

Board of Directors (Public)

Item 3.1

Subject: Research & Innovation Annual Report
Date of meeting: 26 July 2016
Prepared by: Nina Spofforth, Research and Innovation Manager
Presented by: Dr Jay Wright, Clinical Lead for Research & Innovation

BAF Ref	Impact on BAF
5	None

1. Executive Summary

The purpose of this paper is to provide a report on activities within Research & Innovation in the period April 2015 – March 2016. The main report presents a high level overview with more detailed progress against the Research and Innovation Strategy set out in appendix 1 (these slides will be presented) and a forward plan provided in appendix 2.

2. Background

The Board approved the current strategy for Research & Innovation (2015-2017) in April 2015. This report includes a report on progress in implementing the strategy.

3. Progress & Achievements

In 2015/2016, we have met, or surpassed our targets for 2015/2016 in our longstanding priority areas and we have made progress in those areas of expansion of our work as described below.

3.1 Cancer

Work on longstanding trials such as Liverpool Lung Project (LLP) continues, and the addition of Professor Pieter Postmus to our team has enabled collaboration with the Clatterbridge Cancer Centre that will open up new opportunities in 2016/17 and beyond.

3.2 Personalised Medicine

The Trust has begun recruitment of patients to the rare hereditary diseases arm of the national 100,000 genome project. The cancer arm has yet to start nationally, although we understand that this is imminent. The project will sequence 100,000 genomes from around 70,000 people. Participants are NHS patients with a rare disease, plus their families, and patients with cancer. The project has had a difficult start with recruitment, but very recent changes to inclusion criteria should boost performance.

The multi-million pound, UK-wide TRACER X project has now been launched which will exploit the map of the human genome. Locally, LHCH, the Royal Liverpool and Broadgreen University Hospital and Liverpool Biobank at the University of Liverpool are working together to explore and reconstruct the genetic architecture of each patient's disease.

3.3 Regenerative Medicine

Although we have not yet embarked on any regenerative medicine projects, we have made significant progress in this area.

We are in discussion with PeptigelDesign, a local SME developing injectable peptide based hydrogels for cardiac regeneration applications, around trial of its biodegradable biocompatible cardiac prosthesis which acts as a new structural type of aortic stent.

We have also identified an academic partner for regenerative medicine, John Hunt, Professor of Musculoskeletal Biology at the Institute of Aging & Chronic Disease, University of Liverpool, and have opened up our lab to collaborative work with his team. We hope to be able to progress work with Professor Hunt in 2016/2017.

3.4 Digital Healthcare

The SENSOR project involves a self-monitoring system produced by Aseptika. The project aims to reduce hospital readmissions for COPD exacerbations by using self-monitoring to educate, empower and engage patients to better self-manage.

Not yet fully established, the SMARTVIEW project is currently in set up. This is collaboration with the Population Health Research Institute (PHRI) in Ontario, Canada, which will use the SMARTVIEW e-Health-enabled service delivery program. It is based on existing implementable technology and validated interventions, and combines remote monitoring, education and self-management training. The primary outcome measure is improvement in post-operative pain, with secondary outcomes including improvement in post-operative symptoms, reduced health service costs and reduced patient-level cost of recovery.

We have made progress in advancing our work with Farsite, a software query tool that allows information to be searched from general practice. We have approval from Knowsley Clinical Commissioning Group to approach individual GP practices to become early adopters in using this tool for the purposes of population health management. This will, in time become part of our community offering. This tool will allow us to identify patients who are sub-optimally managed for cardiorespiratory disease and organise practice specific improvement programmes. This enhancement to our community offer will provide research opportunities in collaboration with primary care in the medium term.

We have established a "Big Data" warehouse with our ICMS colleagues at the Brompton & Harefield NHSFT. This technology allows us pull information from our joint data warehouses into a single analytical space for the purposes of joint research. Our first project on aortic surgery is almost complete. We will be taking forward data collection prospectively and channelling initiatives through ICE CAP – a programme of work recently approved by the ICMS Board of Directors.

We have succeeded in further increasing our capability for research and innovation within the Trust. An innovation module was introduced into the BSc in cardiothoracic care. The research team has developed an induction course for new staff and this will be launched as the new member of our team begins work with us in April 2016. Research and Innovation are now incorporated into the corporate induction programme.

3.5 Cystic Fibrosis

The cystic fibrosis trials at LHCH significantly contribute to the body of knowledge relating to this condition, but they offer some hope of treatment to patients where no treatments currently exist.

