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ACCELERATED ACCESS COLLABORATIVE (AAC) BOARD

Paper Title: AAC ambition for clinical research in the NHS.

Agenda item: 4

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Paper type: For discussion.

AAC Priority Area:

Demand signalling / horizon scanning	☐	Adoption and spread	☐
Increasing research	☒	Working with partners	☐
Increasing uptake	☐	Other (statutory, governance)	☐

Ask of the AAC Board

1. Recognise the current context for research in the NHS, support the actions being taken through the Reset programme and encourage full engagement of funders and sponsors in order to release capacity and restore a thriving research environment.
2. Support the Research, Resilience and Growth (RRG) partners to ensure we combine our efforts to deliver the long-term sustainability in the research ecosystem and capacity in the NHS.
3. Agree to the ambitions set out in this paper, highlight any significant omissions in our plans to deliver them and work with the AAC and RRG partners over the next three to five years to realise these ambitions.

Executive summary:

1. Our experiences of undertaking clinical research, especially in Urgent Public Health trials, during the pandemic and the increased profile that has given research, for both frontline clinical staff and patients and the public, present us with a significant opportunity to be ambitious about the future of research in the NHS. Our ambitions for the next 5 years are:
    a. **To make the NHS the best place in the world to undertake research**
    b. **Every patient will be supported to take part in research that is appropriate for them and every NHS organisation will be involved in clinical research**

2. To achieve this, we will address three key areas. We will:
    i. increase diversity in research,
    ii. increase the scale of research and
    iii. the pace at which research is undertaken in the NHS.

This paper sets out how we will do this in partnership with our AAC partners.

Background

1. The pandemic has brought the importance of clinical research and the benefits to patients, the NHS and wider society into a sharper focus than ever before. The success of vaccine development and world leading trials, such as RECOVERY and REACT, have raised the profile of clinical research amongst front line staff, patients and the public garnering strong support for research in the NHS and highlighting the benefits of public sector collaborations with industry.
2. The urgency and scale of participation that was required in the first waves has also led to the acceleration of new methodologies with streamlined and decentralised approaches being adopted with significant success. The speed at which urgent public health (UPH) trials were set up and delivered has shown what is possible when the system works together with a common purpose.
3. This context presents us with a huge opportunity to build on this success and learn from what has worked to make the NHS a world leader in clinical research, creating a thriving research ecosystem to improve patient outcomes and experience, eliminate health inequalities, and deliver our ambitions for clinical research[1] and the UK Life Sciences[2].

Our ambitions

4. Our ambitions for research in the NHS over the next five years are:
    1) **To make the NHS the best place in the world to undertake research**
    2) **Every patient will be supported to take part in research that is appropriate for them and every NHS organisation will be involved in clinical research**

5. To achieve this, we need to make significant progress to improve in three key areas; we must increase a) the diversity in research; b) the scale of research being undertaken and c) the pace at which research takes place. Below we set out what needs to be done and how and the metrics we will use to measure our success in each of these 3 areas. We will work with partners across the Recovery Resilience and Growth (RRG) programme (see Annex 1) to deliver the AAC ambitions which are aligned with RRG implementation plans. A programme plan for the AAC research unit this year and high-level plans across the next two years are included in Annex 2.

A) Increasing diversity in research

[1] Saving and Improving Lives: The Future of UK Clinical Research Delivery
[2] Life Sciences Vision (publishing.service.gov.uk)

