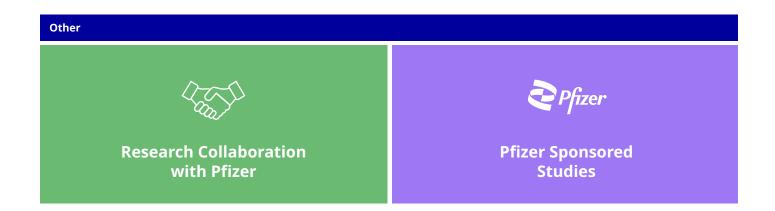
How to undertake research with Pfizer



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Pfizer is committed to improving patient care & achieving the best results for patients and NHS by supporting healthcare and research organisations across the UK undertake research via multiple channels/routes.





How to contact Pfizer concerning any of these types of research opportunities:

To explore the potential for seeking funding for an Independent Medical Grant, of conducting a Research Collaboration with Pfizer, OR to be a study site for Pfizer Sponsored Studies, please contact us on 01304 616161 and ask to be referred to a member of the medical affairs team aligned to your disease / therapy area. You will need to provide your name, role, organisation and organisation email address contact details for someone from the relevant medical affairs team to contact you.

For further information about how Pfizer UK supports Independent Medical Grants and Donations:

Link

Investigator Sponsored Research (ISR) Grant



A research grant to support an organisation's independent research study of a Pfizer medicine or compound.

- The requesting organisation is the **sponsor** of the research study
- Grants are provided to organisations based on medical and scientific merit, where the research study proposal aligns with Pfizer's scientific medical research strategies and where there is Pfizer funding available to support
- Pfizer can accept applications for financial grant support and/or product/compound donation to further medical scientific research knowledge of a Pfizer product

Type of Studies	 Pre-Clinical Clinical Interventional Non-Interventional
Required Elements	 Regulatory approval for clinical trial Ethical approval and where appropriate, Institutional (Capacity & Capability) approvals Informed Consent Pfizer product supply through standard NHS procurement routes if a Non-Interventional Study (Note: Pfizer can only potentially provide free of charge Pfizer Product for a Clinical Trial with Regulatory Approval) Mandatory adverse event reporting for all Pfizer products The Principal Investigator / Organisation will ensure that Pfizer's support is clearly acknowledged and apparent from the outset in any publication of materials connected to the research
Restrictions	 No support for ongoing research If the research study is a non-interventional study of a Pfizer product*(see below)
Independence	 There must be <u>no</u> Pfizer involvement or influence with <u>any aspect of the research study</u> supported by the grant Note: Only exceptions involve investigator sponsored research studies (ISRs) where patient safety concerns are identified, which will necessitate reporting via Serious Adverse Event (SAE) reporting and the involvement of the Pfizer Drug Safety Unit and if required, the specialised Pfizer Medical Team Pfizer product donation requests are only possible for clinical trials with regulatory approval, and where requests align with Pfizer Medical Scientific Research Strategy Pfizer compound requests are only possible for pre-clinical studies where compound is available, and where requests align with Pfizer Medical Scientific Research Strategy

^{*:} If the Research Study is a Clinical Trial of a Pfizer medicine or a Non-Interventional Study of a Pfizer marketed medicine, it will require registration and being made public at Clinical Trials.gov and where relevant, the EU Clinical Trials Register because such studies must be disclosed in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature



General Research Grant



A **research grant** to support an organisation's research study to develop medical knowledge **unrelated to a Pfizer medicine or compound.**

- The requesting organisation is the **sponsor** of the research study
- Grants are provided to organisations based on medical and scientific merit, where the research study proposal aligns with Pfizer's scientific medical research strategies and there is Pfizer funding available to support
- Pfizer provides financial support for the development or refinement of specific and defined scientific medical research knowledge unrelated to a Pfizer product

Type of Studies	 General Research Health Service Research Registry support Outcomes Research (where the primary focus is scientific understanding of disease) Observational studies (e.g. epidemiology studies) Note: Patients/subjects can be on a Pfizer medicine consistent with standard of care, but the research cannot specifically evaluate a Pfizer medicine as part of the study
Required Elements	 Ethical approval and where appropriate, Institutional (Capacity & Capability) approvals Informed Consent as applicable The Principal Investigator / Organisation will ensure that Pfizer's support is clearly acknowledged and apparent from the outset in any publication of materials connected to the research
Restrictions	Research cannot involve the study of Pfizer medicine(s)
Independence	 There must be <u>no</u> Pfizer involvement or influence with <u>any aspect of the</u> <u>research study</u> supported by the grant



Research Collaboration with Pfizer



A **research collaboration** with Pfizer to generate innovative research of **scientific value** in an area(s) of unmet scientific and medical need, aligned with the organisation's priorities and aligned with Pfizer Medical Scientific Research Strategy.

- The collaborating organisation and the Principal Investigator conduct a mutually agreed research project with Pfizer, with the organisation acting as the **sponsor** of the research study
- Pfizer's support may include funding, Pfizer medicine(s), compound(s) (for pre-clinical research collaborations), or other forms of support
- Pfizer can also provide support in trial design, research plans, protocols, statistical analysis plan and informed consent approvals

Type of Studies	 Pre-clinical: <i>in-vivo</i> and <i>in-vitro</i> Clinical: Interventional, Low-interventional and Non-interventional Other: Health Service Research, Outcomes Research and Health Economics
Required Elements	 Confidentiality Agreement (if applicable) Sponsorship obligations Clinical study data, quality, monitoring and transfer Indemnification, subject injury, privacy, and insurance Regulatory approval for clinical trial (if applicable) Ethical approval and where appropriate, Institutional (Capacity & Capability) approvals The Principal Investigator / Organisation will ensure that Pfizer's support is clearly acknowledged and apparent from the outset in any publication of materials connected to the research
Restrictions	No support for ongoing research
Independence	 Unlike an Independent Medical Grant, Pfizer can contribute to research design and statistical plan, reviews and approves study protocol and any informed consent document Pfizer has study oversight capabilities and may access patient level data to facilitate its own research, development, commercialisation and other activities (unlike an Independent Medical Grant Research Study)



Pfizer Sponsored Studies



Research that is **fully sponsored**, **managed** and **funded by Pfizer**.

Pfizer registers all such studies that are:

- Interventional studies in human subjects that evaluate the safety and/or efficacy of a Pfizer product
- Non-interventional studies, regardless of design or data source, where the primary endpoint is to study whether a Pfizer's product is associated with an increased incidence of a specific safety outcome
- Real World Data Studies

Type of Studies	Interventional, low-interventional or non-interventional studies and include Real World Data research
Required Elements & Restrictions	For further details, please speak to a member of the medical affairs team who is aligned to your disease/therapy area
Independence	Research is fully sponsored, managed, and funded by Pfizer

