

## **Cover Sheet**

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**Title:** CRN Thames Valley and South Midlands Annual Progress Report

**Status:** For Information

**History:** Regular Annual Reporting

**Board Lead: Interim Chief Medical Officer** 

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Confidential: No

Key Purpose: Assurance

# **Executive Summary**

- 1. This paper provides an update to the OUH Trust Board as Host of the NIHR CRN Thames Valley and South Midlands (CRN TVSM) on the progress of the network.
- 2. A record number of participants volunteered for health research studies supported by CRN TVSM in 2021-22, with nearly 80,000 participants taking part in NIHR-supported studies from across all parts of the region.
- 3. CRN TVSM was the Lead Network for several platform studies of national importance including the RECOVERY and PRINCIPLE studies into treatments for Covid-19, and also led on a number of other multi-centre studies of national importance such as SYMPLIFY, which is assessing the performance of a multi-cancer early detection blood test, and ASCEND PLUS which is investigating treatments to help protect those with type 2 diabetes from cardiovascular disease.
- 4. Other highlights included progress embedding research across primary care, with over 90% of practices recruiting to studies in-year, which included remote recruitment to PANORAMIC, the world's first Covid-19 anti-viral study. The network also recruited to its first commercial Phase 1 trial for patients with motor neurone disease in Oxford.
- 5. The current hosting contract is due to run until 31st March 2024, and new geographic configurations have been announced with effect from 1st April 2024, which will align more closely with the seven NHSE regions and the new ICSs. As a result, the current TVSM geography will form part of a much larger region which includes Hampshire and the Isle of Wight but excludes Milton Keynes. Other changes in relation to the future shape and remit of the new networks are expected to be announced in September 2022. The Host selection process for the new networks is expected to run from October 2022 until March 2023.

#### Recommendations

The Trust Board is asked to:

- Note this progress report for information
- Note that the CRN Thames Valley and South Midlands 2021-22 Highlights Report has been submitted to NIHR

# **CRN Thames Valley and South Midlands Annual Progress Report**

# 1. Purpose

1.1. NIHR Clinical Research Network Thames Valley and South Midlands (CRN TVSM) has been hosted by the trust since 1<sup>st</sup> April 2014 and the current contract is due for renewal as of 31<sup>st</sup> March 2024. The network prepares an annual progress report for the Board and this paper provides an update on the network's activities during 2021-22 and its plans for the coming year.

# 2. Background

- 2.1. Governance and management arrangements remained unchanged during 2021-22 and the OUH has continued to fulfil its responsibilities as a network Host in line with the DHSC/LCRN Host Organisation Agreement and the Performance and Operating Framework.
- 2.2. The network comprises the three counties of Berkshire, Buckinghamshire, Oxfordshire and includes Milton Keynes. It has a combined population size of c.2.3m.
- 2.3. This year, there was no requirement for a CRN TVSM Annual Report for 2021-22, or a CRN TVSM Annual Plan for 2022-23. Instead, the network was asked to submit a 1-page Highlights Report for 2021-22, and to contribute to the national CRN Annual Plan for 2022-23. These activities were duly undertaken.

# 3. 2021-22 Highlights Report

- 3.1. The 2021-22 Highlights Report that was submitted to NIHR CRN is provided in Appendix 1.
- 3.2. More participants than ever volunteered for health research studies supported by CRN TVSM in 2021-22, with a total 79,066 participants taking part in NIHR-supported studies in Berkshire, Buckinghamshire, Milton Keynes and Oxfordshire.