6. We will increase the diversity of participants in research, ensuring participants reflect the populations to which the research is most relevant. People and communities should also be directly involved in identifying unmet needs and shaping the future research for their communities.
7. We must also ensure that participants from diverse communities can engage in and access research that is relevant to them and that they are interested in. People and communities experiencing the highest burdens of disease must be involved in research otherwise there is significant risk of furthering inequalities. There is an opportunity to use levers presented via the duties relating to research and public involvement in the Health and Care Act to create a stronger focus on research that is developed with communities and is especially applicable to those communities experiencing the greatest healthcare inequalities.
8. This year, in partnership with the NIHR we will scope and set the foundations for a 3-year programme to work with ICSs, starting in pilot sites, to focus on local activation for research across diverse communities.
9. In 2020/21 100% of all NHS Trusts in England and 50% of GP practices were research active[3]. However, only 14% of Trusts accounted for 53% of this activity. We must ensure that we increase the diversity of geographical locations and settings where research is undertaken to enable equitable access and ensure research is undertaken in the communities where it is needed.
10. Therefore, in line with the requirement in the Health and Care Act for ICSs to facilitate research we will expect and support all ICS to be research active and every NHS organisation to be involved in research, giving every patient the opportunity to take part in research that is relevant to them**.** We will also expect ICS to undertake commercial research to ensure populations have access to a full range of research opportunities. We will explore if we should set an expectation that a percentage of their portfolios should be commercial.
11. We will develop a framework for ICSs to support them to fully exercise their duties under the new legislation. This will include guidance on governance and the local partnerships and infrastructure needed to build their research activity alongside their local communities. We will build on the successful regional research events held over the last six months to continue dialogue with regional, ICS and research community leadership on what good looks like in the new infrastructure and engage across AAC stakeholders in development of this framework.
12. We will measure our success in a number of ways, starting with development of a metric this year within NHS England and Improvement to highlight provider involvement in research. We will also develop an assurance process for ICSs in respect of their new responsibilities and then build on this to measure the activity in ICS footprints. We will continue to work with RRG partners in the development of metrics to demonstrate the diversity of participants in research in the NHS which can be used by all partners across they system.

[3] NIHR Clinical Research Network High Level Objectives Outturn Report 2020/21

13. Evidence shows that staff who are involved in research have greater job satisfaction and that it positively impacts job retention (reducing staff turnover in research active Trusts)[4] . Enabling NHS staff to undertake research is critical to ensuring that research and the resulting improvements in services and outcomes is realised. The research workforce will be a recognised part of the NHS workforce. The workforce team at NHS England is currently working with its partners to develop a long-term NHS workforce plan, and we will work with them to ensure that the research workforce is taken account of in this work.
14. The Research team has established a subgroup of the NHS England Research Leaders Group which brings together representatives from all professions in the organisation to provide guidance and leadership in research to the NHS workforce. Last year the Chief Nursing Officer[5] and the Allied Health Professionals[6] published their research strategies and the research team are working closely with the nursing team as they develop their implementation plan. The Chief Midwifery Officer's research strategy is due for publication this year and the medical directorate are planning to liaise with stakeholders to develop a similar approach for the medical workforce.
15. We will increase diversity in the research workforce including the spread across different professional groups, supporting more staff to be research active and all health professionals will understand their role in research and will be supported to get involved. Research will be facilitated at every level throughout an organisation irrespective of whether leaders have a direct role in research.
16. We are working with the staff survey team to consider including research in the national staff survey to capture both the scale and diversity of the current workforce and the exposure of NHS staff to research in their work.

B) Increasing the scale of research

17. The Data for R&D programme within the Transformation directorate is leading the work to build and scale the infrastructure for data driven studies and enabling secure access to NHS data for researchers via trusted research environments (TREs). This programme supports the work of the AAC and RRG in increasing the scale of research in the NHS. In addition, this infrastructure will open further opportunities to increase diversity. The AAC research team and NIHR are all working in collaboration with this programme to ensure complete alignment in our ambitions and delivery.
18. The programme will enable national recruitment to large scale clinical trials through funding NHS DigiTrials[7], which gives all potentially eligible citizens the opportunity to participate in research, with monitoring against diversity and inclusion targets to be conducted. For example, the NHS-Galleri study, which resulted from the deal negotiated by the AAC and the commercial medicines

[4] Rees MR, et al. Postgrad Med J 2019;0:1–5. doi:10.1136/postgradmedj-2019-136501
[5] B0880-cno-for-englands-strategic-plan-fo-research.pdf
[6] HEE Allied Health Professions Research and Innovation Strategy
[7] NHS DigiTrials - NHS Digital

directorate and is supported by DigiTrials, has invited over 1 million citizens to participate, and is delivering good ethnicity and indices of multiple deprivation spread.

