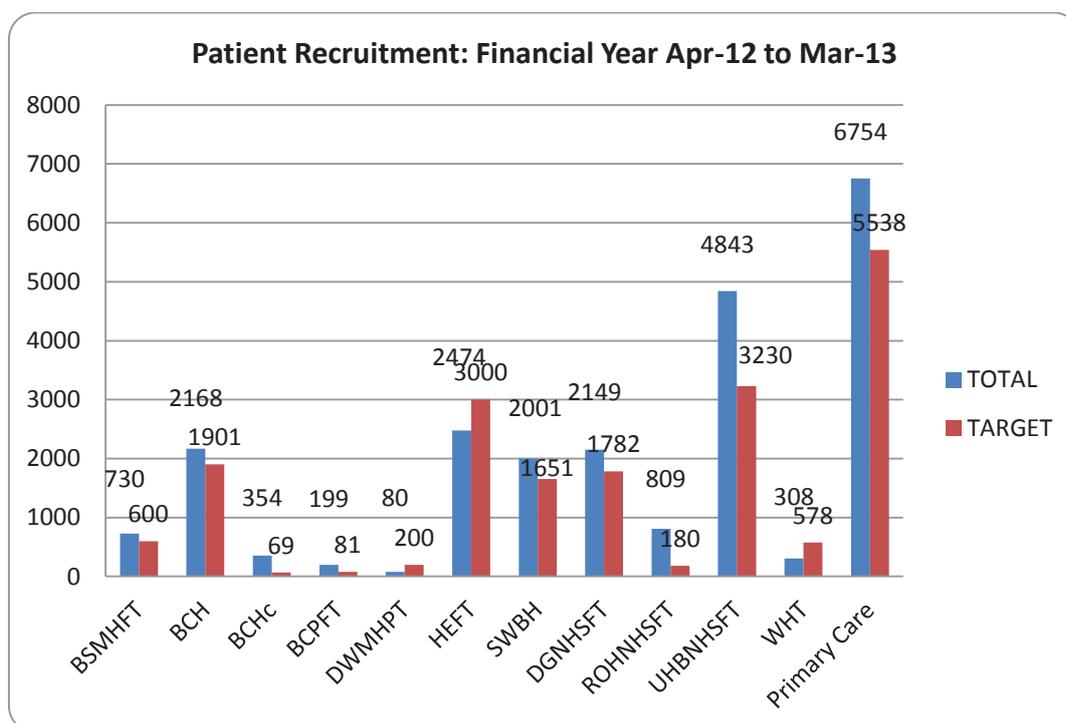
Research activity continued to grow during 2012/13. Table 1 below shows year on year patient recruitment numbers from 2008 to 2013, for UKCRN portfolio studies.

Table 1: Patient Recruitment to UKCRN Portfolio Studies

2008/09	2009/10	2010/11	2011/12	2012/13
3090	3379	3193	2194	4843

Graph 1 below provides a summary of UHBFT performance against BBC CLRN patient recruitment targets for UKCRN portfolio studies for the financial year 2012/13.

Graph 1: Patient Recruitment to UKCRN Portfolio Studies: 2012/13



3.2 Registered Research Studies at UHBFT

Table 2 below provides a year on year summary of the number of research studies registered by R&D at UHBFT, (please note these figures include both UKCRN portfolio studies and non-portfolio studies).

Table 2: Registered Studies: 2009 to 2013 ytd

Year	Commercial Studies	Non-Commercial Studies	Total
2009	62	147	209
2010	46	156	202
2011	64	154	218
2012	109	187	296
2013 ytd	65	105	301 (projected full yr)

Registered studies for 2013 are shown above as a “year to date” (ytd) figure. At current level of activity, UHBFT is projected to, as a minimum achieve equivalence to 2012 out-turn for number of registered studies.

The growth in the number of open research studies at UHBFT has recently been acknowledged in the national research league tables published annually by the Guardian newspaper.

The most research active specialities to UKCRN studies in 2012/13 are Oncology; Renal Medicine/Surgery; Rheumatology; Liver Medicine; Ophthalmology and Critical Care.

3.3 Feasibility Activity

In 2011/12 a total of 180 feasibility requests were processed through the feasibility service in R&D resulting in 38 awarded commercial studies. In 2012/13 a total of 325 feasibility requests were processed through the feasibility service in R&D resulting in 79 awarded commercial studies. At the current time, the median turn-around time for processing of feasibility requests is 2 days.

3.4 Protocol Development Service (PDS) Activity

The Protocol Development Service (PDS) has increased activity as more clinicians have become aware of the support during the grant application process. Table 3 provides a summary of the number of research funding applications to both NIHR and non-NIHR (e.g Charities) funding bodies which have been supported by the PDS.

