

NHS England Commissioning Policy: Continuing funding after the completion of a clinical trial



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NHS England Specialised Commissioning – Continuing funding after the completion of a clinical trial

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Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the service specifications and processes cited in this document, NHS England has:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

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1 Purpose and Scope

The purpose of this policy is to set out the circumstances in which NHS England will provide funding for a treatment once a clinical trial is completed. This includes the circumstances in which funding may be provided after commercially-funded trials and non-commercially-funded trials.

This document also provides, for context, information on when NHS England will contribute funding to support clinical trials, and provides the links to relevant policies which describe this aspect of NHS England policy in greater detail.

2 Background to ‘NHS England Policy on continuing funding after the completion of a clinical trial’

As new treatments develop, or as new applications of existing treatments are identified, the potential benefits and risks of the treatment are tested through **clinical trials**. Trials are conducted in usual NHS care settings, using accepted quality of life and mortality measures.

Clinical trials can be divided into two categories:

- **Commercially-funded trials:** Commercially funded trials are those trials in which the costs of the treatment being trialled are fully funded by a commercial company, and where the NHS does not have responsibility for picking up any costs of the specific intervention either during the trial period, or upon its closure (although the NHS may meet costs of some activities associated with the trial, as described below).
- **Non-commercially funded trials:** Non-commercially funded trials can be funded through a range of sources; often they are funded by research bodies such as the National Institute for Health Research (NIHR) or they may be funded by NHS bodies including NHS England.

The circumstances in which NHS England will provide funding for a non-commercial trial may include the funding of a whole trial, funding of a patient’s participation in an existing trial, funding of excess treatment costs, and continued funding of the intervention after the trial for those patients that were already receiving it.

This policy sets out the circumstances in which this last type of funding may be provided by NHS England, i.e. funding for a particular treatment after the completion of a clinical trial of that treatment.

This policy does not cover the approach for Excess Treatment Costs, details of which can be found [here](#).

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2.1 Funding individuals' participation in existing trials, and funding experimental and unproved treatments

There are some circumstances where NHS England may agree to fund treatments for individual patients. Firstly, there may be some limited situations where the NHS may fund a patient's participation in an existing clinical trial, both commercially-funded and non-commercially funded. This may arise where a treatment is currently being evaluated in a commercial trial which is outside the NHS, for example in another country or healthcare system.

There are also some very rare circumstances where establishing the potential benefits of a treatment for an individual may not be possible through a formal trial, for example because the number of people affected is so small or because the individual concerned has an unusual clinical presentation. There may also be unusual clinical situations where the commissioner agrees that trials of an experimental treatment will be impossible to carry out.

In both circumstances, the responsible clinician is able to apply for funding via the IFR policy process. Please refer to the [IFR policy](#) for further information on this process.

Requests for on-going funding following any experimental or unproven treatment will only be considered if the treatment was begun following approval of an IFR by NHS England, and such applications should be made via IFR process. The treatment provider and the clinician should ensure that patients do not assume that NHS England will fund ongoing treatment once the initial funding period has ended.

3 NHS England policy on continuing funding after the completion of a clinical trial

3.1 Overview

3.1.1 Post-trial funding arrangements must be determined before the trial begins

NHS England expects that all research organisations planning a trial, regardless of how they are funded, must define and agree the arrangements for funding the treatment after the trial, for those patients where the trial has shown a clinical benefit. This is in line with the ethical approval requirements of the [Health Research Authority](#) for clinical trials.

These arrangements must be agreed before the trial commences, and should state the agreed level of proven benefit that will result in ongoing funding being given, and the criteria for stopping the treatment.

NHS England does not fund the continuation of any treatment started as part of a clinical trial unless there is a prior documented agreement to do so between the trial organisers and NHS England, i.e. agreement reached before the trial commences. No assumption can be made that funding responsibility would be transferred to NHS England without NHS England's explicit written approval prior to commencement of the trial.

3.1.2 Informing patients of post-trial funding arrangements prior to giving consent

Patients participating in a trial *must* be made fully aware of the arrangements for when the trial concludes as part of the process of giving their consent to participate in the trial. This includes making patients aware of whether or in what circumstances they can expect to continue to receive treatment after the end of the trial.

It is the responsibility of the NHS provider of treatment, and the patient's clinician, to ensure that patients are fully informed about:

- the circumstances in which funding for the trial is being provided;
- for how long and in what circumstances funding will be provided; and
- what will happen when it is withdrawn.

Clinicians should refer to the HRA Guidance [HRA Guidance](#) which sets out the information that should be provided to participants regarding the arrangements for funding care after a trial, including whether participants will have continued access to any benefits or intervention that they may have obtained during their participation in the trial once it stops.