19. An interoperable system of TREs will cover all of England through both a National TRE and Sub-National TREs. This will ensure all citizens who have not opted out have the opportunity to be represented in research based upon NHS data. The sub-national TREs will cover a population of 5-10 million citizens. The national TRE has facilitated an AstraZeneca study into the safety of COVID-19 vaccinations, which drew insights from over 40m records, and has been published in PLOS medicine.
20. By 2025, the NHS Digital National Trusted Research Environment and NHS DigiTrials will be scaled up from 'MVP' to meet researcher demand and by April 2024 the national TRE will support 250 users and 50 research studies and reduce time to onboard new users to 60 days maximum. NHS DigiTrials will also have a pipeline of 65 studies.
21. Researchers will have access to near real time, granular and multimodal NHS data via an interoperable network of Sub National TREs, with investments covering 80% of the population of England by April 2023.
22. Federation of Genomics assets and connectivity to clinical data will maximise their potential to generate insights to improve patient outcomes.
23. Commercial principles will be applied consistently and coherently to generate fair returns for the NHS and support the sustainability of investments
24. By delivering on ministerial commitments for data security within TREs the programme will shore up public confidence in the use of NHS data for research, contributing to the mitigation of risk of increased opt outs.
25. We are working with the support of the Data for R&D programme team to ensure patients and the public are able to register their interest to take part in research via the NHS App, and bringing together infrastructure to ensure leverage of existing registries of research volunteers, feeding into a central platform (NIHR Be part of Research). It will be streamlined and easy for potential research participants to consent to be contacted
26. We will deliver on our Long-Term Plan commitment of 1 million people registering an interest in research in 2023/24 and significantly build on this number in the following 2 years.

C) Increasing the pace of research

27. In 2019/20 median study set up time for commercial contract research and non-commercial research in the NHS was 74 days and 57 days respectively[8]. During 2020/21 the average set up time for UPH studies was 3 working days. Whilst this dramatic reduction in set up time was restricted to prioritised studies at a time of urgent need it demonstrates what can be achieved when working to a common purpose. Similarly, the "NHS-Galleri" study achieved its first patient recruited within 35 days of study approvals, significantly faster the average 218 days, demonstrating that even in a time of pandemic set up for a study outside

[8] NIHR Clinical Research Network - Research Performance Report 2019/20

the UPH category can be significantly reduced. We must increase the pace of research being undertaken in the NHS, to ensure benefits for patients and to maintain the UK's competitiveness in the global market: these examples have demonstrated what is potentially possible on a wider scale.

28. To speed up set up time we will roll out the next stage of National Contract Value Review (NCVR) (see Annex 3) which will make it easier and faster for NHS organisations and commercial trial sponsors to plan and execute trials in the NHS. This begin for organisations covered by the standard contract from 1st April 2023 with implementation for other NHS organisations in the following year. We will consider introducing a phased approach to mandated timescales in NCVR via the National Directive on commercial research[9] to make costing and contracting of commercial studies in the NHS as fast as possible. In 2023/24 we will begin work for a similar process to speed up costing and contracting for non-commercial research in the NHS including a review of excess treatment costs (ETCs) policy. For 2022/23 we have significantly reduced the ETC provider threshold to facilitate wider provider participation in non-commercial research incurring ETCs.
29. The Data for R&D programme will lead Find, Recruit and Follow-up to convene stakeholders across the ecosystem in order to make it quicker and easier to set up and deliver data driven clinical studies and develop a researcher-facing navigation tool and, for high priority studies, concierge support to speed up the journey from concept to delivery of research studies by making the pathway to underpinning trials with data more transparent and traversable.
30. We will also work with all our RRG partners to increase the focus on faster recruitment to studies once set up is complete. Linking an increase in the scale of data driven research, as described above, in identifying eligible patients for recruitment with an increase in trials using innovative and streamlined methodologies to widen recruitment opportunities and increase site participation.
31. We will measure our success using the established NIHR CRN measure for efficient study delivery: studies achieving or surpassing recruitment targets during the planned recruitment period (time and target). We will begin with commercial research aiming for an 80% rate for all commercial studies by summer 2023 and work to achieve 90% the following year We will then expand our approach to all research using time and target as our key metric.

Current Context

32. Undertaking research in the NHS is currently very challenging. Despite the actions of the managed recovery programme[10] recovery of non COVID research has not reached the levels anticipated. There is a lack of capacity in the system due to overstretched R&D departments and continued pressure on clinical services as well as there being an unprecedented number of studies currently on the NIHR CRN portfolio. We are working jointly with all RRG

[9] NHS England » National directive on commercial contract research studies
[10] Managing research recovery | NIHR

partners to take urgent action as part of the research reset process beginning by supporting funders and sponsors to review their portfolios and make decisions on the deliverability of studies that are not progressing.

