

TRUST BOARD – 22 DECEMBER 2014

Quarterly Research and Development Report

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DATE:	22 December 2014
PURPOSE:	Quarterly update on R&D issues, for Board information and assurance.
PREVIOUSLY CONSIDERED BY:	n/a
Objective(s) to which issue relates *	<input checked="" type="checkbox"/> 1. Safe, high quality, patient-centred healthcare <input type="checkbox"/> 2. An effective, joined up emergency care system <input type="checkbox"/> 3. Responsive services which people choose to use (secondary, specialised and tertiary care) <input type="checkbox"/> 4. Integrated care in partnership with others (secondary, specialised and tertiary care) <input checked="" type="checkbox"/> 5. Enhanced reputation in research, innovation and clinical education <input type="checkbox"/> 6. Delivering services through a caring, professional, passionate and valued workforce <input type="checkbox"/> 7. A clinically and financially sustainable NHS Foundation Trust <input type="checkbox"/> 8. Enabled by excellent IM&T
Please explain any Patient and Public Involvement actions taken or to be taken in relation to this matter:	PPI is embedded within all areas of Trust R&D activity
Please explain the results of any Equality Impact assessment undertaken in relation to this matter:	
Organisational Risk Register/ Board Assurance Framework *	<input checked="" type="checkbox"/> Organisational Risk Register <input checked="" type="checkbox"/> Board Assurance Framework <input type="checkbox"/> Not Featured
ACTION REQUIRED *	
For decision <input type="checkbox"/>	For assurance <input checked="" type="checkbox"/>
	For information <input checked="" type="checkbox"/>

- ♦ We treat people how we would like to be treated
- ♦ We do what we say we are going to do
- ♦ We focus on what matters most
- ♦ We are one team and we are best when we work together
- ♦ We are passionate and creative in our work

- tick applicable box

UHL R&D Quarterly Trust Board Report December 2014

1. Introduction

This report describes current R&D performance against metrics, projects under development, new challenges and potential threats.

2. Research Performance

The activity of UHL in initiating and delivering clinical research is performance monitored by both the NIHR Central Commissioning Facility (NIHR CCF) and the East Midlands Clinical Research Network (EM CRN). In turn the UHL R&D Office reports research CMG level activity and performance to each CMG via the R&D Executive Committee.

2.1 NIHR CCF

In Q1 14/15 UHL initiated 91 clinical trials, making UHL the 17th most prolific trust (previously 11th). This is a slight drop over previous quarters (see Table 1). There are many potential reasons for this, but it does not represent a trend and it is anticipated that performance will return to previous levels. These performance figures will be closely monitored.

Table 1: UHL Performance in initiating clinical research trials

	Number of Trials Initiated	
	2013/14	2014/15
Q1	111	91
Q2	125	
Q3	121	
Q4	116	

UHL is also judged by its performance in recruiting patients into initiated trials – the benchmark is to recruit the first patient into a trial within 70 days of submission by the investigator of a valid research application. Here UHL's performance in Q4 13/14 was 36.1%, thus leaving significant room for improvement. NIHR has indicated that Trusts failing to show significant improvements will face a 5% 'top-slice' of Research Capability Funding (RCF) for 2015/16.

Therefore for Q2 14/15 we instituted:

- '70 days to consent' (Figure 1) communications strategy and action plan
- new managed process to monitor quality and accuracy of data return to NIHR CCF

According to our recently submitted data, UHL's performance for Q2 14/15 is **75%** - a significant improvement in performance which should protect RCF for 2015/16.



Did you know that you have 70 days to consent a research participant from the date of valid application submission? The R&D team can help you meet your study's targets. Contact us at RDData@uhl-tr.nhs.uk

Figure 1. UHL's logo and reminder to researchers of 70 day target

2.2. EM CRN

The last report received from the EM CRN was received in Dec 2014. The EM CRN is currently in the process of refining its data reports for trusts, but the data show that for the year 14/15 UHL is exceeding patient recruitment targets based on a 9% increase over 2013/14 recruitment. This is a significantly positive outcome (Table 2).

Table 2: Cumulative Recruitment Numbers of Patients into UHL Studies 2014/15

	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Aspirational target = 13/14 + 9%	910	1820	2730	3640	4550	5460	6370	7280	8190
Cumulative Recruitment 14/15	939	2029	2989	4063	5295	6202	7147	7266	

3. Projects under development

There are currently 4 major projects in development.

3.1. *Adult and Children's Clinical Research Facility.*

There is an intention to refurbish the Union Offices in LRI into a Children's Clinical Research Facility. This will be adjacent to the existing clinical research facility at LRI and will enable the establishment of a new joint Adult and Children's Clinical Research Facility. This will increase capacity for clinical research and maximise potential income from commercial studies. UHL has received some capital funding for this project but there is currently a shortfall and negotiations are underway to meet this from Charitable Funds.

