Taking part in commercial research: FAQ for practices

[The 2019 impact and value report](https://www.nihr.ac.uk/documents/impact-and-value-report/21427) detailed the significant income and cost savings that commercial research generates for NHS trusts. Between 2016/17 and 2018/19 the NHS received on average £9,000 per patient recruited to a commercial clinical trial and saved over £5,800 in drug costs for each of these patients. This equates to income of £355 million and cost savings of £26.8 million in 2018/19.

(<https://www.england.nhs.uk/long-read/maximising-the-benefits-of-research/>)

The NHS is promoting the benefits of commercial research, for the NHS as a whole, for NHS institutions, and for research as a whole – bringing benefits to patients and the public in developing and accelerating the development of and access to new treatments.

Practices might naturally have questions about whether commercial research is right for them, and how they can go about participating. We are here to support you if you choose to participate.

**What do you mean by commercial research (also known as industry studies)?**

Commercial research means studies run by commercial companies. Many commercial studies operate internationally, so CROs (contract research organisations) may be commissioned to run local or UK-wide operations.

Commercial studies have a commercial sponsor and funder (i.e. not NHS or a University). They may be on the NIHR CRN’s portfolio. There are some studies which are partly funded by commercial companies, or funded by companies but sponsored by Universities or Trusts – these do not count as commercial studies.

**Can my practice take part in commercial research?**

Commercial studies are increasingly reaching out more widely than the traditional hospital setting, e.g. to general practices. Expressions of interest are shared via the NIHR CRN commercial team or directly from the commercial company or CRO. To receive these contact industry.crnyorkshumber@nihr.ac.uk. Once you have experience in commercial studies, you are likely to receive more opportunities, and once you are able to evidence your experience, you will be more likely to be selected as a site for studies.

Some commercial studies require a practice to have specialist equipment, for example freezers down to a specific temperature. All of these requirements are detailed in the initial expression of interest form.

The local CRN team can offer support with delivery of studies so practices should be supported through the whole process of participation. West Yorkshire R&D as well as the CRN are always open to help with any questions.

You shouldn’t feel disheartened if you submit an EOI but are not selected to participate. These studies are usually competitive and it can take a few attempts before you get selected. To get started out, it may be a good idea to start with studies with lower involvement or commercial studies where the only activity in practice is identifying patients and the research activity takes place elsewhere. Any involvement in studies can help to evidence that you can deliver research.

**Will taking part in a commercial study mean more work for the practice?**

A commercial study may mean more involvement – but every study is different. The schedule of events document details everything the practice would be expected to deliver. You will need to make sure your staff are supported to give the required time to the study (this can include any member of the practice team including doctors, nurses, other health professionals and/or administrative staff).

**Should I take part in commercial research?**

Whether commercial research is right for your practice, or for you as a professional, will depend on many factors. It is an area of focus for the NHS and can have benefits for your practice, your patients and for medicine generally. But it can mean more commitment. We know practices are extremely busy – but these studies can offer benefits as well as workload – and any work should be fully costed and reimbursed by the study. Practices can decide on a case-by-case basis if a study is right for them. Staff delivering the study can find professional development as well as bringing a new dimension to their practice.

**What might be involved?**

Like all research, every study is individual and the specifics of what you would be asked to do vary. You should carefully review the information sent by the study team at the expression of interest (EOI) stage. You may not have time to discuss detail at this stage, but should have the opportunity to discuss this before signing up to a study.

**Is it a potential money-spinner?**

Practices should always be reimbursed for participation in studies, and for commercial studies it can be quite lucrative.

|  |
| --- |
| [The 2019 impact and value report](https://www.nihr.ac.uk/documents/impact-and-value-report/21427) detailed the significant income and cost savings that commercial research generates for NHS trusts. Between 2016/17 and 2018/19 the NHS received on average £9,000 per patient recruited to a commercial clinical trial and saved over £5,800 in drug costs for each of these patients. This equates to income of £355 million and cost savings of £26.8 million in 2018/19. |

Historically it has been the case that commercial studies were often facing delays in setup due to negotiating local costings, which could be very time-consuming and involve a lot of back-and-forth between studies and sites. This has led to the introduction of the [NCVR](https://www.nihr.ac.uk/news/new-voluntary-scheme-for-gps-to-speed-up-commercial-study-set-up/34920) (national contract value review) for primary care, an optional programme where practices agree that they will accept a nationally negotiated contract and payment structure for a study, and reduce the need for complex local negotiations. The contract is a national standard one, and the costings are derived from a costing tool, so the payments you receive have been subject to review and negotiation, but this process means that this only needs to happen once and doesn’t need to be negotiated by each practice separately.

The process should help study setup across the board, therefore making the UK a more attractive place for commercial studies to take place. In secondary care, this process has reduced study setup times by a third, so it has major potential for making participation in commercial studies significantly less burdensome for practices.

You can sign up to this scheme [here](https://docs.google.com/forms/d/e/1FAIpQLSe0leFPRmY5cVIeSA9BKFQhRL61aAGHuYBCGREyRbCG6OzY_A/viewform).

You can read about one practice's experience of NCVR [here](https://www.nihr.ac.uk/story/why-ncvr-no-brainer-general-practices-seeking-deliver-commercial-research).

**I am concerned about the motivations of commercial studies – how can I be sure they are safe and right for our patients?**

Don’t worry that these studies are focused on commercial interests – they still need to go through the [same ethics and study-wide reviews](https://bepartofresearch.nihr.ac.uk/about/how-are-studies-regulated%2C-approved-and-funded/) as any other study before they can operate in the NHS, including general practices. This includes the international principle that the participants’ interests are paramount. Any study that you are approached for should have gone through a Health Research Authority (HRA) review. If you are in any doubt, please ask for the HRA approval letter or contact research@bradford.nhs.uk to discuss any concerns. The study team should also be available for any questions at any point.

Studies also need to ensure that patient participants freely give their informed consent before they start any research procedures involving them. Patients can change their mind at any point.

**What is our liability as a practice?**

Research taking place in a GP practice is covered by the [Clinical Negligence Scheme for GP practice](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/frequently-asked-questions-about-research/). You can read more detail about this via the link

The practice will continue to be responsible for the care of their own patients. In addition, the [principal investigator](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities#pi) for the study (usually a member of the practice team) takes on responsibilities, in particular the responsibility for the conduct of the research at the practice.

The study protocol is the ‘instruction manual’ for undertaking a study – and all study activities should always be conducted according to the protocol at all times. Care must be taken to act according to the current version of the protocol and all current documents.

The study sponsor takes on overall responsibility for studies.

At the point of any patient data from the practice record being shared with the study team, the study sponsor becomes a data controller for that data, for the purposes of the research. The practice retains responsibility for the patient data for the purposes of patient care – so it can be the case that there are [two data controllers](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/data-controllers-and-personal-data-health-and-care-research-context/) for a piece of data.

There are also study monitors, who may be from the sponsor or various regulatory bodies, to make sure that the study is being undertaken correctly.

Top tips

* Commercial studies may ask for quite a lot of information from you when you express interest – and often with a short deadline – so it’s good to make sure you make time to discuss as quickly as possible to enable you to reply fully and on time.
* Don’t be disheartened if you put effort into an EOI which is then not successful – consider each one as experience which can be built on for each application.
* Start small with an easy study, or with non-commercial studies, which can be less competitive.
* Keep records of studies you participate in as you may need to show evidence of what you’ve done previously.
* West Yorkshire R&D and your local CRN teams are available to help with free advice and support for participation in any study – just get in touch to discuss.