Table 3: Protocol Development Service (PDS) Activity

Year	No. of Research Bids Submitted
2010	78
2011	50
2012	90
2013 ytd	28 (ytd)

3.6 European Union Funding Bids

EU FP7: Health 2012 Section

EU FP7: Health 2012; (R Stockley); Trigger: King of hearts, joints and lungs; periodontal pathogens as etiologic factor in RA, CVD and COPD and their impact on treatment strategies; UHB **Partner** status (2013-16) – **awarded**

EU FP7: Health 2012; (T Hiwot) Euro Niemann Pick Database: UHB **Host** status (2013-15) – **awarded** - start up meeting in Luxembourg on 17th April 2013

EU:FP7: Health 2012; (N. Inston) Development of haemodynamic solutions in renal dialysis venous access failure: UHB **Partner** status - **awarded**

EU FP7 2nd Call 2013 Section:

EU:FP7 Health (2013): (T. Hiwot): European Galactosaemia network: UHB **Partner** Status: - **submitted awaiting outcome**

EU FP7: Security 2012 Section

EU FP7: Security 2012 (K.Fawcett/J.Coleman) UHB Partner status – **Unsuccessful.**

EU FP7: PEOPLE-2013-ITN

EU FP7: PEOPLE-2013-ITN; (M Sque) UHB Associate partner to support Training Network – **unsuccessful. Re-submission planned for 2013**

EU FP7: PEOPLE-2013-ITN; (M Gray) UHB Associate partner to support Training Network – **unsuccessful**

FP7-PEOPLE-2013-IRSES (International Research Staff Exchange Scheme); P Begg) Partner Status- **Through stage 1, awaiting outcome of Stage 2.**

EU-RDF Section

EU-EDRF (Innovation engine) Partner Status – **submitted (awaiting outcome)**

EU-EDRF (Interactive health) Partner Status- **submitted (awaiting outcome)**

4. **Research Income 2012/13**

4.1 Trust R&D Income

Trust Research income for 2012/13 was £22.5m based on agreed contractual income compared to £21.6m in 2011/12. UHBFT hosts the BBC CLRN which has received £1.1m less in 2012/13 compared to the previous year due to the overall under performance of the CLRN across Birmingham and the Black Country. The direct funding for most member Trusts of the CLRN was cut due to the overall under performance of the CLRN. Flexibility and Sustainability Funding from the NIHR has also been reduced by approximately £100k.

4.2 Non Commercial and Charitable Research Income

The Trust received full year income/new monies for the following grants in 2012/13:

- a) NIHR Surgical Reconstruction and Microbiology Research Centre: £10m over 5 years (part funding received in 2011/12).
- b) NIHR Programme Grant – Investigating the implementation, adoption and effectiveness of e-prescribing systems in English Hospitals: a mixed methods national evaluation (This is a joint UHBFT/University of Edinburgh Programme Grant): £2m over 5 years
- c) High Impact Innovations funding £750k
- d) Healing Foundation Burns Research Centre designation: £1.5m over 5 years

4.3 Commercial Research Income

Commercial research income for 2012/13 was £1.3m. This is based on actual income received in the period and can vary quarter to quarter. The 2011/12 full year total was £1m.

5. **Research Governance**

5.1 Medicines and Healthcare Products Regulatory Agency (MHRA)

All actions identified at the 2011 MHRA statutory GCP Inspection were completed as planned. MHRA provided notification to the Trust that they no longer required quarterly update on progress against actions identified.

MHRA GCP inspection visits run to a two year cycle. In order to ensure preparedness pending notification of the next inspection date, R&D has re-commenced MHRA pre-preparedness meetings.

5.2 Internal Quality Assurance

28 studies were audited or monitored between 1 April 2012 and 31 March 2013. This included 17 audits, 2 start-up reviews, 5 close-down reviews and 4 monitoring visits.

5.3 70 day target reporting

The Government's Plan for Growth, published in March 2011, announced the transformation of incentives at local level for efficiency in initiation and delivery of research. As a consequence, since 1 April 2012, within the new NIHR contracts a clause relating to Performance in Initiating and Delivering Clinical Research was inserted.

The DH has not clarified exactly how the Trust will be penalised if we do not meet the new requirements. However, within the NIHR contract there is an option to place financial penalties on the Trust and take non compliance into consideration when awarding future NIHR grants. The latter came into effect on 1 April 2013.

