ONCOLOGY CONSORTIUM: 
DEVELOPING METHODOLOGICAL STANDARDS FOR COMPARATIVE EFFECTIVENESS RESEARCH IN ONCOLOGY

Project Overview

In 2013, The Center for Medical Technology Policy (CMTP), through its Green Park Collaborative-USA (GPC-USA), established an Oncology Consortium for the development of methodological standards for patient-centered outcomes research and comparative effectiveness research in oncology. The consortium is composed of a diverse group of experts and stakeholders representing patients and consumers, the life sciences industry, payers and purchasers, health systems and care providers, researchers, research funders, regulators and health professional organizations. With general oversight from GPC-USA’s advisory committee, Consortium members participate in the development of methodological standards which are then issued as Effectiveness Guidance Documents (EGDs).

EGDs are sets of recommendations for study designs that address the evidence needs of public and private payers, health technology assessment organizations, guideline developers, clinicians and patients—taken together, “post-regulatory” decision-makers. EGDs provide more than general methodological advice by offering specific study design recommendations relevant to a specific clinical condition or category of health technologies. EGDs issued by GPC-USA are aligned with existing regulatory guidance where relevant, but they are primarily designed to establish methodological standards for studies intended to inform coverage and payment decisions made by health plans.

Addressing Evidence Challenges in Oncology

Comparative effectiveness research in Oncology raises a number of challenges for trial designers and decision makers alike. The Oncology Consortium will build on CMTP’s prior work in this area, which includes four completed effectiveness guidance documents:

- **Recommendations for Incorporating Patient-reported Outcomes into Clinical Comparative effectiveness Research in Adult Oncology**
- **Evaluation of Clinical Validity and Clinical Utility of Actionable Molecular Diagnostic Tests in Adult Oncology**
- **Recommendations for Designing Clinical Trials for New Indications of Approved Oncology Drugs for Treatment of Late Stage Disease**
- **Gene Expression Profile Tests for Early Stage Breast Cancer**

In its first year, the consortium has begun work on an EGD to identify methods and best practices needed to determine the sequence and timing of multiple “lines” (or combinations) of oncology therapy to yield optimal net benefit to patients. This topic is currently of significance for several types of cancer, including renal cell carcinoma, castration-resistant prostate cancer, and relapse of ovarian cancer.
Other oncology topics under consideration for future Consortium work include: study designs for management of cancer-related pain; clinical utility of next-generation sequencing or the role of such sequencing in clinical development; statistical methods for managing early crossovers in oncology trials; and methods for handling heterogeneity of treatment effects in cancer clinical trials.

**Consortium Activities and Process**

Oncology Consortium members are invited to participate in two in-person meetings per year, as well as a number of interim conference calls or webinars. Members discuss and refine potential EGD topics, help to identify experts to comprise the technical working group (TWG)—a specialized body having expertise to address a specific EGD topic—and review and comment on EGD draft recommendations prepared by the TWG.

The TWG for each EGD is composed of methodological, clinical, and other experts who engage with consortium members iteratively to assure multi-stakeholder consideration of, and input into, the recommendations created for each EGD. Consortium members may participate in specific TWGs, as appropriate. Each TWG is constituted to address a specific topic and is dissolved upon completion of the relevant EGD—a term of approximately 9 months. During this time, with support of CMTP staff, TWG members will work to craft methodological recommendations for the selected topic.

**How Can I Get Involved?**

To learn more about the GPC-USA Oncology Consortium and its work, contact:

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