It is the responsibility of the research sponsor to ensure that appropriate research governance is in place and that appropriate ethical review has been undertaken prior to the clinical trial commencing. NHS England expects that patient's prior informed consent to be clearly documented.

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The provider of the trial treatment and the clinician should take care to ensure that they do not make any statements or take any actions which might lead any participant in a trial to assume that NHS England will or might fund ongoing treatment once the trial has completed, unless NHS England has given a written commitment to provide such funding which would apply to that participant.

Prior agreement by NHS England to continue to fund a treatment for a patient on a clinical trial as part of the arrangements for that trial does not represent a policy decision by NHS England to routinely commission the treatment.

3.2 Post-trial funding arrangements for commercially funded trials

NHS England's position is that where a clinical trial of a treatment has been initiated and sponsored by a manufacturer of pharmaceuticals or medical devices, or by some other commercial organisation, responsibility for funding on-going access to the treatment rests with those parties.

The general principles set out in section 3.1 apply to these trials. This includes the principle that, as stated above, commercial organisations sponsoring trials are responsible for putting in place the funding arrangements of post-trial treatment, in advance of the trial commencing, for those patients for whom the trial has shown a clinical benefit.

3.3 Post-trial funding arrangements for non-commercially funded trials

NHS England will consider funding on-going access to the treatment given in a trial, or through a Commissioning through Evaluation scheme, in circumstances where:

- the clinical trial is to be wholly funded by non-commercial bodies and is sanctioned by the National Institute for Health Research; and
- when the request is made *before* the clinical trial commences.

Treatment will be funded only for as long as the patient's supervising clinician agrees that the treatment is clinically appropriate, and that the treatment is meeting the identified clinical outcomes.

The general principles set out in section 3.1 apply to these trials. This includes the principle that any agreement by NHS England to continue to fund a treatment for a patient, following a commercial or NHS England funded trial, does not represent a policy decision by NHS England to routinely commission that treatment for other patients who were not part of the clinical trial.

3.3.1 Transfer of commissioning responsibility

Where commissioning responsibility for a patient on a clinical trial transfers to NHS England from another NHS commissioner, and there is written evidence of an agreement to fund on-going treatment costs (after completion of a clinical trial) by the

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previous NHS commissioner, NHS England will fund those commitments made by the patient's previous NHS commissioner.

3.4 Transition of treatment from trial into routine commissioning

Once the trial is completed, the evidence about risks and benefits of the treatment should be clear. At this stage, where commissioning responsibility for the treatment falls within NHS England's specialised commissioning responsibilities, NHS England will assess whether the treatment should be routinely commissioned through the NHS England [Service Development process](#).

In circumstances where that process leads to a decision that the treatment is routinely commissioned, all patients who meet the access criteria will be funded through NHS England's routine commissioning policy.

The situation may arise where the treatment is not routinely commissioned, or where patients who were previously receiving the treatment do not meet the subsequent access criteria stated in the routine commissioning policy. For trial participants in this situation, whose clinical trial was not sponsored by NHS England through either excess treatment costs or, for instance, Commissioning through Evaluation, responsibility for funding any ongoing treatment will remain with the trial sponsor, or any other body which agreed to fund treatment after the end of the clinical trial. NHS England will continue to fund those patients who were part of an NHS England sponsored trial until they and their NHS clinician consider it appropriate to stop.

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4 Annex

4.1 Definitions

Clinical Trial

¹A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.

Trial sponsor

The sponsor of a trial is the person/organisation who takes on responsibility for the design and management (or for arranging the initiation and management) of the clinical trial, and for the funding (or arranging the funding) for that clinical trial.

Non-commercial trials

Non-commercial trials are conducted by researchers without the participation of the industry/commercial companies. The sponsor / funder should be a university, an NHS organisation, a public scientific organisation, a non-profit institution, a patient organisation or a researcher; there should be no agreements between the sponsor and third parties allowing them to use the data for regulatory or marketing purposes.

Commercial trials

Commercial trials are sponsored and fully funded by commercial companies, including overheads, and they do not qualify for NHS funding through the NIHR Portfolio, including funding for excess treatment costs.

Excess Treatment Costs

Excess Treatment Costs (ETCs) are the difference between the total treatment costs and the cost of standard treatment. As these costs are part of treatment's costs they are covered through normal commissioning arrangements and should be identified at an early stage of a study, preferably prior to an application for research funding being submitted.

¹ World Health Organisation http://www.who.int/topics/clinical_trials/en/