

Performance Operating Framework

2017-2018 Review of the Academic Directorate of **Diabetes and Endocrinology**

1. Executive Summary

The Academic Directorate of Diabetes and Endocrinology continues to deliver high quality clinical research and strengthen its national and international reputation. The research teams, based across two sites [the Royal Hallamshire (RHH) and Northern General Hospitals (NGH)], have 22 diabetes and 9 endocrine studies authorised with a further 15 studies registered with the Clinical Research Office (correct as at Q3). The team is committed to delivering the National Institute for Health Research Clinical Research Network's (NIHR CRN) portfolio of studies with 84% of our authorised studies on the portfolio. Despite the decrease in commercial study opportunities noted over the past 18 months, the Directorate continues to embrace relevant commercial research opportunities and currently has 9 active commercial projects. For the fifth consecutive year the directorate surpassed the Trust and National target of 80% attainment for the NIHR initiating research metric by recruiting the first participant into 100% of our measurable studies within 70-day of site selection, highlighting our teams continued commitment to detailed feasibility assessments that incorporate the development of effective recruitment strategies. Other achievements not specifically captured within the POF include: 1) the successful delivery of a Phase I commercial clinical trial (cohort 1) for which we were the only global site (STH18456 - DITEST); 2) the local initiation of one of our recent large NIHR grants, OPTION-DM (STH18976); 3) the development of the DAFNEplus intervention (STH19555 + STH19608) in preparation for the randomised controlled trial.

2. Commentary on your Directorate's Performance against your **2017/2018** Targets (See Appendix 1 for your Directorate's **2017-2018** POF table)

The Directorate has had another successful year delivering 45 individual research projects to 3659 patients in the locality (Q1-3 2017/18) vastly exceeding our 125 patient accrual target over 40 projects. This was primarily a consequence of employing another successful targeted social media campaign (Facebook) for a diabetes-related questionnaire study (STH19980), which recruited 3525 in two months (Sep & Oct). This recruitment strategy was derived by the Directorate in collaboration with the Clinical Research Network in 2015. Incidentally, our POF recruitment target of 125 participants would have been attained by Q3 without this exceptional study (134 participants).

For the fifth consecutive year the NIHR initiating research metric (70-day benchmark) was attained for all measurable studies (100% at Q2), highlighting the excellent working relationship with the CRIO and Clinical Research Facilities at both sites in the prompt set-up of studies. Although disappointingly

only 1 of 4 commercial studies recruited to time and target in Q1-2 (25% at Q2 for the NIHR delivering metric), which does not reflect the continued effort the team takes to stringently assess the feasibility of study delivery and identify potential participants, but more a combination to the increased complexity of the trials the team is undertaking and the rarity of patients satisfying both the eligibility criteria and having the required time to commit to the trial (many of our participants are of working age).

The combined number of research active, infrastructure and contributing staff within the Directorate is comparative to 2016/17, but distribution across the three categories has changed due to altered clinical commitments meaning at Q3 we had met target for 2 of the 3 categories (research active and contributing staff).

Due to the shift in focus of the diabetes research team last year (2016/17) to converting successfully obtained grants into recruiting studies, the number of grant applications submitted and consequently obtained has been modest in comparison to recent years, although we exceeded our proposed targets (4 submitted, 2 awarded to a value of £254,000 at Q3). The STH grant income has also not been compromised by this decreased activity due to the income from the large grants secured in 2015/16 (STH18173 & STH18976).

The timely publication of research findings is an area of continued attention and if our output continues at the current trajectory our target of 25 original research publications will be met by Q4 (14 at Q2). Due to the ever increasing clinical pressures on our researchers, the engagement of a medical writer is being explored to ensure our research findings are published in a timely manner.

3. Commentary on your Directorate's Performance against your 2017/2018 Annual Plan (See Appendix 3 for your Directorate's Annual Plan)

Excellent progress has been made to achieving the 5 objectives set for 2017/18 with three met outright by the end of Q3. The primary focus of the diabetes research team has been the conversion of secured grants to successfully recruiting projects. This has been achieved for both DAFNEplus and OPTION-DM by the continual examination, revision and implementation of multi-pronged recruitment strategies, including the utilisation of our in-house research database of research willing patients, primary and secondary care participant identification centres, and engagement of multi-discipline teams.

