CTAP Subcommittees – Scope of Work

Randomized controlled trials provide high quality evidence for comparing alternative clinical interventions for specific clinical conditions. These clinical trials comprise an important component of clinical comparative effectiveness research.

Subcommittee on Recruitment, Accrual, and Retention (RAR)

Chair: Margo Michaels

Patient recruitment, accrual, and retention continue to present great challenges in clinical research. According to a 2011 Tufts Center for the Study of Drug Development (CSDD) report, two-thirds of sites don't meet the enrollment requirements for a given trial.

Limited participation in research also impacts the relevance of the clinical data. The proportion of women, minorities and elderly patients participating in clinical research is not consistent with the prevalence of disease in the underlying population. As stated by the FDA in a recent report, "When participants in a clinical trial … reflect a diverse, real-world population (males and females, young and old, various racial and ethnic backgrounds, and patients with differing comorbid diseases and conditions) and when the subgroup data from the trial are appropriately analyzed, much more information can be known … and more meaningful clinical data can be communicated to the public." Given PCORIs mandate to improve the quality and relevance of evidence available to help people make informed healthcare decisions, we must ensure that the ***research PCORI produces is truly representative of the affected population.***

While the research base is limited, there are key best practices in recruitment, accrual and retention that should be employed by researchers. The CTAP Subcommittee on RAR will cull these best practices in order to help

- inform PCORI Funding Announcements and related review criteria;
- guide PCORI monitoring of funded contracts by providing technical assistance and support; and
- provide additional direction regarding the engagement of healthcare stakeholders around recruitment, accrual and retention

Subcommittee on Monitoring of Funded Clinical Trials (MFCT)

Chair: Craig Nichols

It is important that clinical trials be monitored throughout the course of the project, to ensure useful results.

The CTAP Subcommittee on MFCT will provide guidance, as requested, on topics relating to the monitoring of funded clinical trials, which may include, but are not limited to:

- PCORI Data Safety Monitoring Board (DSMB) policy
- Training materials for DSMB members, including non-traditional DSMB members, like patients and stakeholders, who may be less familiar with the role of DSMBs
- Monitoring of PCORI's large pragmatic clinical trials

- PCORI's monitoring process of funded clinical trials, to ensure that post-award changes and other issues are handled appropriately

Subcommittee on Standardization of Complex Concepts and their Terminology (SCCT)

Chair: Merrick Zwarenstein

Providing clearer definitions to potential applicants for PCORI funding will target PCORI's interests for more valid, trustworthy, and useful information that will lead to better healthcare decisions and, ultimately, to improved patient outcomes.

The CTAP Subcommittee on SCCT will provide guidance, as requested, on topics relating to the standardization of complex concepts and their terminology, which may include, but are not limited to:

- 'pragmatic'
- 'usual care'
- 'mixed methods'
- Ideal level of detail with which investigators should describe their interventions and comparison conditions