



External Meeting Summary

Advisory Panel on Clinical Trials

Summer 2021 Meeting

August 10, 2021

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Overview

The Advisory Panel on Clinical Trials (CTAP) Summer 2021 Meeting started with a welcome of the CTAP panel members and attendees and an overview of the day's agenda. Laura Lyman Rodriguez, PhD, provided an overview of PCORI's strategic planning process and the CTAP members provided feedback on the National Priorities for Health. Jason Gerson, PhD, and Jess Robb, MPH, presented on PCORI's response to the COVID-19 pandemic, including funding opportunities and research project adaptations. Claudia Grossmann, PhD, presented on PCORnet®, the Patient-Centered Clinical Research Network's ADAPTABLE trial. Lastly, PCORI asked panelists for suggestions for future meetings and thanked panelists who are ending their CTAP tenure.

Welcome and Goals for the Day

- Catherine Crespi, PhD, MS, CTAP Chair (2019-2021); Professor of Biostatistics, UCLA Fielding School of Public Health
- Anne Trontell, MD, MPH, Associate Director, Clinical Effectiveness and Decision Sciences (CEDS), PCORI
- Jess Robb, MPH, CEDS Senior Program Associate, PCORI

Robb welcomed the CTAP members and the attendees to the webinar, reviewed the housekeeping notes, and read the conflict of interest statement. Crespi and Trontell walked through the agenda for the day.

Overview of PCORI Strategic Priorities

- Laura Lyman Rodriguez, PhD, Interim Chief Program Support Officer & Senior Advisor to Executive Director, PCORI

Lyman Rodriguez provided an overview of PCORI's strategic planning process and opened discussion with the CTAP members on the proposed National Priorities for Health. She noted that the goal of the discussion was to identify synergies among the National Priorities and address the critical needs of the research agenda. Panel members recommended PCORI focus on achieving equitable access to health care and health equity, emphasizing social determinants of health, examining the effects of the COVID-19 pandemic on health disparities in the healthcare system, addressing health literacy in communicating and disseminating research results, and expanding communication with stakeholders.

COVID-19 Impact to Research

- Jason Gerson, PhD, CEDS Senior Program Officer, PCORI

Gerson presented updates on PCORI's COVID Connect activities to coordinate PCORI's response to the COVID-19 pandemic, including COVID-related research programs, and COVID-related PCORnet efforts. During the discussion by CTAP, one panelist noted the merit of news media, rather than journal articles, for rapidly disseminating COVID-19 findings due to the speed of the pandemic and the slower academic nature of journals. Another panel member suggested PCORI focus research on health literacy and mental health related to COVID-19 among youth.

Insights on PCORI Response: COVID Adaptations

- Jess Robb, MPH, CEDS Senior Program Associate, PCORI

Robb presented on PCORI's Adaptation Review Team, which PCORI created in response to research disruptions caused by COVID-19. She explained that the team reviews and approves all proposed changes to studies and provided examples of adaptations that have occurred over the past year. Panelists discussed challenges for journal editors and authors in publishing studies that have undergone adaptations. Panelists also suggested solutions for addressing significant changes to studies, such as conducting sub-studies to test for consistency, doing power and futility analyses, and using Bayesian statistics.

PCORI's Use of PCORnet: Insights from ADAPTABLE

- Claudia Grossmann, PhD, Senior Program Officer, Research Infrastructure, PCORI

Grossmann presented on the Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness (ADAPTABLE) study, PCORnet's® first clinical trial. She explained that the study sought to understand the most appropriate aspirin dosing in heart disease patients and incorporate patient engagement at all levels of the study. The study uncovered no observed differences in death, myocardial infarction, or stroke for patients assigned to 81 mg versus 325 mg. CTAP members suggested that ADAPTABLE has lessons for electronic health records interoperability and standardization through PCORnet, patient engagement and recruitment, best practices for PCORnet sites, and alignment with US Preventive Services Task Force guidelines.

Farewell to Panelists

- Jess Robb, MPH, CEDS Senior Program Associate, PCORI
- Anne Trontell, MD, MPH, CEDS Associate Director, PCORI

PCORI asked panelists for suggestions for its future CTAP meetings. Panel members suggested exploration of PCORnet to facilitate interoperability in electronic health records through engaging vendors, Bayesian approaches in platform trials, an update on data sharing policies and PCORI's data repository and policies, and striking the right balance in research oversight through International Review Board reviews.

PCORI ended the meeting by thanking the presenters and saying goodbye to the Chair and panelists whose terms of service concluded with this meeting.