The Vertex suite of trials evaluates the efficacy of VX661 in combination with ivacaftor in patients with a particular gene mutation (heterozygous for the F508delCFTR mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene and a second allele with a CFTR mutation predicted to have residual function). If successful, this product could enable people with this mutation to live free of the effects of their condition.

3.6 Innovation

Our exciting work in innovation has already been discussed above and in 2015/2016, we have appointed 2 innovation champions. These are enthusiastic people who have demonstrated a commitment to promoting innovation. They will be instrumental in taking innovation forward within the Trust and we have plans to appoint a further 4 innovation champions early in 2016/2017.

3.7 Collaboration

We have been very successful in collaborating with external partners. We have longstanding positive relationships with companies such as Medtronic, Boston Scientific and Quintiles, and, in 2015/2016, as discussed above, we have begun to build new relationships in the areas of regenerative medicine (PeptigelDesign) and digital healthcare (Aseptika).

We have also extended our academic links, strengthening our links with Liverpool University and forging a connection with the Population Health Research Institute (PHRI) in Ontario, Canada (SMaRTVIEW).

3.8 Public and Patient Involvement

The Research and Innovation Department at LHCH continues to receive overwhelmingly positive feedback from patients who have taken part in research and their families. Patients report that they feel they have a more personalised service, and research nurses will always go above and beyond the role for the benefit of patients

The augmented benefits of research reported this year have included patients and family members having a point of frequent contact for questions and help with problems that they have regarding matters of general care. This has included, for example, to clarify medication, or to check on clinic visits. Research nurses educate patients in their condition, enabling better self-management. They have acted as advocates, speaking with their consultants in order to request referrals for chest physiotherapy to help with postural drainage.

The Service User Research Endeavour Group continues to champion the patient perspective within every research project and plays an invaluable part in research and innovation within the Trust.

The Patient Ambassador, Keith Wilson, continues to exceed all expectations of this role through his work across the North West Coast region and beyond, raising considerably the profile of LHCH as a centre of excellence for research and innovation.

Keith accepted a position on the NWC LCRN Partnership Group. This is an Executive Board Level Group which represents the wider interests of the CRN NWC region. He is Public and Patient Involvement (PPI) Lead for the NorthWest Coast Public and Patient Involvement (PPI) Lead for the NorthWest Coast Genomic Medicine Centre delivering the 100,000 Genome Project.

Keith has joined a Steering Group of National cardiovascular outcomes research (NICOR). The steering group supports one of the six cardiovascular national clinical audits that NICOR manages, a National Audit of Percutaneous Coronary Interventions (NAPCI) which audits PCI procedures in the whole of UK in NHS and most of the private providers.

In 2015 Keith was involved in a film for use in Massive Open Online Course (MOOC): Improving Healthcare through Clinical Research for the NIHR.

Keith has also been invited to take part in a the 'NIHR at 10' conference taking place in London in May which will celebrate NIHR's tenth birthday Keith will be a guest in a plenary session at the conference which will be a 'sofa discussion' involving patients and the public about the importance of public involvement in research, the difference it has made to NIHR's work over the last ten years, and what it will help us do in the future.

4. Conclusion

Activity in 2015/2016 has progressed implementation of the Research & Innovation Strategy in many areas.