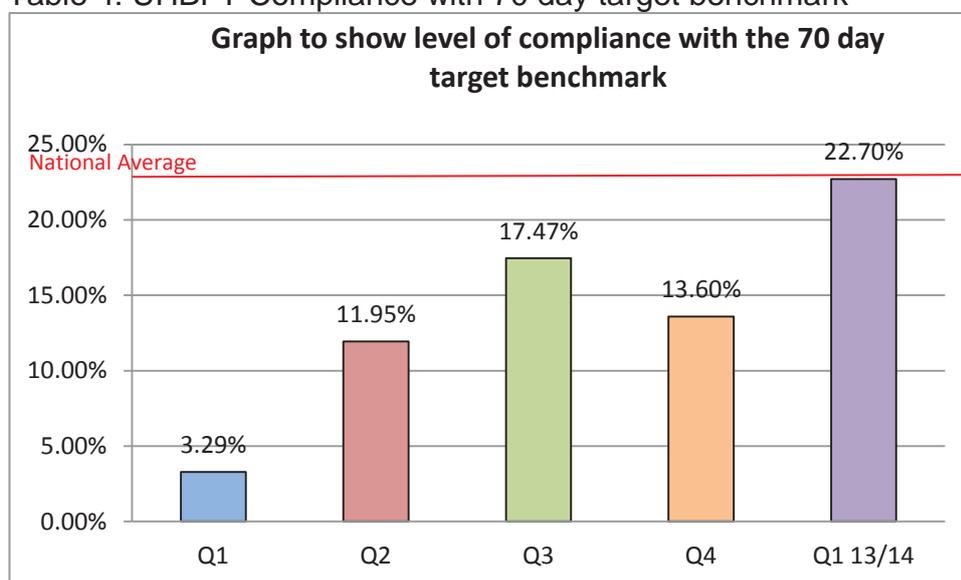
Since 1 April 2012 the R&D Department, with support from Informatics have put in place a system to accurately record the new reporting requirements. This involves extraction of data from the R&D database and recruitment data from PICS which is then presented on the Trust dashboard. This is the first time 'live' data of this kind has been available to the R&D department.

The R&D department have also worked with research staff to ensure they are aware of the new targets and a fortnightly feasibility meeting takes place with key leads to resolve any issues with studies prior to submitting the SSI form, which is when the 70 day target starts.

The 70 day target was discussed at the December 2012 CEAG meeting where concerns with the new target were highlighted. Additional R&D posts to support faster study start-up were agreed to go forward in business planning for 2012/13. These posts will be commencing in August 2013.

Table 4 below shows UHBFT overall compliance with the 70 day target for Q1 – Q4 in 2012/13 and the Q1 of 2013/14. The % compliance is the NIHR analysis of the data that the Trust has submitted. The current assessment of compliance includes studies that recruit less than 5 patients per year (these are highly likely to miss the 70 day target) and where the target is missed due to 3rd parties causing the delay. UHBFT continues to work closely with the DH to improve overall data quality.

Table 4: UHBFT Compliance with 70 day target benchmark



6. Key Achievements in 2012/13

Key Achievements from 2012/13 include the following:

6.1 Maximising translational research potential

Over the course of the year UHBFT has further developed its translational research portfolio:

- a) Experimental Cancer Medical Centre (ECMC) bid for continued designation (5 years) as an ECMC. **Awarded.**
- b) NIHR Liver Biomedical Research. Bid for continued designation. **Awarded.**
- c) NIHR Healthcare Technology Co-operative (HTC) Trauma Bid. **Awarded.**
- d) A significant award was also made in February 2012 to commence in September 2012, for NIHR Clinical Infrastructure funding for the NIHR Wellcome CRF. UHBFT was awarded

£12.8m, an increase of £2.8m and also the highest awarded in the country. This is a joint award to UHBFT and BCH to support Clinical Research Facilities across both sites, employing over 60 research staff (40 UHBFT : 20 BCH) delivering over 150 studies and treating approx 8,000 research patients per year.

- e) UHBFT was originally not awarded CRUK Clinical Hub status under the CRUK Stratified Medicine call in mid 2011. CRUK subsequently revised its position on this decision and UHBFT has contributed to Phase 1 Stratified Medicine as a Clinical Hub during the financial year 2012/13.
- f) NIHR HSR/SDO grant (Prof. Julian Bion) 24/7 Care. **Awarded**

6.2 Research Bids of note in 2013/14

- a) **NIHR CLAHRC** - 2nd Phase. Full application submitted - **awaiting outcome**.
- b) **Academic Health Science Centre (AHSC)** designation - The call for AHSC designation was announced on 15th April 2013. Birmingham Health Partners (UHBFT: UoB,; BCH) submitted the initial PPQ for this on 31st May, and have now been **short-listed** to go forward to full application submission in September 2013.

6.3 Research Support Service (RSS)

The Department of Health requires Trusts to adopt examples of good practice in supporting clinical research within a national framework called the Research Support Service. This includes developing a Research and Development Operational Capability Statement (RDOCS), using a set of tools for early assessment of the impact of new studies, and having in place an appropriate suite of standard operating procedures. The Trust's Heads of R&D Governance and R&D Operations have been working together to implement these guidelines in the Trust. The RDOCS was approved by the Trust Board in August 2012. Trust R&D SOPs are in line with the guidance and we have been using the recommended assessment tools as well as developing some of our own.

