

## **In support of the Life Sciences Sector Deal 2: Plans for establishing 5 commercial centres for late phase commercial research.**

### **A Forum response on request to the Department of Health & Social Care (DHSC)**

#### **Introduction**

The NHS R&D Forum is a UK-wide professional network and community of practice for the research management, support and leadership workforce in health and care organisations.

Members of the NHS R&D Forum working groups have written this response on behalf of the community following a request by DHSC to help ensure the success of the centres and to limit any unforeseen undesirable impacts on research in the NHS. Comments have been received from each of the Forum working groups and from staff working in roles across the NHS research infrastructure landscape including:

- R&D Director & Associate Directors
- Lead nurse for research
- Clinical trials management
- Sponsor representatives
- Primary care and commissioning R&D leads
- Research managers/operations leads with Clinical Research Facilities within their remit
- Acute, community, primary care and ambulance Trusts.

This response has been written in the spirit of partnership and as such we trust our comments will be taken constructively as they are intended. For further information on the NHS R&D Forum and our membership please see [www.rdforum.nhs.uk](http://www.rdforum.nhs.uk)

We should be delighted to continue conversations with industry partners; the NIHR, Devolved Administrations and the Department of Health & Social Care to ensure our contribution towards enabling the ambitions in the Industry Sector Deal 2 are realized.

## Background

- The NHS R&D Forum is committed to supporting the Life sciences Industrial strategy and to play our part in the [Sector Deal 2](#), which includes supporting the development of some key initiatives within it.
- One of these initiatives is the introduction of 5 centres for late phase commercial research, which aim to enable the UK to deliver an ambitious increase in contract clinical research opportunities for patients. Our members and the organisations they represent welcome this. *For details from the Life Science Sector Deal 2: Strengthening the UK environment for clinical research, see p12 (Appendix B)*
- These 5 centres are expected to provide additional capacity and capability within the NHS/NIHR infrastructure to deliver exceptional service and fast study set up such that the UK is better able to compete for this research. It is hoped once the first 5 are established in England that additional centres will be enabled in the future across the UK.
- We understand that all centres will be expected to utilise nationally agreed systems and provide a consistency of service to Industry Sponsors and CROs.
- This paper sets out a basic framework of principles aimed at ensuring that this new initiative derives success for all stakeholders and that patients and healthcare research benefit optimally. This paper follows a review previously undertaken by the Forum's **Research Strategy & Leadership working group** who looked at the initial concept entitled 'High throughput centres'.
- Forum members expressly welcome the shift from high throughput to late phase commercial research, ensuring that research is grown rather than drawn from existing organisations.

### Summary of our response

1. The 5 centres have the potential to increase overall UK clinical trial capacity and on this basis they are to be welcomed. It is recognised that the existing NIHR infrastructure has a well-developed approach to delivering commercial research and there would be a synergy if the centres were fully integrated, operating in a way that complements the existing practice and process.
2. There is the potential for unintended consequences if the centres introduce additional bureaucracy, if they disrupt NIHR funding arrangements, promote more competition or silo working, or if they make it difficult for patients with the highest clinical need to access research. There is a risk that the centres draw from rather than increase commercial research to Providers and we should mitigate this risk as commercial research income maintains important R&D infrastructure and supports a wider R&D activity with all the associated benefits to patient care and professional development of clinicians.
3. We propose a framework of principles that we believe should underpin the development of the centres, to minimize the risk described and to ensure the delivery of their full potential
4. There is an opportunity in the design of these centres to develop acute, community and primary care partnerships that support improved collaborative working for research with public involvement at the core. A systems change that enables full recognition of all contributions to the research journey would facilitate this further and at pace.
5. If partnerships can ensure facilities also reach out to communities in addition to providing extra physical capacity and infrastructure we will move closer towards our aim of bringing research to those who need it most in line with the NHS England Long Term Plan.

## **Principles**

Through this paper we aim to help shape the development of the 5 centres and how they optimally deliver benefit for all stakeholders. Each heading represents a principle we believe should form the set-up of the centres with some practical considerations and solutions.

- **Principle 1:** The centres should add value to the research patient pathway. They should learn from and compliment existing NIHR clinical research infrastructure, and be fully embedded in the NHS.
- **Principle 2:** The centres should be a catalyst for true primary, community and secondary care partnerships with a role to extend the reach of our research and enabling more patients to benefit from opportunities. To align with the Long Term Plan, the partnerships underpinning the design of the centres should aim to enable research to go out to patients wherever possible as well as providing extra physical clinic space.
- **Principle 3:** Development of the NIHR portfolio activity recognition methodology should be considered in conjunction with the establishment of the centres in order to recognise and reward all organisational contributions to the research journey and facilitate better partnerships working across boundaries. This includes all participation in research in addition to participant identification.