The figures include:

- Berkshire Healthcare NHS Foundation Trust 38 studies, 1,723 participants
- Buckinghamshire Healthcare NHS Trust 58 studies, 5,337 participants
- Milton Keynes University Hospital NHS Foundation Trust 57 studies, 4,564 participants

- Oxford Health NHS Foundation Trust 60 studies, 2,357 participants
- Oxford University Hospitals NHS Foundation Trust 487 studies, 17,527 participants
- Royal Berkshire NHS Foundation Trust 90 studies, 6,263 participants
- 41,295 participants in studies in non-hospital settings, such as at GP surgeries and studies delivered in peoples' homes
- 3.2. CRN TVSM was the Lead Network for several platform studies of national importance including the RECOVERY and PRINCIPLE studies into treatments for Covid-19. It also continued to support many other Covid-19 studies running across the region including CCP-ISARIC (rapid collection of data and biological samples), OCTAVE and OCTAVE-DUO (investigating vaccine responses in patients with impaired immune systems).
- 3.3. It also led on a number of other multi-centre studies of national importance such as SYMPLIFY which is assessing the performance of a multi-cancer early detection blood test and ASCEND PLUS which is investigating treatments to help protect those with type 2 diabetes from cardiovascular disease.
- 3.4. CRN TVSM made significant progress embedding research across primary care, with over 90% of practices recruiting to studies in-year. Of note, this included remote recruitment to PANORAMIC, the world's first Covid-19 anti-viral study.
- 3.5. The network recruited to its first commercial Phase 1 trial for patients with motor neurone disease in Oxford.
- 3.6. The network also expanded its flexible Direct Delivery teams in Oxford and across primary care, with additional satellite posts across the DGHs which can also be accessed for non-NHS recruitment. Other workforce activities included the appointment of 5 clinical fellows in September 2021 and the management of 20 medical student placements.
- 3.7. CRN TVSM continued to deliver an active communications and engagement programme. Numerous events were held and over 30 items of coverage across regional and national media, and 800,000 posts on social media were generated. Over 1,700 participants completed the Participant in Research Experience Survey (PRES) to help improve the delivery of studies in the region and an action plan was formulated in response to their valuable feedback.
- 3.8. A budget of £18.1m was awarded to the network in 2021-22. This included an amount of £1.7m to support the development of its flexible workforce and to meet additional cost pressures, and £300k of additional funding for the Managed Recovery process. All required financial returns were submitted

to NIHR CRN Co-ordinating Centre (CRN CC) in line with requested timescales and a break-even position at year end was delivered. The NIHR CRN provided quarterly feedback on the quality of the financial returns reporting that the work of the OUH R&D Finance team and the network core team was of high quality. The next internal audit is due to take place in November 2022.

#### 4. 2022-23 Annual Plan

- 4.1. The CRN High Level Objectives for 2022-23 are provided in Appendix 2. These focus on efficient study delivery for both commercial and non-commercial studies and increasing participation by provider organisations including those in primary care and non-NHS settings.
- 4.2. The network will continue to support the delivery of studies which form part of the CRN Managed Recovery Programme and the NHSE RESET programme.
- 4.3. CRN TVSM will also continue to support current, and any new, studies as part of the research response to the Covid-19 pandemic.
- 4.4. At a national level, the CRN CC are responsible for the funding model to determine the allocations of funding to each of the 15 networks to support their activities. For 2022-23, this resulted in allocations to each of the networks that were broadly unchanged compared to the prior year in order to maintain stability as a result of the impact of Covid-19. Therefore, CRN TVSM also allocated 'flat' funding to each of its partner organisations for 2022-23, but with a ca. 3% uplift which it took from its available contingency funds in order to support local inflationary pressures
- 4.5. This year, there was no requirement for a CRN TVSM Annual Plan for 2022-23. Instead, the network was asked and contributed to the national CRN Annual Plan.

# 5. Beyond March 2024

- 5.1. The current contract is due to run until 31<sup>st</sup> March 2024, and details of the re-tendering process are currently awaited.
- 5.2. DHSC has already announced that the new geographic configurations will be known as NIHR Regional Research Delivery Networks (RRDNs), which, together with the national CRN coordinating centre, will form the NIHR Research Delivery Network (RDN). Determinants for the new RRDNs included size of population, number of Trusts/Partner organisations, patient pathways, and geographic area covered. Better alignment with the seven NHSE regions and ICSs was also considered to be vital to recognise the

- importance of CRN research right across the NHS footprint and the increased focus on social care and public health. As a result, the current TVSM geography will form part of a much larger region which includes Hampshire and the Isle of Wight but excludes Milton Keynes.
- 5.3. The CRN CC will be running the RRDN Host selection process on behalf of DHSC, and this is expected to run from October 2022 until March 2023.