3.3 *Hope Unit at Glenfield Hospital*

The Hope Against Cancer Charity has offered funding support to refurbish a suitable clinical area into a satellite recruitment centre at Glenfield Hospital, associated with a small laboratory for clinical sample processing. Discussions are underway to identify suitable space.

3.2 *The Life Study.*

UHL has developed a strategic partnership with academic colleagues from University College London to host the Life Study in Leicester. Life Study will collect information about babies and the determinants of their health, wellbeing and development. UHL will be the second Life Study Centre and we aim to recruit at least 50% of 11,000 deliveries annually at UHL beginning in first 3-4 months 2015. Participation will result in significant reputational enhancement for UHL and will generate significant R&D income from the Clinical Research Network based on recruitment levels.

The disused Sports and Social Club building at Leicester General Hospital has been identified for refurbishment into the Life Centre and the costs are included in the 2014/15 Capital Plan. A Steering Committee chaired by Director of R&D is supporting the project with input from Women and Children's CMG, HR, IT, CCGs, EM CRN. The aim is to have The Life Study Centre completed and supporting recruitment by early 2015.

3.3. *The 100,000 Genome Project.*

Since August 2014 UHL has developed a partnership with:

- Cambridge University Hospitals NHS Foundation Trust
- Norfolk and Norwich University Hospitals NHS Foundation Trust
- Nottingham University Hospitals NHS Trust

The consortium has made first and second stage applications to NHS England, and hosted a site visit by NHS England as part of an application to become a Genomic

Medicine Centre. CUH will be the host organisation. If successful this will become the East of England Genomic Medicine Centre (EEC GMC).

This is an NHS transformation project that aims to deliver advances in genomics directly into the clinical care of patients with rare/inherited diseases and cancer. Successful implementation will require significant alterations to care pathways and job plans of clinical staff. Attainment of GMC status will help with recruitment of high calibre staff into vacant posts.

The EEC GMC bid has been supported by:

- EM AHSN
- Eastern AHSN
- Health Education England
- empath

4. Contracting and Innovation Activities

The R&D Office team are handling an increasing number of contracts relating to research and innovation activities, both commercial and non-commercial.

Two examples of recent innovation projects:

- Optimal project - £50k awarded by AHSN to evaluate
- Activate Your Heart – £75k National NHS Innovation Challenge Finalist

5. New/Existing Challenges

5.1 EM CRN Financial Allocation Process 2015/16

The EM CRN has not yet finalised how it will be managing its financial allocation process to Trusts for 2015/16. This is leading to some uncertainty, but UHL will have a greater ability to direct funding strategically. We have begun constructive discussions with CRN Division Leads and with NUH R&D to ensure a unified approach where possible. We are optimistic that the process and outcome will be fair and equitable.

5.2 Health Research Authority Research (HRA) Approvals Process

From late 2015 a new mechanism of research approvals will be introduced. HRA Approval will provide a single approval for research in the NHS that will incorporate assessments by NHS staff employed by the HRA alongside the independent Research Ethics Committee opinion. This essentially replaces parts of what is currently known as R&D or Trust Approval. The HRA will provide a general NHS permission and will be available for all studies, NIHR portfolio and non-portfolio alike. This will be implemented to incorporate ALL research by December 2015. Whilst the purpose is to streamline and speed processes, there is the potential for confusion in the early stages and impact on job roles currently undertaken by current staff members in R&D and CMGs.

The following steps will be taken to mitigate this risk:

Stage 1 – Complete by end November 2014

- A scoping exercise to establish job descriptions, funding streams and individuals currently employed within CMGs who currently undertake an Ethics & Regulatory Affairs role
- Identify current work load of individuals
- Identify areas where this role does not exist and also areas where this role is a part of a wider role

Stage 2 – Complete by end January 2015

- Review job descriptions
- Seek authorisation from the employing CMG for discussions with the individuals to roll out a new process
- Engage with HR as required – there may be a management of change process required to amend Job Descriptions

- Begin development of Trust wide SOP for study feasibility / delivery
- Stage 3 – Complete by end June 2015
- Complete and finalising of Trust wide SOP for study feasibility / delivery
 - Finalise all relevant staff / finance / HR negotiations as relevant
 - Begin to embed new process within CMGs

6. Research Office Issues

The following changes to trust R&D activity are proposed

6.2 Office Re-naming

We propose that Research and Development Office (R&D) be renamed '**Research and Innovation Office**' (R&I) to take account of the role in supporting innovation throughout the Trust and in line with naming in other Trusts.

6.1 New Website

To support the new name of the office and to refresh UHLs R&I profile a new website will be launched.



Figure 2: New Logo for re-vamped R&I website