**Principle 1:**

The centres should add value to the research patient pathway, learn from and compliment existing NIHR clinical research infrastructure, and be embedded in the NHS.

- 1.1. Commercial clinical contract research is very important to NHS providers and commissioners; it brings new therapies to patients and taking part *in itself* improves health and care. Being research-active as an organisation brings benefit in addition to any impact from the research intervention.
- 1.2. It is imperative that we balance the need to specialise in expert, focused, facilities for rapid study delivery with the knowledge that we are now improving care through research within hospitals, community organisations and primary care services. We must therefore find a synergy between these two things.
- 1.3. It is really important that the centers add value and don't detract from what we have already built or destabilize existing infrastructure. Trusts/GPs must be incentivized to participate or refer in because they meet a need and ideally the delivery partners should be allowed to decide which infrastructure best delivers a study to achieve locally agreed targets. The centers must not be competition for existing patients, or draw research out of the NHS. Their niche must be explicit and the added benefit to NHS research very clear.
- 1.4. NHS organisations must be able to see these centres as an extension of their current service provision such that this hard fought-for benefit continues for all. Staff for example might have flexibility in their job role to prevent the clinical workforce moving out to the units, whilst at the same time adding NHS support to their role in the research centre.
- 1.5. All NIHR and NHS R&D Infrastructure should be joined up to ensure the full research patient pathway is delivered as seamlessly as possible and to promote the value of the NIHR Clinical Research Network to Sponsors and Clinical Research Organisations. Whilst acknowledging the importance and power of focused centres of excellence we are also seeking less fragmentation of early through to late phase clinical trial delivery.

- 1.6. Therefore, Forum members who contributed to this response were clear: **these should be fully integrated NIHR/NHS centres for commercial research sitting within our existing excellent infrastructure and not separately networked commercial research centres into which NHS patients are referred.**
- 1.7. We believe it is important to learn from what we already have in place across the UKCRF network. Expertise and mentorship should be sought from these existing centres of excellence and the organisations that host them. We also believe it would be beneficial to continue to use familiar language (such as Clinical Research Facility) so that everybody understands their purpose and role in the research pathway, providing a clear message that these centres sit within the existing system.
- 1.8. We are clear that these centres must bring *extra* work to the UK and fill gaps in our clinical research portfolio. Forum members have reported that late phase research can indeed be difficult to accommodate within both the existing experimental medicine and clinical infrastructure and therefore additional capacity and capability is welcome, however, we must still be mindful to develop the best facilities for this purpose.
- 1.9. Clinical service capacity and capability is likely in some cases to remain a significant barrier to study set up and it would be unrealistic to expect resolution for some studies by running them through a CRF. We should therefore be realistic about the types of studies we can accommodate and be clear to drive them through the centres when appropriate.

For example:

Many phase 3 studies are now increasingly complex and require hospital care with all the associated back up i.e. resuscitation and emergency facilities etc. If studies do require complex support services, specialist facilities or staff whose availability cannot be guaranteed (because they are fully integrated with a busy service provision), then the CRF may either be unsuitable or fail to enable the quick and consistent study set-up and delivery that is hoped for.

We can see, however, that treatment of some chronic conditions for example might benefit hugely from extra CRF capabilities, where patients who might otherwise be managed between primary, community and secondary care services, could be seen in accessible specialist research clinics

1.10. Staff management structures, training, quality assurance and improvement initiatives should all link into existing NHS Organisational R&D management functions to ensure benefit for both the centre and the NHS organisation.<sup>1</sup>

**The relationship between the center and NHS organisation/s is key for a number of reasons but not least:**

- For relationships between roles. This is important for clinical teams, centre staff and research departments.
- Staff development, support and opportunities
- Flexibility and expertise
- Facilities and easy access to hospital for emergency procedures
- Training opportunities for clinical fellows
- Governance and accountability procedures
- Contracting: with the progress being made nationally it would be a mistake to create a relationship so complicated that the standard commercial contracts can't deliver
- To ensure the benefits flow back and forth between the centre and the NHS and don't just sit in the centre
- Promotion and all the benefits of NIHR and NHS R&D infrastructure

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<sup>1</sup> NHS R&D Forum R&D Functions wheel [https://www.annualrdforum.org.uk/wp-content/uploads/2016/11/WHEELv4\\_SCALE.pdf](https://www.annualrdforum.org.uk/wp-content/uploads/2016/11/WHEELv4_SCALE.pdf)

**Principle 2:**

The centres should be a catalyst for primary, community and secondary care partnerships with a role to extend the reach of our research and enabling more patients to benefit from opportunities. To align with the Long Term Plan the partnerships underpinning the design of the centres should aim to enable research to go out to patients wherever possible as well as providing extra physical clinic space.