33. Within this context we must be realistic about what can be achieved and prioritise actions over the next six to 12 months that will release capacity in the system, maintain the momentum gained by advances made during the pandemic and lay the foundations for our wider ambitions. The AAC research unit will direct our resource over this period on the following actions:
    a. Implementation of the necessary actions that are identified as part of the reset process.
    b. Roll out the next stage of NCVR for organisations covered by the standard contract by 1st April 2023.
    c. Develop and test a metric to be included in provider assurance frameworks and agree accountability of the ICSs as part of overall ICS governance.
    d. Work across our partners to combine our efforts on actions that will enable long term sustainability such as developing and implementing CRN deliverability criteria for portfolio studies.
    e. Publication the NHS England and Improvement Research Roadmap, setting out our strategy to the system, bringing together the research framework and metrics.
    f. Publication of the ICS research framework and further development of our regional/ICS engagement networks to ensure implementation of the new research duties in the Health and Care Act.

AAC Board members are asked to:

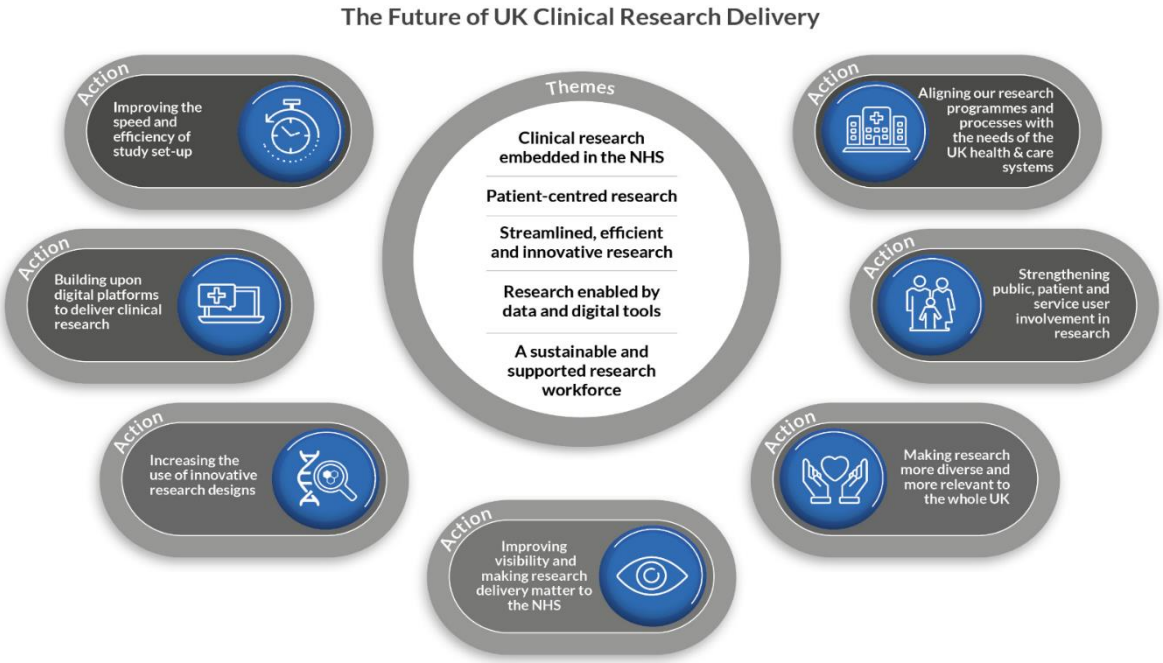
- Recognise the current context for research in the NHS, support the actions being taken through the Reset programme and encourage full engagement of funders and sponsors to release capacity and restore a thriving research environment.
- Support the RRG partners to ensure we combine our efforts to deliver the long-term sustainability in the research ecosystem and capacity in the NHS.
- Agree to the ambitions set out in this paper, highlight any significant omissions in our plans to deliver them and work with the AAC and RRG partners over the next three to five years to realise these ambitions.

Annex 1: Summary of Research Resilience and Growth (RRG) and the Reset programme

Research Resilience and Growth

Overview

1. Last year Government published the National Vision For Clinical Research, the phase 1 implementation plan and the Life Sciences Vision. These made clear the ambition to increase research in NHS, as it improves care, health outcomes and has financial benefits to NHS and UK plc.



