

Implementation of the National Contract Value Review process for Commercial Contract Research

NHS England and NHS Improvement



Improving Commercial Contract Research

The **NHS Standard Contract** places a contractual obligation on NHS providers in England to adhere to the new streamlined processes for Commercial Contract research, from 1 October 2018.

The **National Directive** sets out what these processes involve, specifically:

- mandated use of an **unmodified model site agreement**
- mandated use of **standard costing methodology**
- introduction of a **National Contract Value Review process**

The **National Directive** will continue to be reviewed and will be revised at the end of 2019/20, building on learning gained during the pilot implementation phases of the **National Contract Value Review process**.

The scope of the new arrangements includes multi-site studies and currently excludes phase 1, phase 2a, Advanced Therapy Investigational Medicinal Products (ATIMPS) and primary care studies.

Improving CCR Study Set-up

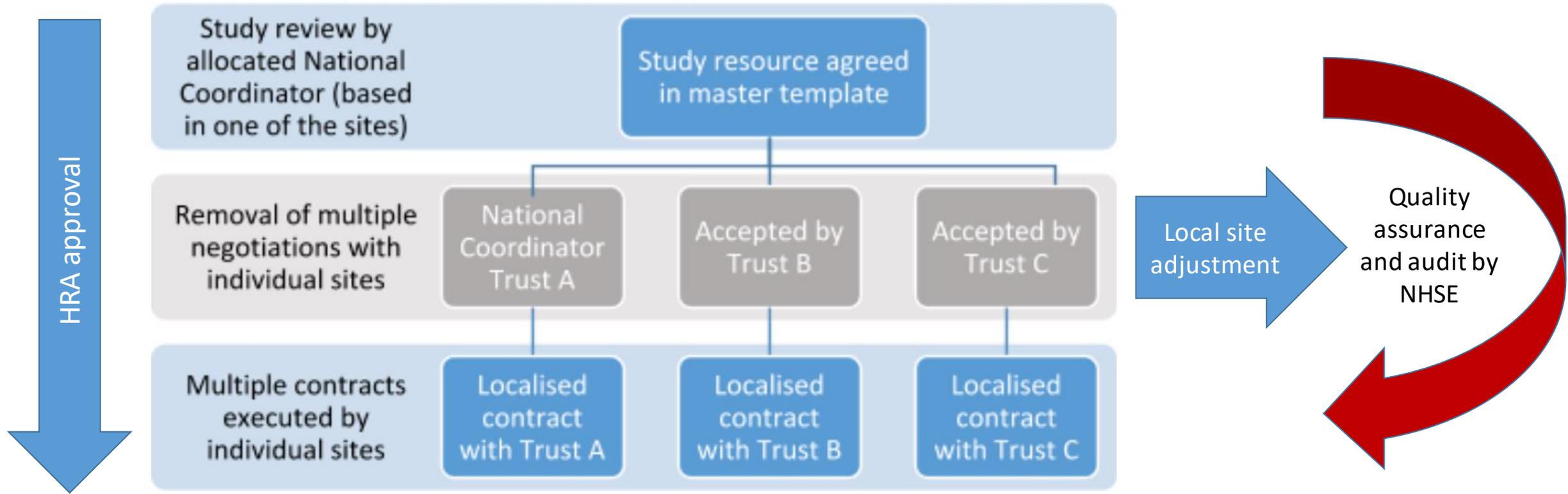
The **National Contract Value Review** process brings together three key elements to improve CCR study set-up:

1. Mandated use of an **unmodified model site agreement** and **standard costing methodology**, including the use of the new **interactive Costing Tool (iCT)**
2. Establishing **standards for nationally defining and allocating** commercial study resource and procedure requirements
3. Introduction of a **National Coordinator** role responsible for completing the **National Contract Value Review** for the study, ensuring that NHS providers achieve full cost recovery associated with delivering a commercial research study

Benefits of the National Contract Value Review process

- A new, standardised, national approach to costing and contracting for commercial contract research improving consistency in study set-up
- Increasing the speed and efficiency of research set-up in England increasing the capacity for more research in the NHS
- Separates national resource allocation for the study from specific local site resource allocation
- Builds on local expertise to establish a national process for defining and allocating resource and procedure requirements
- Ensures that NHS providers achieve full cost recovery associated with delivering a commercial research study
- By simplifying and improving research arrangements, we can speed up access to new treatments and support patients to receive the best care.