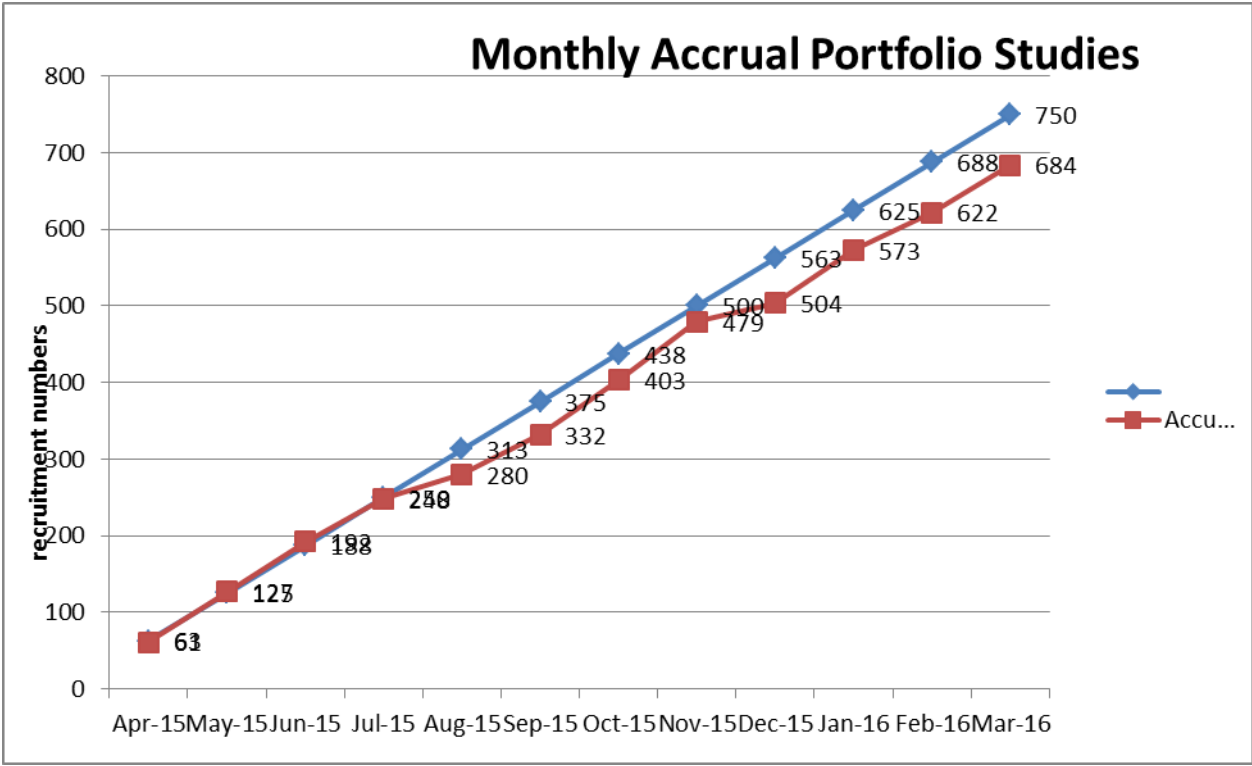
5. Recommendations

The Board of Directors is asked to review this report and be assured that good progress is being made against the Research & Innovation Strategy.

A detailed slide set is included as appendix 1. A forward plan is set out in appendix 2.