## 6. Conclusion

6.1. This has been another successful year for CRN Thames Valley and South Midlands, and it has continued to play a key role in the delivery of many high-profile activities, including the research response to the Covid-19 pandemic.

#### 7. Recommendations

- 7.1. The Trust Board is asked to:
  - Note this progress report for information
  - Note that the CRN Thames Valley and South Midlands 2021-22 Highlights Report has been submitted to NIHR

#### 2021/22 CRN Thames Valley and South Midlands Highlight Report

Throughout 2021/22, the LCRN has continued to support urgent COVID-19 research, whilst increasing the focus on Managed Recovery, life sciences, primary care and non-NHS settings.

#### **Study Delivery and Lead Network Activities**

- CRN Thames Valley and South Midlands (CRN TVSM) was the Lead Network for platform studies of national importance including PANORAMIC (CPMS ID: 51313), RECOVERY (CPMS ID:45388) and PRINCIPLE (CPMS ID: 45457).
- Applied learnings from UPH/CUE-TIP lead network studies across other nationally-important studies, including SYMPLIFY (CPMS ID:49672), and ASCEND (CPMS ID: 51088).
- Continued active support to many UPH/CUE-TIP studies running locally including:
  - CCP- ISARIC (CPMS ID:14152): Royal Berkshire NHS Foundation Trust was one of highest recruiting sites, Oxford University Hospitals NHS Foundation Trust (OUHFT) was the second highest for tier 2 samples.
  - RECOVERY (CPMS ID: 45388): Milton Keynes University Hospital NHS Foundation Trust was one of highest recruiting sites
  - OCTAVE (CPMS ID: 48426): Oxford University Hospitals NHS Foundation Trust (OUHFT) in top 3 sites. OCTAVE-DUO (CPMS: ID 50087): OUHFT highest recruiting site.
- Further progress made embedding research across Primary Care, with over 90% of practices recruiting to studies in-year, including remote PANORAMIC recruitment.
- First commercial Phase 1 trial with patients with Motor Neurone Disease recruited in Oxford
- Developed a new module for the Local Portfolio Management System (LPMS), CENTRELINE,
   which can capture data on demographics and disease prevalence, across primary care activity.

#### Workforce/transformation

- Expanded flexible Direct Delivery teams in Oxford and across Primary Care, with additional satellite posts across District General Hospitals, which can be accessed for non-NHS recruitment:
  - PANORAMIC: 3 CRN TVSM hubs were in top 6 national recruiting GP hubs
  - o SYMPLIFY: CRN TVSM recruited 20% of the total recruitment of 6000 recruits.
- Undertook Virtual Ward project as part of lead network activities to support PANORAMIC study.
- Managed medical student placements and continued a successful clinical fellow programme.
- Rolled out resilience training and managers' mental health toolkit pilot work.

#### **Non-NHS settings**

- Successful local authority engagement with public health posts in Oxfordshire County Council (OCC) and with other teams, including regional LA Public Health Research Group.
- Supported OCC application for NIHR Health Determinant Research Collaboration funding and two successful applications to NIHR PHIRST Scheme.
- Led nationally on review of schools-based research projects and perceptions
- Joint work with RDS and Wessex to develop a new Social Care Research Network.

#### **Communications and Engagement**

- 1,700+ Participant in Research Experience Survey (PRES) returns and action plan formulated in response to participants' feedback.
- 34 items of coverage, across regional and national media and 800,000 posts on social media.
- 7 events were held (in-person and remote), with a range of patient and public audiences and mobile exhibitions rotated across 5 venues.
- Over 500 participants completed Media, PPI training, and study rehearsals training sessions.
- Work with under-served groups including workshops and research-ready project with Asian community in High Wycombe.
- Membership on OUHFT Health Inequalities Steering Group.