6.4 UHBFT Research Website

A new R&D website, (<http://www.research.uhb.nhs.uk>) has been created and went 'live' in May 2013. The website has public-facing information on all aspects of research activity and is aimed at patients and the public, academic and clinical researchers, and industrial partners.

A key feature of the website is the Studies page, which provides a detailed summary of each study, current recruitment data, study inclusion and exclusion criteria. This page has been set up so that data from the R&D database is automatically populated onto the website to ensure the data is as accurate as possible.

Throughout 2013/14 the website will continue to be updated with the addition of a publications page being added to showcase UHB researchers' publications in high impact peer reviewed journals.

6.5 PICS research tab.

A PICS research tab to support the identification of patients participating in research studies and trials, and to ensure easy access to information about the specific trial, and researchers associated with the trial is now in place on PICS. Use of this facility by research teams to record recruitment to specific trials is now in place, monitoring and compliance is reported to UHBFT R&D Management Group.

6.6 Increasing patient involvement in Trust research activities

The NIHR undertook a "mystery shopper" exercise in 2012/13 to assess NHS organisational capability to involve patients in research. Following publication of the finding from this the Trust undertook its own internal assessment. Key actions identified to be taken forward during 2012/13 and into 2013/14 are:

- an additional tab/link on the outpatient self-check-in kiosks asking if patients are interested in research – **in progress**
- Information on research at reception areas - **completed**
- An additional sentence identifying the Trust as a research active organisation on all out-patient letters - **completed**
- Raising awareness with GP's and PALS – **in progress**
- Release of new Trust R&D website with information on clinical trials active in the Trust - **completed**

6.7 Increase in research infrastructure

a) Research Nurses

During the last year the numbers of research nurses have increased substantially. In August 2011, 36 research nurses were employed outside the NIHR Wellcome CRF. This number has now increased to 54 nurses and trials practitioners. Four of the new posts are peripatetic, working across several trusts, which is a novel way of working. R&D are also piloting research roles for individuals who are not healthcare professionals.

b) Protocol Development Service

Currently the Trust employs 2 full- time PDS staff in addition to 3 other R&D staff members who have a PDS role as part of their job descriptions. An additional full-time, fixed term PDS member of staff has been recruited to commence in post in Q2 2013/14.

c) Annex U Posts

Annex U posts are 2 year fixed term A4C Band 4 and specifically target recruitment of graduates who wish to undertake master's level study while gaining work experience within the NHS. Two new Annex U posts

were agreed in 2013/14 business planning to support the increase in Trust R&D activity.

d) Head of Academic Innovation

Prof. Phil Begg has been appointed to this new role in January 2013. Prof. Begg has a remit across education and research in the Trust. Within research a key deliverable for this role is an increase of academic activity across nursing, allied health professional and clinical scientist staff groups.

7. Research Directorate activities of note for 2012/13

7.1 Institute of Translational Medicine (ITM)

The ITM is a £24m project which is 50% funded via a grant administered through West Midlands Business Innovation & Skills and 50% funded by UHBFT and UoB. The design team to support the ITM project was appointed week beginning May 6th 2013 following a tender process.

ITM governance and reporting structures are in place. Clinical Academic leadership to the ITM project is provided by a 4th ADR, Prof. Charles Craddock, Associate Director of Research - ITM. An ITM Project Manager and ITM Project Assistant have been appointed and will commence work in August/September 2013.

At the current time the ITM project is progressing to plan. The ITM is due to formally open in June 2015.

7.2 Academic Health Science Network (AHSN)

UHBFT played a lead role in the preparation of the West Midlands AHSN bid. This was submitted for adjudication on 1 October 2012. Formal notice of WM AHSN designation was received in May 2013. Work is now on going to establish WM AHSN structures, appoint to senior roles, and negotiate the terms of the DH- AHSN license to operate.

7.3 Intellectual Property Protection and Commercialisation

To ensure that the Trusts' commercial interests are protected a register detailing any potential and actual IP arising from any research has been created and is currently maintained by the Research Contracts and Governance Manager. This is shared with the Trust Commercial Director and Midtech to ensure appropriate action is taken.

Due to the large volume of contracts between the Trust and the University of Birmingham there was a need to have a standard collaboration agreement in place, which would include IP clauses to protect the Trusts' interests. A template was agreed by the Investment Committee in October 2012. This has resulted in greater consistency in research contracts between the Trust and the University of Birmingham and increased contract turnaround

During 2013/14 the R&D department will be working with Midtech and the Trust Commercial Director to ensure information about Innovation and IP is well promoted across the Trust and encourage innovation amongst staff.

8. Recommendations

The Board of Directors asked to:

8.1 **ACCEPT** this research activity annual report for 2012/13

Tim Jones
Executive Director of Delivery
16 July 2013