What the NHS National Directive on Commercial Contract Research Studies means for the Life Sciences Sector

The commitment to creating the best environment for clinical research and achieving the ambition for the NHS to make the UK a top tier global hub for biomedical and clinical research and medical innovation is set out in the Life Sciences Industrial Strategy and the NHS Long Term Plan. In response to direct feedback from the Life Sciences Industry and the NHS England consultation for supporting research in the NHS, we are simplifying processes for NHS commercial contract research through requiring site use of unmodified template site agreements, a standard costing methodology, and a single contract review process as confirmed in the Twelve Actions to Support and Apply Research in the NHS and the second Life Sciences Sector Deal.

A National Directive

National Health Service (NHS) providers in England operate as independent legal and financial entities and it is on this basis that they participate in commercial contract research. The introduction of a National Directive on Commercial Contract Research, which has been jointly developed by NHS England, the Health Research Authority (HRA) and the National Institute for Health Research (NIHR), enables an England-wide study-based approach to the costing and contracting elements of commercial contract research, in order to speed up set up times and benefit patients.

Health and Care Research Wales (HCRW) has confirmed the Welsh Government policy position on the use of the model agreements, as part of HRA and HCRW Approval across England and Wales, and continue their commitment to using the NIHR Industry Costing Template. Scotland and Northern Ireland have individual policies and processes to support the use of these tools.

Across the devolved nations within the UK, there are existing models that coordinate commercial contract research cost reviews. The current activities for the management of commercial contract research mandated in England aim to establish similar coordination models within England. These activities include a continued commitment to work closely with our cross-border colleagues to further align and integrate the way we work together to deliver for the life sciences sector.

Developed as part of the ongoing activities to simplify research arrangements led by NHS England in partnership with the Department of Health and Social Care, National Institute for Health Research and Health Research Authority alongside Health and Care Research Wales.

Impact of the National Directive on the life sciences sector

NHS providers in England* are mandated to use an unmodified model site agreement to:

- remove variability across NHS providers by using the same model contract terms. This will minimise legal review requirements.
- save time and resource for all future studies in the NHS.
- continue to ensure content remains fit for purpose through the Association of the British Pharmaceutical Industry (ABPI) and Association of British HealthTech Industries (ABHI) representing the life sciences sector and HRA (alongside devolved administrations), representing NHS providers.

* Health and Care Research Wales policy also requires the use of unmodified model site agreement for NHS organisations in Wales (unless HRA/HCRW waiver is provided).

NHS providers in England* are mandated to use the standard costing methodology
(the NIHR Industry Costing Template) to:

- remove variability across NHS providers by using the same costing methodology. This will enhance overall cost predictability, which in time will be better reflected in global commercial budgeting tools.
- apply a single costing methodology by all NHS providers when determining resource requirements to deliver the study and inform internal distribution, which will save time and resource.
- continue to ensure content remains fit for purpose through the multi-stakeholder governance group across the life sciences sector and the health and research infrastructure.

*The Devolved Administrations incentivise the use of the Industry Costing Template outside of this Directive.

NHS providers in England are implementing a single contract review process to:**

- assign a National Coordinator for each study, who is already responsible for one of the selected study sites, to undertake a single review that will determine the study resource requirements and agree these with the commercial company.
- increase potential efficiencies through sharing the study review with the study sites in order for them to localise their site's respective financial appendix within their individual model agreement. Localisation elements are

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pre-defined to avoid unnecessary further negotiation that could create delays (e.g. Market Force Factor application, service level agreements between the individual NHS provider and third parties delivering specific elements of their healthcare services). An impact assessment will be undertaken during implementation to monitor this.

- clarify standards for cost review to establish mutual assurance across NHS providers and transparency for the life sciences sector. This ensures full cost recovery for a publicly funded health and care system whilst balancing this with swift patient access achieved by a pragmatic do once and share approach for study costing and contracting.

**Wales and Scotland already have a single review process in place. This mandate will enable England to establish such an approach while supporting further alignment for cross-border studies.

Adherence to the requirements

Please contact supportmystudy@nihr.ac.uk to raise any concerns relating to:

- individual NHS provider compliance with the requirements outlined above, which will be escalated to the Health Research Authority, Local Clinical Research Networks and NHS England as the contract holder.
- commercial company engagement with the requirements outlined above.

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