Appendix 1: Research and Innovation Strategy 2015-2017 Progress Report

Recruitment of Participants to Research Trials



Performance in Individual Trials

Study	Portfolio	PI	Nurse	Target	Approval Date	Current Total	1st Patient Recruited	Days to 1st recruit	Closure Date
Cardiology									
REFINE	Y	Jay Wright	Verity Mather/Catherine Whitmore	20	20/05/2014	6	01/06/2014	12	31/12/2017
REVIVED	Y	Jay Wright	Jan Barton	30	22/04/2014	3	27/06/2014	66	30/03/2013
Prætorian	N	Jay Wright	Ian Kemp	20	21/01/2014	22	N/A	N/A	01/06/2016
WRAP IT	Y	Jay Wright	Janet Barton	50	06/01/2016	8	25/01/2016	19	06/01/2016
UNTOUCHED	Y	Jay Wright	Verity Mather	20	06/01/2016	0	N/A	N/A	06/01/2016
Pan Surveillance	Y	A Rao	Catherine Whitmore	200	14/05/2014	183	23/04/2014	15	01/04/2024
ADAPT (Medtronic)	Y	A Rao	Catherine Whitmore	40	20/04/2015	11	08/06/2015	49	20/04/2017
THINK HF	N	Karen Dickman	Ian Kemp	N/A	06/12/2012	17	N/A	N/A	06/12/2013
AVATAR AF	Y	D Todd	Maureen Morgan/ Chris Roys	30	26/03/2015	16	28/04/2015	33	30/11/2016
AXAFA-AFNET	Y	D Todd	Maureen Morgan/ Chris Roys	40	02/02/2016	1	22/03/2016	49	01/08/2017
IDEAL	Y	R Stables	Janet Barton / Ian Kemp	10	09/06/2015	0	N/A	N/A	31/12/2020
Mendelian	Y	M Field (ICMS)	N/A	10	15/05/2013	65	11/07/2013	57	08/12/2016
COMPLETE	Y	J Mills	Catherine Whitmore	20	18/11/2014	35	03/12/2014	15	18/02/2016
PICSO-Miracor	Y	N Palmer	Jan Barton	10	05/02/2015	12	23/02/2015	18	05/02/2016
Gene Therapy	Y	S Welch	N/A	20	14/04/2015	3	14/05/2015	30	13/02/2017
Amulet	Y	D Gupta	Maureen Morgan	15	06/11/2015	17	03/11/2015	3	03/11/2018
PRAISE	Y	D Gupta	Maureen Morgan/ Chris Roys	30	09/02/2016	4	11/02/2016	3	20/01/2018
DDRAMATIC Acute Medical	N	M Hall	Maureen Morgan	10	20/01/2016	4	25/01/2016	5	20/01/2017
Respiratory									
LongArt	Y	M Ledson	Sarah Feeney / Lindsey Butcher	3	18/07/2012	2	11/12/2013	511	18/01/2016
VERTEX VY-108	Y	M Ledson	Sharon Burnett	2	24/07/2015	1	03/03/2015	47	31/03/2016
VERTEX VY-106	Y	M Ledson	Sharon Burnett	8	03/08/2015	8	17/08/2015	14	31/03/2016
VERTEX VY-110	Y	M Ledson	Sharon Burnett	5	18/02/2016	3	22/02/2016	4	16/01/2018
OligoG	Y	M Walshaw	Sharon Burnett	4	24/02/2015	4	16/03/2015	20	27/05/2016
InsMED TB Trial	Y	D Sloan	Sharon Burnett	2	12/08/2015	5	01/03/2015	20	31/12/2015
Liberate	Y	K Mohan	Sharon Burnett/Fiona Andrews	2	30/10/2015	3	17/11/2015	18	31/12/2022
Cancer									
LLP trial	Y	Prof Field	Perris Widdows/ Angela Tobin	800	11/10/1998	2600	27/03/2003	N/A	22/06/2016
PULMICC	Y	M Shackcloth	Sarah Feeney / Lindsey Butcher	5	13/01/2011	71	06/01/2011	7	30/03/2014
MesoBank Retrospective	N	M Shackcloth	N/A	N/A	04/02/2015	0	N/A	N/A	N/A
MesoBank Prospective	N	M Shackcloth	Sarah Feeney / Lindsey Butcher	N/A	04/02/2015	26	N/A	N/A	N/A
VIOLET	Y	M Shackcloth	Sarah Feeney / Lindsey Butcher	42	30/09/2015	22	14/10/2015	20	31/03/2020
Cardiac Surgery									
CAYIAR	Y	S Agarwal	Fiona Andrews	27	22/03/2016	0	N/A	N/A	22/03/2017
UK TAVI	Y	M Kuvallli	Ian Kemp	50	31/03/2015	26	15/04/2015	15	30/11/2018
Aorta									
Acetazolamide in aortic surg	N	M Field	N/A	60	09/04/2014	3	N/A	N/A	09/04/2016
ETTAA	Y	A Oo	Ian Kemp	20	19/06/2014	6	23/03/2015	277	31/03/2013

	below target
	near target
	on target

al Recruited 15/16 All Stu
841

Total Recruited Portfolio
684

tal Recruited Non-portfo
157

Progress in Key Areas

Promote Research Across All Clinical Areas

Number of projects in each research priority area:	Target 2015/2016	Year to date
Interventional Cardiology	5	5
Heart Failure	6	8
Arrhythmia	3	4
Aorta & Valve Surgery	2	4
Respiratory and mycobacterial infection	2	2
Lung Cancer	5	6
Cystic Fibrosis	3	5
Critical Cardiothoracic Care	1	2
Cardiothoracic Anaesthesia	2	1
Personalised Medicine	1	2
Regenerative Medicine	1	0
Digital Healthcare	2	1

Develop Culture that Supports and Values R&I

	Target 2015/2016	Year to date
Number of major service developments evaluated for potential commissioner support	0	0
Number of "hits" (annually) on research & innovation e-information exchange	100	32**
% patients recruited into research studies as % activity	10%	7%
Publications - Overall; (split by medics and non-medics)	90	121
Organisational <i>h</i> index (measure of citations)	45	39
Number of research & innovation "re-tweets"	50	53
Number of innovative ideas contributed, and number implemented	24/1	1/0
Number of LHCH "own account" research project findings or innovations implemented into clinical practice	1	0

Develop Capacity and Capability for R&I

	Target 2015/2016	Year to date
Fundraising income for the Department of Integrated Clinical Evaluation (ICECAP)	£1m	0***
Number of externally sponsored clinical trials managed by in-house team	1	1
Number of staff completing the on-line research & innovation training	0	0
Percentage of staff trained in Good Clinical Practice	>98%	100%
Number of job descriptions including a research role and responsibility	4	0****
Number of staff with a formal academic position	2	2
Number of additional staff with an academic role	5	8
Number of Research Fellows	3	3
Number of Research Nurses	15	15
Number of innovation champions	6	2
Number of higher degrees registered in research & innovation	3	3