2. **The Research Resilience and Growth Programme** (RRG) was established as a UK wide, cross sector programme to deliver the Vision. Many AAC partners are involved in the RRG which has the following structures:
   - RRG oversight Group – Chaired by Lord Kamall,
   - RRG Programme Board – Chaired by Louise Wood (DHSC Director: Science, Research & Evidence). This is the workhorse of RRG.
   - RRG Advisory Group – Chaired by ABPI/AMRC

3. The first phase of the implementation plan was published in June last year and focused on activity which could support the recovery of non-Covid research in the NHS. As the CSR settlement is now understood, the RRG is developing their phase 2 implementation plan which will cover a 3-5-year period.
4. At the start of the pandemic research rightly pivoted to COVID research which have led to the development of new treatments and vaccines, and generated evidence that has underpinned the response to the pandemic. Whilst research into other conditions continued, it was severely affected.

5. In Spring 2021 a managed approach to the recovery of the UK clinical research portfolio was implemented. **Managed Recovery** sought to coordinate and sequence delivery of a sub-set of multi-centre studies identified by funders so these could be completed at pace. The intent was to clear the path for other studies paused or delayed in the early stages of the pandemic to return to the levels of recruitment that would normally be expected.
6. The Managed Recovery process has had a degree of success. However, some studies have been unable to return to the levels of recruitment that would normally be expected. The number of studies on the portfolio is now higher than ever before. The RRG agreed that further action was needed to revitalise research in the UK
7. In March DHSC/NHSE/I, as an initial step in the **Research Reset** programme, has written to Sponsors urging them to review their portfolio to identify studies which could be closed. If this does not have the desired effect DHSC will be mandating action through NIHR CRN.
8. Since then NIHR have been analysing individual trial data and identifying those studies that are at most risk of failing to deliver. In May DHSC/NHSE/I wrote to the funders with details of which of their studies have identified as “at risk” as part of this process. This is intended to inform sponsor decision making and they have been asked to provide feedback on their intended approach to address “at risk” studies within 3 weeks of receiving the lists.
9. A Reset Oversite Group has been established, jointly chaired by DHSC and NHSE/I, this group will monitor progress and impact on the overall portfolio and intelligence gathered from across the sector. If substantial improvements in study delivery cannot be achieved the Group will make recommendations on further actions including nationally mandated action.

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Annex 2: AAC Research Unit Programme Plan

Workstream	Activity	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	2023/24	2024/25
A. Overarching															
1. NHSE/I Research Roadmap	1.1 First draft			■											
	1.2 Final draft enters PAC					■									
2. ICS Guidance & performance	2.2 First draft			■											
	2.2 Final draft enters PAC					■									
3. Regional Engagement	3.1 Complete 1st round events	■	■												
	3.2 Complete analysis of recommendations				■	■									
	3.3 Develop plans for national themed events				■	■									
4. Metrics in provider assurance	4.1 Discovery work	■	■												
	4.2 Draft metrics developed			■	■										
	4.3 Groundwork for pilot				■										
	4.4 Metrics pilot					■	■	■							
	4.5 Pilot report							■							
	4.6 Update metric & guidance							■	■						
	4.7 Beta testing									■	■	■	■		
	4.8 Discovery work - ICS Metrics						■	■	■						
	4.9 Inclusion in ICS assurance process													■	
5. Evidence for Research Review	5.1 Develop business case	■													
	5.2 Approval of BC	■													
	5.3 Commission CSU		■												
	5.4 Interim findings submitted				■										
	5.5 Final report submitted					■									

Workstream	Activity	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	2023/24	2024/25
	5.6 Publication of report, dissemination														
B. Increasing Diversity															
6. Research Conversation toolkit	6.1 Work carried forward from 2021/22														
	6.2 Finalise toolkit														
	6.3 Launch toolkit and training package														
7. ICS Research Forum Pilot	7.1 Discovery work														
	7.2 Business case (2 year)														
	7.3 Identify 3-5 pilot sites														
	7.4 Pre-pilot set up														
	7.5 Pilot & evaluate														
8. Using Pharmacies to raise awareness	8.1 Discovery work														
	8.2 Business Case (2 year)														
	8.3 Identify 3-5 pilot sites														
	8.4 Pre-pilot set up														
	8.5 Pilot & evaluate														
C. Increasing scale															
9. MPR - interoperability of registries	9.1 Business case sign-off														
	9.2 Launch open tender														
	9.3 Agree scope with supplier														
	9.4 Set up governance framework														
	9.5 Deliver work														
	9.6 Final report														
	9.7 Implement recommendations														