- 2.1. To truly capitalize on unmet need and disease prevalence in line with the [Long Term Plan](#) these centres need to be established in areas where there is capacity to grow and to extend the reach of research in areas of high disease burden. To avoid conflict with the direction of travel towards primary care and new models of care these centres need to have excellent Primary and community care relationships and could act as an enabler of improved research partnerships if developed in response to collective need.
- 2.2. We must be careful not to set up centers in big well-established organisations *just because* they are big and well-established whilst at the same time ensuring that the new centres are embedded and linked to experienced CRF teams, R&D infrastructure and a supported workforce. Mental Health Trusts currently struggle to access commercial studies outside of some of the big specialist centres (see McPin Foundation report [Everywhere and everyone included: Research in NHS Mental Health Trusts in England](#)) and we hope this initiative will improve not exacerbate this.
- 2.3. Patient pathways span organisational boundaries and the NHS England Long Term Plan makes it clear that we must work collectively to deliver care across communities. The Long Term Plan is also focused on prevention, mental health and primary care services and so it is important that the centres support research across these services rather than inadvertently drawing it away into disconnected research centres. This means that it is important to build **true partnerships** for research between primary, community and acute services utilizing the creation of these centres, as a catalyst to bridge the gap.
- 2.4. This is an opportunity to build partnerships that will support and design these centres in such a way that commercial research can be delivered **to** the patients in the community wherever possible rather than expecting patients to come into the centres at all times. To align with the ambitions in the long-term



plan this might include for example a greater use of technology, digital consultations and linking in with existing initiatives to reach under-represented populations in rural communities. Such solutions might also offset some of the extra cost of running studies through dedicated centres, which can be high.

- 2.5. We believe the benefits to being research active are maximised through being an integral and connected part of the research journey akin to the principles of [team science](#), where all contributions are recognised and that there is significant benefit if we realize the value in partnership.
- 2.6. Whereas Participant identification is of course fundamental to accessing research opportunity for patients, ensuring Participant Identification Centres (PICS) are linked into formal learning groups or networks that benefit from feedback and a connected workforce can strengthen the role of a PIC
- 2.7. Hub and spoke models can help to deliver research at scale and lessons learned from across the R&D community (particularly in primary care) can be shared here. For example models of [hub and spoke](#) good practice articulated by Nottingham City CCG have resulted in a successful community of practice in the region and growth in research activity in the spokes themselves.

### **Principle 3:**

- 3.1. [Development of the NIHR portfolio activity recognition methodology should be considered in conjunction with the establishment of the centres in order to recognize all organisational contributions to the research journey and facilitate better partnerships working across boundaries. This includes all participation in research in addition to participant identification.](#)
- 3.2. It is absolutely critical to get the right level of incentivisation into the system. Issues of funding by proxy measures such as consent and recruitment activity sometimes stifle cross boundary/sector working and some organisations report improved collaboration when sharing of recruitment activity or research posts has been enabled locally. This has recently been written up in a letter to the NIHR CRNCC by a collaborative of CCGs and NHS Trusts in the East of England, who articulate the challenges for partnership working inherent in a system that only recognizes recruiting sites. Forum members have further reported difficulties when Providers who support recruitment occurring in commercial

centres can't secure acknowledgment for their participatory work. NB: as this is also now critical to supporting ETCS for non-commercial studies it seems timely to improving system-wide.

- 3.3. Whilst we acknowledge that AcORD guidance for *non-commercial* research may mean there are challenges in the system for funding certain types of research activity per se. We believe it should at least be possible to better enable visibility and recognition of study participation by site type, beyond consent and recruitment alone. This is particularly true for commercial activities not subject to AcORD attribution. Indeed if the value of research to NHS organisations is in participation then visibility of this in itself will go some way towards valuing contribution of all roles participating in the research journey including but not limited to continuing care, shared care, participant identification, recruitment, and research delivery, treatment and follow-up.
- 3.4. NIHR CRN performance metric HLO 1 currently measures patient recruitment against which organisations and regions are compared. Regions that secure a centre will naturally get higher HLO1 performance in a way that will then not be proportionate around the country and an understanding of this in the performance management of research would be helpful in avoiding unintended and potentially unwanted consequences. If we agree that research should follow patient need then we must ensure we bring all facilities up to meet this purpose with specialist facilities adding extra value on top for work not otherwise possible.