Following the renewal of the research ethics committee approval of our database of research willing patients, which encompasses primary and secondary care diabetes patients from across Sheffield and endocrine patients across the region, the database team has received more requests to

identify potentially eligible participants for studies hosted within the Directorate (5 projects); administrative care is being taken so as not to overburden this patient pool. Alongside the extensive searches performed by our dedicated team of nurses, the utilisation of this database has contributed to another extremely successful year of recruitment into portfolio studies (3659 participants at Q3), surpassing our objective to maintain the level of recruitment into our research studies. Despite this, as stated above we have been unable to maintain recruitment to time and target above 80% (commercial studies), there have been a number of contributing factors to this, but we will strive to do better next year.

We continue to publish our research findings, but need to ensure this is done in a timely fashion i.e. within 6 months of analysis. The engagement of a medical writer may alleviate the strain on our busy clinicians and help meet this objective in coming years.

4. Please provide a commentary of your directorate's research performance against your research income listed within Appendix 2.

This financial year the Directorate attained an impressive annual return on investment of 665% (£1,016,900: £132,972) with the highest combined grant and commercial income within the Trust. This largely reflects the grant income from two large multi-million pound NIHR programme grants (STH18173 & STH18976) awarded in 2015/16. Despite the team's involvement in 18 commercial studies in 2017/18 (comparable to 2016/17), our commercial income decreased by 47% compared to 2016/17 (£93,297 in 2017/18: £197,481 in 2016/17). This is due to the combined effect of fewer studies initiating this year (as predicted by the significant decrease in calls for expression of interest) and more studies progressing to the follow-up stage where study activity is often lower. The overall downward trajectory of funding from other funding sources supporting research delivery seen over recent years has continued (14% decrease; £153,931: £132,972). Despite this the Directorate has sustained its capacity to deliver high quality research and support its current infrastructure, but has again been unable to strengthen it.

5. Do you have any other comments you would like to add to your 2017-2018 Review of your POF performance?

The research teams within the Directorate are continually adapting and exploring innovative ways of delivering high-quality research relevant to our patient population. The team successfully utilise the contribution of CRF nursing and support staff for projects that do not require specialist nurse input in order to maximise our research output. The Directorate also prides itself on the extensive collaborative research it performs both within STH (inter-departmental) and externally, and this year has been the major driving force in initiating a primary care collaboration with a cluster of research active

GPs within Sheffield. It is hoped that by jointly assessing potential research proposals across both primary and secondary care, we can extend and maximise the number of research opportunities provided to people in the locality in line with the NIHR research strategy.

This year has seen the initiation of a number of large academic projects that have, and continue, to require input from a multi-disciplinary team (MDT) outside for the core research team. HARPdoc (STH18485) has utilised DAFNE educators (DSNs and dietitians) to successfully deliver the first HARP and BGAT courses to patients with hypo-unawareness with further courses planned in 2018/19. Delivery of this intensive programme was facilitated by backfilling the educators' time with other members of the clinical team, highlighting the support of senior management in the delivery of this important research. Recruitment to the OPTION-DM trial (STH18976) requires the concerted effort of our team of diabetes doctors, nurses and podiatrists to identify potential participants with painful diabetic neuropathy. Considerable work has been undertaken to extend recruitment activities to other hospitals in surrounding areas and more recently to our primary care colleagues in the Sheffield Primary Care Collaboration, providing more patients from across the region access to this clinically beneficial research.

6. Please justify here why your directorate should retain Academic status?

The directorate has built a strong, reliable infrastructure encompassing a research coordinator, research nurses and administrators, and specialist research laboratories, which in combination with research PAs for NHS clinicians allow the directorate to deliver high quality, innovative research to people across the region. Retention of the academic status is a necessity for the Directorate to achieve its key research objectives including the successful delivery of prestigious trials such as the DAFNEplus (Programme Grant for Applied Research) and OPTION-DM (HTA Grant). The directorate's research portfolio demands the continued support from this well-developed research infrastructure to succeed, particularly due to the increased complexity of trials undertaken, and ensure research opportunities are translated into real patient benefit.

