

FAQ and Glossary

Frequently Asked Questions

1. What are the outputs of this project?
 - a. This group will develop 15-20 research data use scenarios that will be distilled into a smaller subset of use cases. The scenarios will be patient-centric and relate to PCOR/CER. The goal is to tease out each scenario's specific requirements as they pertain to policy, legal/ethical considerations, and some technical considerations that intersect with policy. Developing technical solutions; however, is out of this project's scope.
2. What is the expected commitment for a participant?
 - a. The NORC team recognizes that work group members have many other commitments. The team welcomes involvement even if participants are unable to join all of the workgroup meetings. Time commitment will depend on the level of participation:
 - i. Committed contributors: individuals who are able to participate in most of the biweekly meetings.
 - ii. Secondary contributors: individuals who are interested and would like to contribute but find it more feasible to join a few calls, review specific project documents, and provide feedback to the NORC team as appropriate.
 - iii. Web-based contributors: individuals who provide feedback on materials posted on the collaboration website without a formal explicit commitment.
3. What types of "stakeholders" are involved in this effort?
 - a. We have a diverse group of participants including providers, researchers, technical standards experts, patient advocates, and federal representatives. There is a full list of active participants available on the [Project Stakeholders page](#).
4. How does this work overlap with PCORI and PCORnet, specifically the PCORnet demonstration projects, as the use cases are currently proposed?
 - a. PCORnet has already generated several research data use scenarios. Our team will apply lessons from those scenarios, as applicable, but focus on different scenarios so as to avoid replicating PCORnet's work. Multi-stakeholder group participants who are/were engaged in PCORI and PCORnet projects can help guide the team in this respect.
5. What will the research data use scenarios address?
 - a. The team plans to work with the multi-stakeholder group to identify priority areas related to PCOR and CER and to develop research data use scenarios that describe how data from providers and patients is captured, managed, and used. Our goals will be to ensure that the research data use scenarios address key issues that researchers face, are representative of practical research needs, and are valuable for solving real-world PCOR/CER challenges. The team will also make sure the research data use scenarios are representative of issues affecting underserved populations and others to which unique legal requirements apply (e.g., minors).
6. How will the team translate the research data use scenarios into use cases?
 - a. Some scenarios may have similar underlying requirements that would likely map to a smaller set of use cases. Other scenarios may have different preconditions, data requirements, and/or privacy considerations that require separate sets of requirements. The overarching goal is to take different scenarios, align them with a set of consistent use cases, and avoid duplication.

7. What types of data will the team consider? Will the project consider social determinants of health that may not be traditionally thought of as "health-related" data (e.g., income, residence, proximity of recreation centers and grocery stores, environmental health issues, air quality issues, etc.) or is the project locked into a certain range of data types? Additionally, will the use cases be driven primarily by research interests?
 - a. The team is still in the process of determining what data sources we will include for this project. We have outlined a preliminary scope in the [project charter](#). Throughout the subsequent work group meetings and development of the scenarios, we will continue to discuss the types of data that are in-scope and out-of-scope. All data types included must be relevant to PCOR and CER.
 - b. In addition to clinical and administrative data, other data types of interest would include: patient-generated health data; genomic data; bio-specimens; behavioral health data; survey data; social determinants of health; and data from special populations of interest, including under-represented and culturally diverse populations. We may consider issues related to data characteristics (identifiability, type, source); data handling (storage, transmission, collection); data uses (purpose, scope of consent); the users and facilities interacting with the data (collector, data user, location of collection and use); and others raised by the multi-stakeholder group.
8. How much of these proceedings is public? Is the team obligated to keep anything confidential?
 - a. ONC wants this process to be transparent in order to engage the broader public. Access to the initiative's website and its artifacts will be public.

Glossary Terms

1. **Patient Centered Outcomes Research (PCOR):** In accordance with our project charter, we define PCOR as research that incorporates:
 - a. Advanced approaches to assessing provider and patient preferences, health-related quality of life (HRQoL), clinical efficacy, potential side effects of treatment and drug therapies, and the impact of patient genetic predisposition and;
 - b. The capacity to capture, manage, and analyze data from providers and patients.

PCOR's goal is to produce findings that give patients and providers an individually tailored view of their treatment options and the possible benefits and harms associated with a particular course of action, allowing the patient and provider(s) to make informed decisions about the patient's health and healthcare.

2. **Patient Centered Outcomes Research Institute (PCORI):** The Patient-Centered Outcomes Research Institute (PCORI), an independent nonprofit, nongovernmental organization located in Washington, DC, was authorized by Congress in 2010. Our mandate is to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make informed health decisions. Specifically, we fund comparative clinical effectiveness research, or CER, as well as support work that will improve the methods used to conduct such studies.

The goal of our work is to determine which of the many healthcare options available to patients and those who care for them work best in particular circumstances. We do this by taking a particular approach to CER called Patient-Centered Outcomes Research, or PCOR, research that addresses the questions and concerns most relevant to patients, and we involve patients, caregivers, clinicians, and other healthcare stakeholders, along with researchers, throughout the process. (PCORI)

- a. According to the PCORI definition of PCOR, Patient-Centered Outcomes Research helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions, such as:
 - i. "Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?"
 - ii. "What are my options, and what are the potential benefits and harms of those options?"
 - iii. "What can I do to improve the outcomes that are most important to me?"
 - iv. "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?" (PCORI)
3. **PCORnet:** The National Patient-Centered Clinical Research Network. It is an innovative initiative of the Patient-Centered Outcomes Research Institute (PCORI). It is designed to make it faster, easier, and less costly to conduct clinical research than is now possible by harnessing the power of large amounts of health data and patient partnerships. In the process, it is transforming the culture of clinical research from one directed by researchers to one driven by the needs of patients and those who care for them. (PCORnet)
4. **Comparative Effectiveness Research (CER):** CER is defined as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels." (Institute of Medicine)
5. **Precision Medicine Initiative (PMI):** An initiative launched by President Obama and the White House, the Precision Medicine Initiative will pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients. (White House)
6. **NORC:** NORC at the University of Chicago, the primary contractor on this project. NORC is an independent research institution that helps governments, nonprofits, and businesses make better decisions through data and analysis. (NORC)