

## Executive Summary

### Report to the Board of Directors

Being Held on 31 March 2020

<b>Subject</b>	Clinical Research Network Yorkshire and Humber (CRN Y&H) Annual Delivery Plan 2020/21
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<b>Status<sup>1</sup></b>	A*

### PURPOSE OF THE REPORT

Sheffield Teaching Hospitals NHS Foundation Trust (STH), as Host Organisation of the CRN Yorkshire and Humber (CRN Y&H) is contractually required to submit an Annual Delivery Plan setting out the direction of the network and including strategic initiatives, projects and activities to support the Achievement of the local and national performance indicators.

### KEY POINTS

#### Annual Delivery Plan

CRN Y&H is required to provide the Clinical Research Network Coordinating Centre (CRNCC) with an Annual Delivery Plan for the next financial year. The CRNCC has advised that Annual Delivery Plans are submitted by 27 March 2020 and acknowledge that the content of Delivery Plans may not be updated given the current COVID-19 circumstances. In addition the NIHR has recently published FAQs about COVID-19 and one of these related to NIHR CRN High Level Objectives. This states that the CRNCC will take a pragmatic approach and suspend these during the period in which resources are being diverted to support the response to COVID-19.

The CRN Y&H Annual Delivery Plan does not currently reflect COVID-19 planning and we may be requested at a future date to update the Plan.

#### Key Points - Annual Delivery Plan

- The Annual Delivery Plan is still subject to change; the ambition values for the High Level Objectives and the Specialty Objectives have not yet been agreed by the Department of Health & Social Care (DHSC) and confirmed by the CRNCC.
- HLOs are now restated as ambition values, reordered and carry a descriptor rather than a number.
- The Recruitment to Time and Target ambition is now stated as a primary objective.
- Objectives relating to the 30 clinical specialty areas have been replaced by a requirement to identify up to ten priority disease areas where a 5% increase in recruitment can be achieved. CRN Y&H has taken the view that the only specialty objective will relate to public health research and COVID-19 studies in the next year.
- See Table 1 for CRN Y&H proposed ambition targets and rationale for 2020/21.

#### Annual Delivery Plan - Performance and Operating Framework Requirements

The Annual Delivery Plan is required to demonstrate compliance with all seventy-nine mandatory requirements as set out in the Performance and Operating Framework. We have identified how we intend to maintain/ensure compliance within the Plan but further work will be required around governance, financial assurance and monitoring of Partner organisations.

## Annual Delivery Plan - Local Initiatives

The network is also required to detail local initiatives and projects to be delivered in 2020/21. We are planning to undertake thirteen projects in relation to the following areas:

- CRN Specialties
- Information and Knowledge
- PPIE
- Workforce Learning and Organisational Development
- Business Development and Marketing

## IMPLICATIONS<sup>2</sup>

AIM OF THE STHFT CORPORATE STRATEGY 2017-2020		TICK AS APPROPRIATE
1	Deliver the Best Clinical Outcomes	x
2	Provide Patient Centred Services	
3	Employ Caring and Cared for Staff	
4	Spend Public Money Wisely	x
5	Deliver Excellent Research, Education & Innovation	x

## RECOMMENDATIONS

The Board of Directors is asked to **RATIFY** the Clinical Research Network Yorkshire and Humber (CRN Y&H) Annual Delivery Plan.

## APPROVAL PROCESS

Meeting	Date	Approved Y/N
Trust Executive Group	25/03/2020	Y
Board of Directors	31/03/2020	

<sup>1</sup> Status: A = Approval  
A\* = Approval & Requiring Board Approval  
D = Debate  
N = Note

