

# Pragmatic Research During COVID-19

## COORDINATING CENTER (CC) EFFORTS



**41 COVID-19 Grand Rounds**

**12,599 total attendees**

**323 average attendees per session**

**Supported early dissemination** of pivotal trial results (eg, TOGETHER ivermectin trial)

**Top session (870 attendees):** May 1, 2020

Can the COVID-19 Crisis Lead to Reformation of the Evidence Generation Ecosystem? (Robert Califf, MD, MACC)



- CC and Cores held consultations and stayed in close contact with trial teams to offer support as they navigated issues related to COVID-19

*"They were a great help in planning our new study design, particularly making sure that our analysis would still be effective in this new way."*

-ACP PEACE

- Tracked COVID-19 challenges and adaptations/resolutions centrally
- Added COVID-19 resources to program website
- Biostatistics and Study Design Core published Statistical Analysis Plan Checklist for Addressing COVID-19 Impacts on the Living Textbook
- Summarized COVID-19 impacts on pragmatic trials in a manuscript

## DEMONSTRATION PROJECT EXPERIENCES

**6 COVID-19 publications**



TSOS (2)  
EMBED (2)  
PROVEN  
ACP-COVID

**1 CC COVID-19 manuscript (submitted)**

**2 CC surveys fielded to Demonstration Projects**

**14 trials completed**



3 trials asking if patients have or had COVID

**Qualitative results**

3 trials have the ability to determine if patients have long-haul COVID

### Healthcare system operations–related changes

Trial delays	Staffing challenges	Effects on outcomes
Created statistical challenges, particularly with stepped-wedge designs	Reallocation, furlough, hiring freeze	Potential increases in rates of hospitalization and death, missing follow-up data due to missed care visits

### Social distancing–related changes

Virtual intervention delivery	Modified data collection strategies	Recruitment impacts	Adaptation benefits
Required careful consideration of whether virtual delivery would be as effective	Added COVID-19 data elements and focus group/interview questions	Fewer provider referrals to specialty care, lower patient attendance at appointments	Expanded outreach capabilities, ability to study virtual intervention

## KEY LESSONS LEARNED



- All trial teams were able to adapt to pandemic-related modifications
- Projects used existing stakeholder-driven approaches to adapt

- Trials least affected had enrollment systems already in place and relied heavily on automated data collection through the EHR and/or mobile technologies



- Continued flexibility and anticipation of future issues needed going forward