Appendix 1- Directorate 2017-2018 POF table

Objective		2014/15 Year FINAL	2015/16 Target	2015/16 Year FINAL	2016/2017 Target	2016/17 Year Final	2017/2018 Target	2017/18 Performance					2018/2019 Target
								Q1	Q2	Q3	Q4	Year to date	
1	Number of research active staff ¹	38	20	21	20	26	22					24	20
2	Number of research publications	33	48	32	35	28	25					14 at Q2	25
3	Grant Activity Data												
3.1.	Number of grants submitted	6	1	7	4	2	2	1	1	2	0	4	2
3.2.	Number of grants awarded	1	0	4	1	1	1	1	1	0	1	3	1
3.3.	Total value of successful grant applications	£256,296	£0	£5,956,040	£150,000	£2,086,998	£100,000	£250,000	£4,000	£0	TBC	£254,000	£100,000
4	STH Research Income (Portfolio & non-Portfolio)												
4.1.	Grant and Commercial Income	£259,123	N/A	£335,282	N/A	£1,587,149	N/A			£1,016,900		£1,016,900	N/A
4.2.	Other Funding Sources Supporting Delivery	£233,258	N/A	£216,327	N/A	£190,103	N/A			£132,972		£132,972	N/A
5	No. of Active Portfolio Studies	41	40	44	40	47	40	42	42	41		45	40
6	Patient Accruals to Portfolio Studies	213	100	871	100	2942	125	39	1543	2077		3659	135
7	70 day benchmark (%)	100.00%	80%	100%	80%	100%	80%	100%	100%	TBC		100%	90%
8	Recruitment to time and target (%)	35.40%	55%	46.5%	50%	100%	80%	50%	0%	TBC		25%	80%
9	Directorate specific KPIs (examples below)												
9a	¹ Number of Infrastructure staff		4	5	4	6	4					2	2
9b	¹ Number of contribution staff		12	13	12	10	10					16	15

Please provide a commentary of your Patient and Public Benefits-

All research proposals are carefully evaluated by the research teams within the Directorate and Directorate Research Executive to ensure the research performed within the Directorate is directly relevant to our patient population. Many projects are also reviewed by the Lay ADvice for Diabetes and Endocrinology Research (LADDER) panel of current and past patients, which represents the patient voice for the research projects conducted within the Directorate. One such project is the DAFNEplus programme of research that aims to incorporate emerging theories of behavioural change and technological advances into the DAFNE educational intervention to enable more adults with type 1 diabetes to self-manage more effectively. In Q3 2017/18 recruitment began to OPTION-DM a large multicentre clinical trial to identify the most clinically- and cost- effective treatment pathway for painful diabetic neuropathy; the results from this trial will help standardise the way patients with this debilitating condition are treated. Furthermore, clinical trials of new therapies developed by our endocrine researchers are well underway and if successful will directly benefit the quality of life and symptoms of patients with adrenal and testosterone insufficiency.

Appendix 2 – Directorate 2017-2018 Financial Information up to Quarter 3

Data supplied by finance, please contact Julie.Patchett@sth.nhs.uk if you have any queries regarding this information.

Grant and Commercial Income Received to STH				Other Funding Sources Supporting Delivery							Grand Total Income
Grant Income	Commercial Income	Other Research Income	<u>Total</u> (Grant & Commercial)	LCRN Infrastructure Support (A)	Research Lead (D)	CRF & CCTC LCRN Infrastructure Support (A)	NIHR Experimental Medicine Support (A & D)	LCRN Service Support (D)	RCF (A & D)	Total Other Funding	
£923,604	£93,297	£0	£1,016,900	£17,347	£7,200	£25,891	£0	£92,121	£7,760	£132,972	£1,149,873

Appendix 3 - Directorate 2017-2018 Annual plan (current years)