<sup>2</sup> Against the five aims of the STHFT Corporate Strategy 2017-20

**Table 1**

Proposed LCRN Targets 2020/21

Objective		Measure	National Ambition (TBC)	Draft LCRN Target	Rationale
Time and Target	Deliver NIHR CRN Portfolio studies to recruitment target within the planned recruitment period	(A) Proportion of commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed CRN sites	TBC	80%	Assumption that the national target will remain the same
		(B) Proportion of non-commercial studies achieving or surpassing their recruitment target during their planned recruitment period	TBC	80%	Assumption that the national target will remain the same
Participant Recruitment	Deliver significant levels of participation in NIHR CRN Portfolio studies	(A) Number of participants recruited to NIHR CRN Portfolio studies	TBC	60,951	For planning purposes we are proposing an overall recruitment target of 60,951 as the CRN Y&H contribution to the national target, which has yet to be confirmed. This is based on the current portfolio and studies in set up that are in the pipeline for opening in 2020/21. To calculate this we have excluded recruitment from large studies that recruited on average over 1000 participants per year within that period and that closed during 2019/20. We have reviewed our pipeline and added the recruitment from the expected proportion within FY2021 based on 5% of the study sample size assuming patient cohort, capacity, number of sites etc. in Y&H
		(B) Number of participants recruited to commercial contract NIHR CRN Portfolio studies	TBC	2,348	Nationally this year has seen a significant decline in commercial recruitment with the expected year end position at 28,992 against a target if 40,000  In CRN Y&H the target was set at 4000 i.e. 10% of the target in line with our population, however we are forecast to achieve 2040 - 51% of target.  Anecdotally Brexit is the reason for most of the decline - alongside the fact that study populations are getting smaller as medicine becomes more personalised. Nationally we are expecting to see some recovery as the Brexit effect wears off

					<p>and as confidence in the UK direction is now clear. However, there are not enough studies in set-up to demonstrate this recovery will happen in time to fully recover the figures within the next financial year - especially with the COVID-19 likely to remove significant resources.</p> <p>In light of the above and assuming that nationally next year's recruitment will be level with 2019/20 achievement (i.e. 28,992) we have looked at several options:</p> <p><b>1. Population based:</b></p> <ul style="list-style-type: none"> <li>- 10% of overall forecast commercial recruitment in line with population (target = 2899)</li> <li>- 8.1% of overall forecast commercial recruitment in line with average achieved (<b>target = 2348</b>)</li> </ul> <p><b>2. % of portfolio based against our HLO 1 target.</b></p> <ul style="list-style-type: none"> <li>- 5 year portfolio balance average 4.4% of 60915 (target = 2680)</li> <li>- 5 year portfolio balance average minus large obs. studies 6.1 % of 60915 (target = 3693)</li> <li>- 5 year national portfolio balance average 5.6% of 60915 (target = 3472)</li> </ul> <p><b>3. Average recruitment last five years</b> (target = 3391) - not applicable due to Brexit/COVID 19 impact (Note: we cannot use forecast recruitment in region as we only have 717 forecast for 20/2)</p> <p>To remain in line with this year's approach we have proposed retaining the population based model but have amended this to reflect the actual average performance of the network over the last five years. Our target therefore is <b>2,348</b>.</p>
New Commercial Studies	Increase the number of studies delivered for the	(A) Number of new commercial contract studies entering the NIHR CRN Portfolio	TBC	N/A	This is managed nationally and local targets are not applicable

	commercial sector with support from the NIHR Clinical Research Network	(B) Number of new commercial contract studies entering the NIHR CRN Portfolio as a percentage of the total commercial MHRA CTA approvals for Phase II–IV studies	TBC	N/A	This is managed nationally and local targets are not applicable
Provider Participation	Widen participation in research by enabling the involvement of a range of health and social care providers	(A) Proportion of NHS Trusts recruiting into NIHR CRN Portfolio studies	TBC	100%	Assumption that the national target will remain the same
		(B) Proportion of NHS Trusts recruiting into NIHR CRN Portfolio commercial contract studies	TBC	70%	Assumption that the national target will remain the same
		(C) Proportion of General Medical Practices recruiting into NIHR CRN Portfolio studies	TBC	50%	Assumption that the national target will remain the same
		(D) Number of non-NHS sites recruiting into NIHR CRN Portfolio studies	TBC	192	Number of Non-NHS Sites recruiting in FY1920 is 183. Proposed ambition is a 5% uplift on this value.
Dementia and Neurodegeneration Recruitment	Deliver significant levels of participation in NIHR CRN Portfolio Dementias and Neurodegeneration (DeNDRoN) studies	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio, each year	TBC	1,000	We are proposing a reduction of approximately 52% in the target for FY 2020/21 in comparison to FY 2019/20. The DeNDRoN portfolio and pipeline has been reviewed and given the limited availability of high recruiting studies nationally and a large recruiting study closing prior to the start of this financial year the target for 2020/21 has been set to 1000.
Participant Experience	Demonstrate to people taking part in	(A) Number of NIHR CRN Portfolio study participants responding to the Participant	TBC	1,000	% of patients recruited to Portfolio studies in 2019-20