Maximise Opportunities for Patients to Take Part

	Target 2015/2016	Year to date
Research income (sub-accounted by source; grants, commercial trial etc.).	£1 100 000	£1,065,392
Innovation income	£50K	£ 50k
Research recruitment time line:		
Site specific information completion to research approval	80%	100%
Research approval to time of first patient recruited	80%	79%
Percentage of NIHR adopted studies	70%	90%
Number of studies which the Trust acts as a Participant Identification Centre	3	2

Maximise Collaboration with External Agencies

	Target 2015/2016	Year to date
Number of research & innovation portfolio projects that involves at least one an external partner	2	3
Number of staff registered with the Practice Development and Research & Innovation Partnership	2	0
Number of industrial partners engaged in collaborative work with the Trust on innovation	3	4

Governance

	Target 2015/2016	Year to date
Percentage of research governance audit plan delivered	>95%	100%

Appendix 2: Forward Planning at LHCH 2016/2017

The Challenges

A changing landscape for research alongside a restricted funding environment across health and social care means that, as we move into 2016/2017, LHCH Research and Innovation faces a number of tough challenges. The major challenges are set out below.

- Reduction in Funding from the Clinical Research Network.
- Financial pressures on our industrial partners potentially reducing available commercial income.
- Increasingly specialist and complex studies requiring intensity of workforce resource input.
- Workforce Pressures
- Sourcing Trials

Reduction in Funding from the Clinical Research Network

The reduction in funding from the CRN is set out below.

Funding Proposal	
Funding in 2015/2016	-489179
Proposed funding in 2016/2017	-412973
Difference	-76206
Adjustments	
Funding to cover payment to Liverpool University - no longer charged	-24392
Increase in staff pay costs (4% 2015/2016 income)	19567.16
Adjusted Funding Proposal	
Expected funding for 2016/2017 (based on 2015/2016 figure)	-494004
Proposed funding for 2016/2017	-412973
Difference	-81030.8
% difference	16.4%

We have managed this decrease in funding through the termination of some short term contracts specific to projects that have come to a natural end and improved commercial trial activity. There should be no impact on research capacity going forward.

Increasingly specialist and complex studies requiring intensity of workforce resource input

Alongside financial reimbursement, recruitment of high numbers of patients must be a strategic goal for LHCH, given the importance attached to this by NIHR, through the Local CRN. However, this aspiration is not necessarily consistent with high quality research or improved patient care. This point is further explained in the example below.

Example

The Vertex suite of cystic fibrosis trials evaluates the efficacy and safety of the VX-661 in combination with Ivacaftor in people homozygous for the F508del CFTR mutation. The new drug has the potential to eradicate the effects of the mutation allowing patients to live their lives effectively free of cystic fibrosis and, as such, it is vital that we support these trials. However, the trials are resource intensive and, although we have successfully recruited all of our eligible patients, this is a very small number of people (7 participants). These trials will no longer receive CRN funding in 2016/2017 and current commercial income does not cover all of the costs associated with the trials.

Given the competing priorities for research, the Research and Innovation Committee needs to be equipped with robust, relevant information when deciding whether or not to approve a trial for LHCH participation.

Financial pressures on our industrial partners potentially reducing available commercial income

Anecdotally, experience in 2015/2016 has been that our industrial partners are reporting greater financial restrictions compared with previous years and a corresponding increase in the scrutiny to which trial finance is subjected has been experienced. The plan going forward is to only take on trials which contribute academically to the Trusts objectives and / or make a small surplus.

Workforce Pressures

The LHCH research portfolio is rapidly expanding into new areas whilst support for existing trials continues. However, the potential to recruit more participants to research trials is limited by the number of research nurse hours available.

Financial and participant recruitment challenges add pressures to the workforce with the consequent challenges associated with managing competing priorities. Going forward, the Trust will only take on trials which are remunerated in accord with effort expended, and a much more holistic approach to matching workload with current activity will be established.

Sourcing Trials

It is believed by the team of the R&I Department that on a proportion of trials that could be conducted at LHCH ever reach the R&I Committee. Decisions to refuse trials may be made by well-meaning clinical staff aware of capacity issues and not wishing to exacerbate them. However, decisions about which trials to accept need to be made using robust information.