Objective	Actions Required	Resources required	Evidence of success	Lead & Completion date
1. Convert successful grants into successful, recruiting portfolio studies	Ensure studies are open to recruitment and any risks to continued delivery are identified addressed promptly	<ul style="list-style-type: none"> Sufficient Research Nurse time Sufficient Research PA time Access to appropriate research facilities 	Grant studies recruiting to time and target (based on monthly accrual targets)	<p>CIs</p> <p>Study close</p>
2. Utilise the Directorate Research Database (STH16577) of patients for targeted recruitment to studies	Ensure recruited patients previously recorded in Infoflex are transferred to SystmOne so up to date clinical data can be accessed.	<ul style="list-style-type: none"> Sufficient Research Administrator time to transfer data 	Use of the database to identify potential participants for at least 2 studies.	<p>Dr Elliott and all PIs</p> <p>Mar 2018</p>
3. Maintain the number of participants recruited to portfolio and commercial research studies (excluding recruitment to STH19468)	Ensure portfolio and commercial studies are approved in a timely manner and are actively recruiting	<ul style="list-style-type: none"> Sufficient Research Nurse time Sufficient Research PA time Access to appropriate research facilities Access to the Directorate Research Database 	Maintain recruitment to research at the level obtained in the financial year 2016/17, excluding recruitment to STH19468 (2514 participants)	<p>All CIs and PIs</p> <p>Mar 2018</p>
4. Maintain the recruitment to time and target above 80%	Ensure stringent feasibility assessments are performed and any risks to recruitment identified and addressed	<ul style="list-style-type: none"> Sufficient Research Nurse time Sufficient Research PA time Access to appropriate research facilities and infrastructure 	Maintain the NIHR delivery metric to above 80% for each quarter	<p>All PIs</p> <p>Mar 2018</p>
5. Publish original research articles from clinical studies in a timely manner	Write and submit research manuscripts for publication within 6 months of analysis	<ul style="list-style-type: none"> Sufficient Research PA time 	Maintenance of publication rate of the financial year 2016/17	<p>All research active staff</p> <p>Mar 2018</p>

Appendix 4 - Directorate 2018-2019 Annual plan.

Over the next 12 months we will:

Objective	Actions Required	Resources required	Evidence of success	Lead & Completion date
1. Ensure successful grants recruit to target	Ensure any risks to continued delivery are identified addressed promptly	<ul style="list-style-type: none"> • Sufficient Research Nurse time • Sufficient Research PA time • Access to appropriate research facilities 	Grant studies recruiting to time and target (based on monthly accrual targets)	<p>CIs</p> <p>Study close</p>
2. Maintain the number of participants recruited to portfolio and commercial research studies (excluding recruitment to STH19980)	<p>Ensure portfolio and commercial studies are approved in a timely manner and are actively recruiting</p> <p>Engage the primary care research cluster in a timely manner</p>	<ul style="list-style-type: none"> • Sufficient Research Nurse time • Sufficient Research PA time • Access to appropriate research facilities • Access to the Directorate Research Database 	Maintain recruitment to research at the level obtained in the financial year 2017/18, excluding recruitment to STH19980 (3525 participants)	<p>All CIs and PIs</p> <p>Mar 2019</p>
3. Improve recruitment to time and target	Ensure stringent feasibility assessments are performed, studies are approved in a timely manner, and any risks to recruitment identified and addressed	<ul style="list-style-type: none"> • Sufficient Research Nurse time • Sufficient Research PA time • Access to appropriate research facilities and infrastructure 	Maintain the NIHR delivery metric to above 80% for each quarter	<p>All PIs</p> <p>Mar 2019</p>
4. Publish original research articles from clinical studies in a timely manner	Write and submit research manuscripts for publication within 6 months of analysis	<ul style="list-style-type: none"> • Sufficient Research PA time • A Medical Writer 	Maintenance of publication rate of the financial year 2017/18	<p>All research active staff</p> <p>Mar 2019</p>
5. Encourage junior researchers to lead on projects	<p>Mentorship of junior researchers</p> <p>Identification of suitable projects</p>	<ul style="list-style-type: none"> • Sufficient Research PA time • Support from senior researchers and Coordinator 	Increased number of junior researchers as PIs	<p>All research active staff</p> <p>Mar 2019</p>