National Contract Value Review Approach



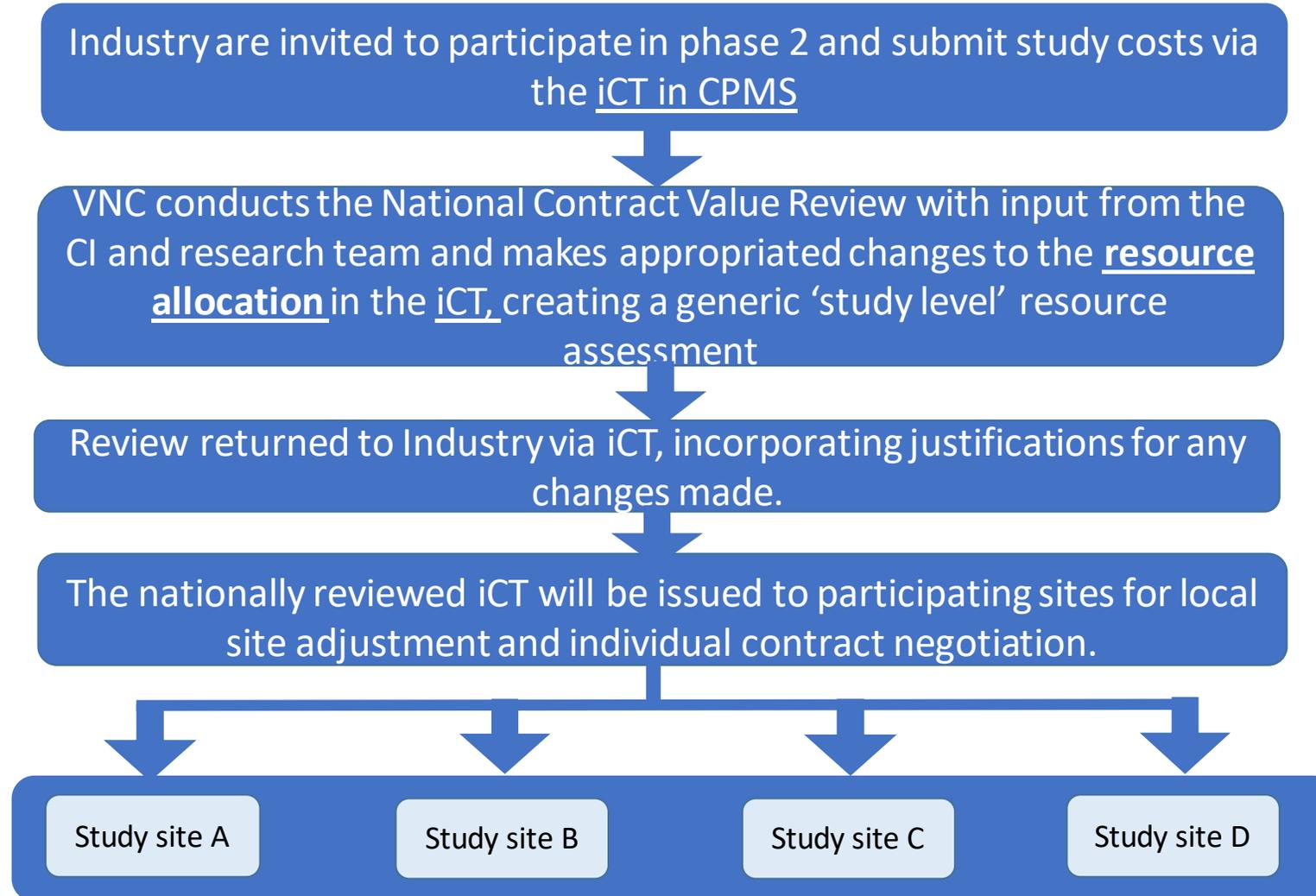
Phased Implementation



The role of the Volunteer National Coordinator (VNC) in the National Contract Value Review process

- 67 individuals from across the 31 most research active NHS organisations in England have been put forward as VNC.
- The VNC will conduct the National Contract Value Review to validate the resource allocation provided by the study Sponsor.
- During phase 2, the VNC will receive support from the Clinical Research Network's Phase 2 Team, to conduct the National Contract Value Review for studies assigned to them.
- The VNC will work with Chief Investigator and/or Principal Investigators for the study alongside relevant clinical and service support expertise to determine the appropriate resource required to deliver the study in England.
- The VNC will use the standard costing methodology via the interactive Costing Tool (iCT) to complete the review. Justification for all amendments will be captured in the iCT.

