NHS SCOTLAND
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HSC Health and Social Care

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

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Four nation portfolio studies: principles for commercial contract recruitment target setting

These principles have been developed in partnership with Industry Stakeholders, NIHR CRN Industry Roadmap Group and ABPI, and the NHS R&D community via the UK R&D Leaders and the R&D Forum Strategy and Leadership group. Underpinned by standard operating procedures across the four nations, these principles provide clarity for agreeing a recruitment target for all parties to work collectively towards delivering.

1. A mutually acceptable site target is agreed as a collective between each site (consisting of the Investigator, their study team and R&D office) and Sponsor/Contract Research Organisation. The Local CRN/ devolved administration support should be involved as defined by the relevant locally agreed processes.

2. Site targets based on recruitment duration should:
    a. Be for enrolled/randomised participants with a separate screening target provided if necessary for the study.
    b. Be based on a detailed feasibility assessment.
    c. Be a single figure or minimum target where the sum total across all study sites equates to the country target*. This will allow over-recruitment by a site without the need to amend the model Clinical Trial Agreement (mCTA). If the sponsor needs to prevent over-recruitment without prior agreement, then the mCTA should state the number above which prior agreement and mCTA change would be required.
    d. Align with the target in the mCTA with only very minimal exceptions when a collective agreement by all parties cannot be reached for a specific and documented reason.
    e. Only be provided for extension studies where there is an operational need.

3. Site recruitment performance will be measured against the original target. Retrospective adjustment of any site target is not anticipated for the majority of studies and only applicable in exceptional circumstances. Such revisions should be discussed and agreed in advance by each site and the Sponsor/Contract Research Organisation, involving the relevant Local CRN/devolved administration support as per agreed processes to ensure impact on country total is managed accordingly.

4. The study milestone schedule or equivalent formally documents the agreed targets and key dates for each site participating in the study and should be updated throughout the lifecycle of the study as per agreed processes.

5. A review on study closure, which also includes opportunities for customer feedback, ensures the participating sites, recruitment targets and milestone date information accurately reflects the delivery of the study to inform future site selection decisions.

*exceptions may apply for rare disease/population studies

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