Appendix A:

**Suggestions for a late phase CRF.** We advise linking to the [UKCRF network](#) for further expertise and guidance:

**For physical infrastructure & space:**

- Dedicated generic outpatient space
- Centrifugation labs
- PK bay
- Digital maturity, EPR and e-CRF capability
- Nurse-led
- Storage labs
- Patient beds
- Sufficient disabled WCs
- Monitoring room
- Strong operational management
- Nurses station/office
- Mechanisms for reaching out to communities for example: eMobile units, flexible teams and digital solutions

**For the partnerships underpinning the centres:**

- Each centre should be designed and underpinned by established partnerships across acute, community and primary care and include patients and the public with an aim to extend the reach of research out to communities.
- Excellent communication routes agreed from the outset that set out:
  - The flows of patient data across organisations to be agreed at study set up
  - How the NHS clinical teams are alerted if a patient is recruited into a trial outside of their usual care giver
  - How organisations in the partnership are impacted if the majority of research activity is within a centre which fails to meet recruitment to time and target standards (i.e. whose metrics would be affected?).
  - IMP management and accountability – if Sponsors are reluctant to pay for Pharmacy set up across more than one site agreement will need to be reached upfront to ensure sites remain attractive to sponsors
  - Legal accountability and governance arrangements for contractual, safety and indemnity issues. See the [hub and spoke](#) model in primary care for examples of good practice in the NHS R&D Forum resources exchange.

**For the partnerships to work together rather than in competition:**

- A system that recognises all partners and their contributions to the research activity

## Appendix B

### Details from the Life Science Sector Deal 2: Strengthening the UK environment for clinical research

<https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal-2-2018>

Sector action	Government action
The government's comprehensive plan to improve our clinical research environment has unlocked new commitments from companies:	We will further improve the speed and efficiency of clinical trials by:
* Celgene provides support for studies and is making a new investment in excess of £7m, with an overall £38m investment.	* Establishing 5 centres for late phase commercial research.
* With National Institute for Health Research (NIHR) facilitation support, IQVIA Ltd. will invest £24m over 5 years into a fourth UK Prime Site for clinical trials across the North of England.	* Exploring opportunities to recognise and incentivise NHS Trusts and GP practices acting as participant identification centres.
* IQVIA Ltd. and Genomics England are investing £20m over 5 years to develop services that will enable more efficient drug research.	* Continuing to improve research set-up timelines.
* The Brain Tumour Charity will invest £2.8m in the Tessa Jowell BRAIN-MATRIX, a trial aimed at increasing opportunities for brain tumour patients to try non-standard treatments.	* Addressing challenges in NHS workforce resourcing to deliver commercial research.
	We will consolidate our world-leading position in delivering novel and innovative trials by:
	* Promoting the UK's expertise in designing and delivering innovative trials.
	* Enabling industry, including SMEs, and the wider research community to access advice to support innovative trial design.
	* Delivering a skills programme to embed expert understanding of how innovative studies can be run across the NHS.

- Establishing 5 purpose designed centres dedicated to late-phase commercial research in 2019 to 2020. Identified through NIHR Clinical Research Network (CRN) competition, the centres will offer rapid set-up of late phase commercial research, standardised contracting and delivery approaches where appropriate, and dedicated facilities and staff. They will increase the NHS's capacity to deliver research, enabling significant growth and opportunities for patients to benefit from early access to innovation.
- Identifying opportunities to recognise and incentivise NHS Trusts and GP practices acting as participant identification centres. The NIHR CRN will explore mechanisms to ensure patients are offered the opportunity to participate in research of relevance to them, whether or not it is being delivered by their regular healthcare provider, making recommendations to the Department of Health and Social Care by spring 2019.
- Continuing to improve research set-up timelines by achieving HRA approval within timelines specified in the EU Clinical Trials Regulation; increasing the transparency of performance data through common use of the HRA/NIHR research study minimum dataset across NHS organisations, and providing industry with access to this data in a searchable format to inform site selection and intelligence-driven performance improvement.
- Addressing challenges in NHS workforce resourcing required to deliver commercial contract research. Working closely with industry and NHS Trusts, the NIHR CRN will investigate the workforce resource challenges in commercial contract research, and develop recommendations to government for innovative approaches to tackle them by summer 2019.