Executive Summary

Patient Registries

The purpose of this document is to serve as a guide to the design, implementation, analysis, interpretation, and evaluation of the quality of a registry for understanding patient outcomes. For the purpose of this handbook, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other)to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s). The registry database is the file (or files) derived from the registry. Although registries can serve many purposes, this handbook focuses on registries that are created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how the populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure.

Planning

There are several key steps in planning a patient registry, including articulating the purpose of the registry, determining whether the registry is an appropriate means for addressing the research question, identifying stakeholders, defining the scope and target population, assessing feasibility and securing funding. The registry team and advisors should be selected based on expertise and experience. The plan for registry governance and oversight should clearly address such issues as overall direction and operations, scientific content, ethics, safety, data access, publications, and change management. It is also helpful to plan for the entire lifespan of a registry, including how and when the registry will end and any plans for transitioning the registry at that time.

Registry Design

A patient registry should be designed with respect to its major purpose, with the understanding that different levels of rigor may be required for registries that are designed to address focused analytical questions to support decision making, in contrast to those intended primarily for descriptive purposes. The key points to consider in designing a registry include formulating a research question; choosing a study design; translating questions of clinical interest into measurable exposures and outcomes; choosing patients for study, including deciding whether a comparison group is needed; determining where data can be found; and deciding how many patients need to be studied and for how long. Once these key design items have been determined, the registry design should be reviewed to evaluate potential sources of bias (systematic error); these should be addressed to the extent that is practical and achievable.

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Best regards,
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