## 2022/23 NIHR CRN High Level Objectives (HLOs)

The HLOs are the national, overarching objectives for Clinical Research Network research delivery, and constitute the most important set of NIHR CRN Performance Objectives. The HLOs are collective objectives for the whole NIHR CRN system. The NIHR CRN Performance Objectives for 2022/23, relative to the NIHR CRN Performance Objectives for 2021/22, are summarised below.

### **HLO review and update process**

The 2022/23 High Level Objectives were developed in keeping with the spirit and practice of One CRN. Seven working groups were convened, each to discuss one of the seven areas of strategic focus as set out in <a href="Best Research for Best Health: The Next Chapter">Best Research for Best Health: The Next Chapter</a>. The workshops were attended by members of the CRNCC Executive Team, LCRN Clinical Directors, LCRN Chief Operating Officers, LCRN Deputy Chief Operating Officers, members of the CRNCC Senior Management, Research Delivery, Medical Directorate and Business Intelligence teams, and others including National Speciality Leads and an LCRN Research Delivery Manager. The seven workshops resulted in an HLO being recommended aligned with two areas of strategic focus. The recommendations of the working group were assessed, alongside the 2021/22 HLOs, by a CRNCC data team including representatives from Research Delivery, Business Intelligence and Performance Management. Colleagues from other parts of the CRN (internal and external to the CRNCC) were also consulted. This draft reflects the outcome of review and approval by the NIHR CRN Executive Team.

#### **Unchanged HLOs**

- Provider Participation (3): Percentage of General Medical Practices with recruitment in NIHR
  CRN Portfolio studies. The ambition value is unchanged from 2021/22. It is anticipated that
  this will be the final year for this Objective in this format. Work is ongoing to refine this
  Objective for 2023/24 to better reflect Primary Care participation, for example as demonstrated
  by learnings from the PRINCIPLE and PANORAMIC studies.
- Participant Experience: Number of NIHR CRN Portfolio study participants responding to the Participant Research Experience Survey.

#### **Amended HLOs**

- Provider Participation (1): Percentage of NHS Acute trusts with recruitment in NIHR CRN
  Portfolio studies every quarter. This HLO has been refined to reflect greater and sustained
  research activity; in order to achieve the ambition a NHS trust must recruit one or more
  participants each quarter, rather than one or more participant each reporting year. It is
  recognised that this remains an imperfect measure however this is considered a valuable
  interim step. This new Objective is Provider Participation (4).
- Provider Participation (2): Percentage of NHS Acute trusts with recruitment in commercial contract NIHR CRN Portfolio studies every quarter. This HLO has been refined to reflect greater and sustained research activity, in order to achieve the ambition a NHS trust must recruit one or more participants each quarter, rather than one or more participants each reporting year. It is recognised that this remains an imperfect measure however this is considered a valuable interim step. This new Objective is Provider Participation (5).

#### **Removed HLOs**

 Efficient Study Delivery (1): Proportion of new commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed CRN sites. This Objective has been removed as continuing to give this objective HLO status could be considered to draw emphasis from other, more time-relevant, Objectives.