Phase 2 pilot process



Participating site will be **contacted directly by the CRN** if a study they are participating in is going through the national review process.

Participating sites and industry will have **full transparency of all amendments** and justifications made by the VNC via the iCT.

Phase 2 progress update

Aim: To test and refine the National Contract Value Review process, to understand the resource and training requirements needed to undertake the review and gain insight into any additional information required

Progress:

- 27 studies have been submitted via the interactive Costing Tool for consideration
- 8 of these studies are eligible for phase 2 and have been allocated to a Volunteer National Coordinator to undertake the National Contract Value review
- 12 studies were found to be ineligible (did not meet the criteria) and a further 7 are currently being reviewed

Phase 2 progress update

Preliminary findings:

- Reviews carried out where the VNC and Chief Investigator are co-located have been easier to organise and quicker completion
- Companies submitting for validation before confirming CI and/or formalising sites impacting on allocation of VNC
- Concerns from Industry partners that sites will re-review submission if there is not a strict definition of what can/ cannot be amended by a participating site. This will be reviewed once the data becomes available in CPMS.

Phase 3: what happens next?

- The National Contract Value Review process will be undertaken for all in scope studies
- Training completed for all VNCs
- Engagement and communication of the new processes to all participating sites
- Engagement and communication of the new processes to commercial partners
- Gradual reduction in 'hand-holding' support from CRN Phase 2 Team
- Explore arrangements for study types not currently included in Phase 2 pilot (phase 1, phase 2a, ATIMPs and primary care studies)
- Phase 3 will continuously follow phase 2 as new studies enter the system

What does this mean for my organisation?

Participating site: If you are a **participating site** in a study going through the National Contract Value Review process as part of phase 2 you will be contacted directly by the CRN who will support you through the process. You will receive a VNC validated template via iCT. You will be able to see where the VNC has made amendments to the template and any comments from the VNC. You will be required to only make **local site adjustments** to reflect local procedures. You will be required to provide justification for any amendments.

Studies outside phase 2: If you are a participating site **not** going through the National Contract Value Review process the costing template will go through the standard LCRN validation and then provided to participating sites for a full study resource review.

What does this mean for my organisation?

VNC host organisation: If you are a **VNC host organisation**, when an eligible study is allocated to your organisation your VNC will be contacted by the Clinical Research Network (CRN) and asked to complete the **National Contract Value Review for the study**. You will receive hands-on support and guidance through the process from the CRN.

If the study is **not** allocated to a VNC in your organisation but you are a **participating site** in the study you will follow the process for participating sites. You will receive a VNC validated template via iCT. You will be required to only make **local site adjustments** to reflect local procedures. You will be required to provide justification for any amendments to the validated template .

How do I explain to my organisation that a National Contract Value Review is being undertaken by a VNC to validate the national costs for the study?

- This is a standardised, national approach to costing and contracting commercial research in England and is mandated in the National Directive via the Standard Contract.
- The new process ensures that NHS providers achieve full cost recovery associated with delivering a commercial research study
- VNCs have been trained to undertake the National Contract Value Review and will be supported by CRN throughout the pilot phase
- The Chief Investigator and/or Primary Investigators for the study and relevant clinical and service support expertise will be involved in determining appropriate resource requirements
- VNC validated template will be provided to participating sites for local site adjustment and individual contract negotiation
- Sites will be able to make amendments to the validated template provided there is justification for the amendments

Next steps

- Visit NIHR website for more information on the National Contract Value Review process <https://www.nihr.ac.uk/partners-and-industry/industry/run-your-study-in-the-nhs/faster-costing-and-contracting.htm>