	health and social care research studies that their contribution is valued	Research Experience Survey, each year			
Site Set-up	Reduce intra-study site set-up times for NIHR CRN Portfolio studies	(A) Median intra-study site set-up time for commercial contract studies, at confirmed Network sites (days)	TBC	80	Assumption that the national target will remain the same
		(B) Median intra-study site set-up time for non-commercial studies (days)	TBC	60	Assumption that the national target will remain the same
Priority Specialties	Improve access to research by increasing recruitment in local priority areas (including underserved groups)	(A) Percentage increase in the number of participants recruited to NIHR CRN Portfolio studies within local priority areas	5%	LCRN	* See below Delivery of COVID-19 studies
		(B) Proportion of LCRN local priority areas with an increased recruitment of 5% or more	80%	CRN	This target is managed nationally

\* (A) Ambition value 5% - an LCRN-level baseline for each local priority research area will be calculated, this will be the mean of the equivalent annual out-turn values for the 2-year period 2018/19 to 2019/20. The ambition is to recruit at least 5% more participants in each local priority research area in 2020/21. (So, if CRN had recruited a mean average of 60,000 participants to these areas for the years 2018/19 and 2019/20, then the ambition would be to recruit at least 63,000 participants (i.e. 3,000 or 5% 'more' participants) in 2020/21).

## Appendix 1:

Source: ODP (Data cut apps)

FY	Recruitment	Local Target	Aspirational Target	Population
1415	56,449	67,416	71,250	5,423,805
1516	60,169	60,000	64,527	5,445,296
1617	74,630	65,000	65,000	5,468,101
1718	84,130	65,000	65,000	5,499,053
1819	91,426	65,000	65,000	5,534,527

The figures above provide an average actual recruitment figure of 73,361 over the 5 year period.

Large recruiting studies (as below) which have recruited on average over 1000 participants per year within the above period have been excluded from our proposed target. This is on the basis that, with the exception of the Born in Bradford Growing Up study (closure date Dec 2020) all other studies have closed and so no recruitment is expected in 2020/21.

- Yorkshire Health Study
- Born in Bradford: The Primary School Years
- Evaluation of Potential Negative Impacts of MUP in Sexual Health.
- Factors that influence antibiotic prescribing habits for acne
- HepFree
- LifeInfo Survey: What do you think about use of your data?
- Born in Bradford Growing Up

By removing these recruitment numbers the average is 53,470 over the last 5 years.

We have undertaken an analysis of the pipeline of studies that are currently in set up in LPMS/ODP and there appears to be 5 large studies due to open in 2020/21 (Large = 1,000 study sample size). A number of these studies are expected to be delivered over more than one year so the sample size has been divided into the number of years so assuming linear recruitment in all years. If CRN Yorkshire and Humber has 10% of the England population we can model recruitment based on 10%. However this assumes that all studies will be set up at the beginning of the year, available patient cohort, capacity, number of sites etc. A model of 5% was also calculated.

The LCRN proposes our target to be based on a 5% calculation given our current portfolio and studies in set up to provide a realistic and achievable ambition.

Based on this analysis 7,445 participants are added to the average recruitment of the last five years i.e. 53,470 totalling **60,915**.