The Plan

Bringing Large Projects to LHCH

Priorities for the coming year have been agreed with the aim of maximising recruitment, whilst ensuring quality of research which will contribute to the body of medical knowledge and, thus, produce changes in practice. Some of our large projects which will be active in 2016/17 are described below.

- RIPCORDER 2 will run for 3 years and aims to recruit at least 300 people in the period from April 2016 to March 2017. It has attracted a grant of £1.8million, most of which will come to LHCH.

- CASA AF is collaboration with Royal Brompton and Harefield NHS Trust has attracted a NIHR grant to LHCH of £166k. It aims to recruit 40 people at LHCH in the period from February 2016 to July 2017.
- SACRED 2 aims to recruit at least 300 people in the period from April 2016 to March 2017.
- WRAP-IT aims to recruit at least 120 people in the period from April 2016 to March 2017.

Addressing the Issue of Reduced CRN Funding

Partnership working with CRN is vital to the LHCH research profile as well as through its financial support. It is important, however, to understand fully the importance of the latter in going forward.

CRN funding pays for staffing only, with no provision for overheads and other indirect costs, such as management costs. In 2015/2016, 58% of our staffing costs were met by CRN funding, which means that only 42% of the workforce was, in theory, available to conduct commercial trials, which provide resources to pay for indirect costs.

The key message here is that the reduction in funding from the CRN will be addressed through effective business planning in the sourcing, costing and approval of trials. As such, the removal of funding could be seen as making staff time available to commercial trials which will bring income to cover indirect costs.

A process for business planning is outlined below.

Going Forward in Planning Our Clinical Trial Portfolio

Regardless of the magnitude of the trials we attract in terms of recruitment targets, financial reimbursement or workload implications, the key to successfully addressing the challenges presented to us in 2016/2017 will be the introduction of systems that facilitate effective planning of finance, recruitment and staff time and skills, and timely monitoring of resources. The proposed features of this system are set out below.

1. A database into which will be input:
 - a. all trial income details agreed in the contract;
 - b. all trial expenditure information as percentages of income items;
 - c. all activity as set out in the schedule of events;
 - d. nurse daily activity (electronic time sheets)
2. A finance administrator who will be responsible for managing the database.
3. A standard form for proposing a trial to the R&I Committee which presents robust and consistent information.

4. Engagement of PIs in understanding the range of issues facing R&I and the importance of bringing to the R&I Department all trials for which they receive information, as well as sourcing new opportunities for research.

The above measures aim to accomplish the following.

1. Adequate information for planning trials.
2. Robust Information to Aid Decision Making
3. Timely Monitoring of Trial Finance

Other Actions

Supporting LLP

We have seen that recruitment to this study is increased by allocating extra staffing resources to it. At the moment, we have a constant 1.6 WTE research nurses dedicated to LLP and extra ad hoc support to the study of between 0.2 and 0.8 WTE per week. The extra support affords more time to recruit and also enables more clinics to be targeted and we have noticed a clear correlation between extra support and numbers of patients recruited.

Respiratory trials

The portfolio of respiratory trials is expanding and, as a centre for cardiovascular research, LHCH is ideally placed to conduct these trials. We have exceeded our capacity within existing resources to support respiratory trials and need to increase this capacity to meet demand. We need to use the trial planning system outlined above to make decisions about which of these trials are to be supported.

Skill Mix

As the portfolio of trials expands across all areas, nurses spend an increasing amount of time entering patient data, thus reducing time spent attending clinics to recruit patients. Additional administrative support would be a cost effective way to liberate research nurse time for patient recruitment.

Additional support

In summary, LHCH proposes 3 areas where additional support would increase recruitment numbers into research studies, supporting our objectives.

1. Increased research nurse time for LLP. Our figures over the past 18 months suggest that 1WTE research nurse could increase recruitment to this trial by at least 15 patients per month.
2. Increasing support to respiratory trials. This would enable LHCH to expand its respiratory portfolio increasing recruitment in this area.
3. Increasing data support. This would free nurse time to focus on recruitment of patients.

6. Summary

Going forward into 2016/2017 and addressing the challenges that face LHCH Research and Innovation will involve a strategic approach to sourcing and approving trials. This will determine success in both financial management and recruitment. This will involve a system for simply planning and monitoring of trials and this depends on robust and timely data availability. CRN funding reduction appears significant, but the impact of this will depend on the resources made available by the trials conducted throughout the year.