#### Added HLOs

- Efficient Study Delivery (5): Percentage of closed commercial studies which have achieved their recruitment target. This objective has been added to reflect the expectation that the CRN demonstrates efficiency in terms of study delivery (with a focus on commercial studies). A revision may be required pending the outcome of discussions on the NIHR CRN Portfolio.
- Efficient Study Delivery (6): Percentage of closed non-commercial studies which have achieved their recruitment target. This objective has been added to reflect the expectation that the CRN demonstrates efficiency in terms of study delivery (with a focus on non-commercial studies). A revision may be required pending the outcome of discussions on the NIHR CRN Portfolio.
- Provider Participation (6): Percentage of NHS Ambulance, Care and Mental Health trusts with recruitment in NIHR CRN Portfolio studies every quarter. This Objective has been added to disaggregate these important Partners from the larger NHS Acute trusts. Historically these organisations have participated less than their larger NHS counterparts, and the ambition of 95% (mean of 2019/20 and 2018/19 out-turn, rounded up) reflects this. Disaggregating the NHS Ambulance, Care and Mental Health trusts also makes their important contribution more explicit. The method for recording and reporting contribution towards the Objective is consistent with Provider Participation Objectives (4) and (5).
- Expanding our work with the life sciences industry to improve health and economic prosperity: Number of new commercial contract studies entering the NIHR CRN Portfolio as a percentage of the total MHRA CT approvals for PHASE II-IV studies. This Objective, last reported in 2019/20, reflects the CRN's expansion of commercial contract research support to reflect all of the commercial portfolio, i.e. both contract commercial and investigator initiated (industry funded) studies. This measure also helps to evidence the extent to which the CRN is supporting the commercial research which takes place in England.

# **Managed Recovery HLOs**

- A decision on the inclusion of one or more HLOs relating to Managed Recovery is pending the outcome of discussions on the NIHR CRN Portfolio, and are omitted from this draft. For reference in 2021/22 the associated HLOs were:
  - Efficient Study Delivery (2): Proportion of commercial contract studies in the managed recovery process achieving or surpassing their recruitment target during their planned recruitment period).
  - Efficient Study Delivery (3): Proportion of non-commercial studies in the managed recovery process achieving or surpassing their recruitment target during their planned recruitment period).

Table - 2022/23 NIHR CRN High Level Objectives

Objective		Measure	Ambition	Level	Note
Efficient Study Delivery	Deliver NIHR CRN Portfolio studies to recruitment target	(4) Percentage of closed to recruitment commercial contract studies which have achieved their recruitment target	ТВС	CRN	A
		(5) Percentage of closed to recruitment non-commercial studies which have achieved their recruitment target	ТВС	CRN	В
Provider Participation	Widen participation in research by enabling the involvement of a range of health and social care providers	(3) Percentage of General Medical Practices with recruitment in NIHR CRN Portfolio studies	45%	CRN	С
		(4) Percentage of NHS Acute trusts with recruitment in NIHR CRN Portfolio studies every quarter	99%	CRN	D
		(5) Percentage of NHS Acute trusts with recruitment in commercial contract NIHR CRN Portfolio studies every quarter	70%	CRN	Е
		(6) Percentage of NHS Ambulance, Care and Mental Health trusts with recruitment in NIHR CRN Portfolio studies every quarter	95%	CRN	F
Participant Experience	Demonstrate to participants in NIHR CRN supported research that their contribution is valued through collecting their feedback and using this to inform improvement in research delivery	Number of NIHR CRN Portfolio study participants responding to the Participant Research Experience Survey	14,000	CRN	G

Expanding our work with the life	Sustain or grow commercial	(1) Number of new commercial contract studies entering the	75%	CRN	Н
sciences industry to improve	contract research	NIHR CRN Portfolio as a percentage of the total MHRA CT			
health and economic prosperity		approvals for PHASE II-IV studies			

#### Notes:

- A. Efficient Study Delivery (4). A new objective.
- **B.** Efficient Study Delivery (5). A new objective.
- C. Provider Participation (3). The 2022/23 ambition value of 45% is unchanged from the 2021/22 ambition value.
- **D**. Provider Participation (4). A new objective.
- **E**. Provider Participation (5). A new objective.
- F. Provider Participation (6). A new objective.
- **G**. Participant Experience. The 2022/23 ambition value of 14,000 represents an increase of 2,000 on the 2021/22 ambition value of 12,000.
- **H.** Expanding our work with the life sciences industry to improve health and economic prosperity (A). This Objective, last reported in 2019/20, reflects the CRN's expansion of commercial contract research support to reflect all of the commercial portfolio (i.e. both contract commercial and investigator initiated (industry funded) studies). The 2022/23 ambition value of 75% is equal to the 2019/20 ambition value.