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HMRC internal manual

Corporate Intangibles Research and Development Manual

From: [HM Revenue & Customs](#)
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CIRD84400 - R&D tax relief: categories of qualifying expenditure: application to clinical trial volunteers

Clinical trial volunteers in the pharmaceutical industry

When pharmaceutical companies develop a drug they have to gain the approval of regulatory authorities in order to market the drug. The process of approval involves the appraisal of the safety and efficacy of the drug in a series of clinical trials. These are described at [CIRD81920](#)

<https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird81920>).

The trials involve the testing of the drug in both healthy patients and patients with the target disease or condition. Pharmaceutical companies and contract research organisations will often make payments to people volunteering to take part in clinical trials. Trials are conducted under ethical guidelines and the nature of the trials and what is expected of the volunteers will be fully explained to them and documented.

FA06/S28 and FA06/SCH2 introduced a new category of qualifying expenditure for R&D tax relief claims, the cost of relevant payments to subjects of clinical trials. A 'relevant payment' is defined as a payment made to the subject of the trial in return for participating in the trial. The term 'clinical trial' is defined as 'an investigation in human subjects undertaken in connection with the development of a health care treatment or procedure' (CTA09/S1140). The relief applies for expenditure incurred on or after 1 April 2006 for the large company scheme, and for expenditure incurred on or after 1 August 2008 for the SME scheme. If an SME carrying out an R&D project subcontracts the clinical trial element of the project to another company, then the principal can claim relief under the normal subcontracting rules in CTA09/Ss 1133 - 1136. If a large company subcontracts clinical trials to another UK company, then that company will normally be able to claim relief itself under the large company scheme. ([CIRD81470](https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird81470) (<https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird81470>)).

Treatment prior to FA06

The cost of paying trial volunteers does not fall within the definition of consumable stores, or consumable materials. The volunteers are not stored or consumed by the company, neither are they consumable or transformable materials used

in the R&D process. Consumable stores, is dealt with at [CIRD82450](https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird82450) (<https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird82450>) and consumable materials at [CIRD82300](https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird82300) (<https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird82300>).

Clinical trial volunteers are not employees of the companies and so the expenditure cannot be on staffing costs ([CIRD83000](https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird83000) (<https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird83000>)).

The trial volunteers are not contracted to undertake R&D activities on the companies' behalf. This is usually made clear by the contracts that the volunteers sign, which explains their obligations and also explains their right to withdraw from the trial at any time. Subcontracted activities are dealt with at [CIRD84200](https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird84200) (<https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird84200>).

The cost of the trial volunteer's services, are not a cost of externally provided workers. The trial volunteer's services are not provided to the companies by or through a staff provider, and the services that the trial volunteer provides are not under the terms of a contract between the trial volunteer and the staff provider. Externally provided workers are dealt with at [CIRD84000](https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird84000) (<https://www.gov.uk/hmrc-internal-manuals/corporate-intangibles-research-and-development-manual/cird84000>).

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