There are multiple project types that are eligible for funding through an Independent Medical Grant. When submitting a grant request, organizations will be asked to choose an application that best represents their project.

- Independent Research
- Quality Improvement
- Independent Medical Education

More information on these classifications can be found in the Decision Matrix below. Please note, independent research is divided into 2 categories but utilizes the same application.

### **Project Classification Decision Matrix**

	Independent Research		QI	Independent Med Ed	
Title	Investigator Sponsored Research (ISR) Grant	General Research Grant	Quality Improvement Grant	Medical Education Grant	
Туре	Pre-clinical/Clinical/ Non-interventional	General Research, Health Services Research, Registries, Outcomes Research, Research/QI Fellowships	Quality Improvement/ Practice Improvement	CME (accredited and non- accredited)	
Category	Research	Research; Learning & Change	Learning & Change	Learning & Change	
Definition	See below	See below	See below	See below	
Required Elements	IRB, Informed Consent, Drug Supply, Adverse Event Reporting	IRB and Informed Consent*	IRB and Informed Consent*	Standards for Commercial Support; Academy for the Accreditation of CPD	
Restrictions	No support for ongoing research	Research cannot involve the study of a PFE asset <sup><math>\dagger</math></sup>	QI cannot involve the study of a PFE asset <sup>†</sup>		
Independence	No Pfizer involvement or influence with any aspect of the study/initiative/activity supported by the grant				

NOTE: Only exceptions involve patient safety concerns (ISR) and Collaborations (EF)

\*Not required for General Support; as applicable for Research Grant and QI Grant

<sup>†</sup>Patients/subjects can be on a Pfizer asset consistent with standard of care, but the research cannot specifically evaluate a Pfizer asset as part of the study.

# **Definitions**

Independent Medical Education (MedEd)

Quality Improvement (QI)

### **General Research**

## Investigator Sponsored Research (ISR)

A type of grant which consists of Pfizer funding for independent medical education (MedEd) activities or initiatives which serve to maintain, develop, or increase the knowledge, skills, and/or professional performance of a healthcare professional (e.g. continuing medical education, continuing health education, continuing education). MedEd activities or initiatives may or may not be accredited.

The content of the MedEd activity or initiative can relate to a Pfizer asset or not; if it does, the content can be related to approved or unapproved uses (unless the latter is prohibited at the country level). Pfizer cannot be involved in any type of review or approval of the content, including a prohibition on the review by Pfizer for accuracy of information related to a Pfizer asset.

A type of grant which consists of Pfizer funding to support independent projects for systematic and continuous actions that lead to measurable improvement in health care services and the health status of individuals and targeted patient groups and do not relate to a Pfizer asset. Quality improvement considers aspects of quality such as clinical competence, outcomes and process assessment, program evaluation, quality indicators, and quality assurance using methodologically rigorous protocols with an endpoint goal of readiness for application to practice. A QI grant cannot include a Pfizer asset, nor can it support QI that involves the study of a Pfizer asset

A type of grant that supports independent research where the investigator or organization is the sponsor of the research and where Pfizer provides financial and/or non-financial support for the development or refinement of specific and defined medical knowledge unrelated to a Pfizer asset. This grant type is used to support research that does not include the study of a Pfizer asset, including support for an organization's general research fund, health services research unrelated to a Pfizer asset, registry development and/or queries unrelated to a Pfizer asset, outcomes research unrelated to a Pfizer asset, and research fellowships.

A type of grant that supports an independent research study where the investigator or organization is the sponsor of the study and where Pfizer provides financial and/or nonfinancial support for the development or refinement of specific and defined medical knowledge relating to a Pfizer asset. These grants are made to an organization (e.g., universities, hospitals, clinics, National Institute of Health, etc.) to conduct independent research based upon medical and scientific merit. This grant type is used as support for pre-clinical and clinical studies (including interventional and noninterventional), that involve a Pfizer asset (e.g., commercial drug, investigational drug, pure compound).

Category Title	ISR		General Research		
	Pre- clinical/Clinical	Non- interventional (NI)	Health Services Research	Outcomes /Surveillance/ Other NI Researc	Registry Development
Application Type	Research Application	Research Application	Research Application	Research Application	Research Application
Definition	See below	See below	See below	See below	See below
Required Elements	Protocol, IRB/IEC approval, Informed IRB/IEC approval and Informed Consent (as applicable) Consent, Drug Supply, Adverse Event Reporting				
Restrictions	No support for ongoing research		Research cannot involve the study of a PFE asset. Patients/subjects can be on a Pfizer asset consistent with standard of care, but the research cannot specifically evaluate a Pfizer asset as part of the study.		
Independence	No Pfizer involvement or influence with any aspect of the study/initiative/activity supported by the grant. NOTE: Only exceptions involve patient safety concerns (ISR)				

### Clinical/Pre-Clinical Research\*

## Non-interventional

### Research<sup>+</sup>

Clinical Research (Interventional): A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol.

Preclinical Research: Research using animals to find out if a drug, procedure, or treatment is likely to be useful. Preclinical studies take place before any testing in humans is done. Non-interventional (NI) study refers to a study where a medicinal product(s) is/are prescribed in medical practice and the assignment of the patient to a particular therapeutic strategy is not decided in advance by the study protocol but falls within current practice, and the decision to prescribe the medicinal product(s), if used, is clearly not driven by the decision to include the patient in the study. No additional diagnostic or monitoring procedures, other than normal clinical practice shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data. Normal clinical practice may include routine diagnostic

NI studies include both primary data collection, termed de novo studies (e.g., studies that enroll and follow patients in routine clinical practice) and secondary data collection, termed database studies (e.g., studies that use previously collected health-related data that typically exists in an electronic form).

procedures (e.g., blood samples),

interviews and questionnaires.

Health services research is a "multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately, our health and well-being

**Health Services Research** 

## Outcomes / Surveillance Other NI Research<sup>‡</sup>

Outcomes research seeks to understand the end results of particular health care practices and interventions. End results include effects that people experience and care about, such as change in the ability to function. In particular, for individuals with chronic conditions—where cure is not always possible -- end results include quality of life as well as mortality. By linking the care people get to the outcomes they experience, outcomes research has become the key to developing better ways to monitor and improve the quality of care. Supporting improvements in health outcomes is a strategic goal of the Agency for Healthcare Research and Quality (AHRQ, formerly the Agency for Health Care Policy and Research).

Surveillance is the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice.

# Registry Development

A registry is a collection of information about individuals, usually focused around a specific diagnosis or condition. Grants may be requested for the development of a registry or to support queries to an existing registry

\* A clinical or preclinical research request unrelated to a Pfizer asset may be submitted under the General Research: Pre-clinical/Clinical Project type. \*Note: Non-interventional Studies that do not involve observation of a specific Pfizer product (as defined in the protocol research objectives) would fall under General Research. \*NI Research that does not involve observation of a Pfizer asset and does not fit under another General Research Project type can be submitted under General Research: Outcomes/Surveillance/Other Non-Interventional Research.