Workstream	Activity	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	2023/24	2024/25
10. Trialling features in registries to increase participation	10.1 Business case sign-off			■											
	10.2 Launch open tender				■										
	10.3 Agree scope with supplier					■									
	10.4 Set up governance framework					■									
	10.5 Deliver work						■	■	■	■	■	■			
	10.6 Final report												■		
	11.7 Implement recommendations													■	
11. Biomarkers as incentives	11.1 Business case sign-off			■											
	11.2 Launch open tender				■										
	11.3 Agree scope with supplier					■									
	11.4 Set up governance framework					■									
	11.5 Deliver work						■	■	■	■	■	■			
	11.6 Final report												■		
	11.7 Implement recommendations													■	
12. Use of NHS App as portal to MPR/BPoR	12.1 Groundwork engagement with stakeholders	■	■	■	■	■									
	12.2 Develop feasibility & options						■	■	■	■					
	12.3 Formal agreement with NHS App team										■	■	■		
	12.7 Development of key features of App (tbc)													■	
13. Including Research in the New Hospital Programme	13.1 Agree content & structure of Playbook Chapter		■											■	
	13.2 First draft Research chapter				■			■							
	13.3 Final draft														
D. Increasing Pace															
14. NCVR Stage 1	14.1 Cost variation exercise	■	■												
	14.2 Identification & training of coordinators	■	■												
	14.3 Go live			■											

Workstream	Activity	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	2023/24	2024/25
	14.4 Ongoing rapid learning cycles														
	14.5 End of year report														
	14.6 Detailed cost collection engagement throughout														
15. NCVR Stage 2 - Preparing for end stage	15.1 Develop & agree high level product														
	15.2 Develop detailed prog plan														
	15.3 Implement plan														
	15.4 Rollout Phase 2														
	15.5 Develop metric & monitoring														
15. Non-Com Research - ETC	16.1 Reduce threshold														
	16.2 Evaluate impact of reduced threshold														
	16.3 Transfer ETC CCG-ICS														
	16.4 ICS ETC guidance published														
	16.5 Scope out review of ETC														
	16.6 Develop options for future of ETC														
	16.7 2023/24 Budget set														
16. Non-Com Research - National Directive	17.1 Early discussion with stakeholders														
	17.2 Discovery work														
	17.3 Develop & consult on directive														

Annex 3: Summary of the National Contract Value Review programme

Overview

- The National Contract Value Review (NCVR) is a standardised, national approach to costing for commercial contract research improving consistency in study set-up and making it easier to conduct research in the NHS. It will replace the current time-consuming process whereby each NHS organisation negotiates with each commercial sponsor for every study in order to agree bespoke contract value.
- The NCVR is a key part of the RRG programme and one of a number that aim to increase the speed and efficiency of research set up to make the UK a more attractive place for international commercial organisations to undertake research studies, ensuring our patients have rapid access to cutting edge treatments.
- It is a UK-wide programme, with active involvement across all nations and reciprocal recognition of Contract Value Reviews conducted by NHS organisations across the UK.
- While NCVR is being led by NHSE/I it is a partnership programme involving HRA, NIHR/CRN, DHSC and the Devolved Administrations.
- In England NCVR is underpinned by the National standard contract and the National directive on commercial research studies
- Work on the NCVR process began in 2018/19 with the aim of bringing the unmodified model site agreement and the interactive costing tool (iCT) together with the introduction of a single National Contract Value Review.
- While the use of the unmodified site agreement and iCT continued during the pandemic, the introduction of the National Contract Review was paused. Following a review and incorporation of learnings to date, the overall NCVR process has been revised and is now ready to be re-introduced.

A Phased Approach to Introducing NCVR

In the medium term NCVR will mean:

- Site specific organisation costs will be available up-front prior study negotiations commencing,
- this transparency will help to inform site selection
- there will be a single national negotiation with no local negotiation.

But we are not yet in a position to roll out this end product, there are details to work through. This along with where we are both with elective recovery and research capacity the National NCVR team came to the conclusion that a phased approach to implementing NCVR was needed, phase one has begun and we anticipate going live with this in June.

Stage One of the NCVR Implementation will have two core elements:

- Data will be gathered to identify whether a study site intends to adhere to their local prices as generated by the Standard Costing methodology. The information on adherence will be made available to companies prior to site selection.

- From summer 2022 the introduction of the Contract Value Review process will begin. This will involve assessment of the consistency of the research study protocol activities and the completed costing template, together with the negotiation of the resource required to deliver the protocol at any UK-based NHS location. NCVR Contract Value Review Coordinators will carry out the review.