

Core Accomplishments

SINCE 2012



132
Publications and products

119
Presentations

197
Demonstration Project consultations



607
Core meetings

"There is much collective wisdom and knowledge among the various Core members, and having multiple members of the study team involved with the Cores increases the probability of taking advantage of that shared knowledge for your trial."

—Jerry Jarvik, PI of LIRE

"Advice for future trials? Rely on the Biostats Core as much as possible."

—Gloria Coronado, Co-PI of STOP CRC

Thank you to all our Core Chairs and members!



BIostatISTICS & STUDY DESIGN

Key Products

- "Two weights make a wrong" publication on analysis with various cluster sizes (Wang et al. 2022)
- Statistical lessons learned publication (Cook et al. 2017)
- Living Textbook chapter on Design and Randomization
- Guidance documents on statistical considerations for ePCTs



Major Achievements

- Consultations had a direct impact on many Demonstration Projects, resulting in revised statistical analysis plans, sample sizes, or trial designs
- Led Design and Analysis of ePCTs Workshop
- Made substantial contributions to the literature on design and analysis of group-randomized trials



ELECTRONIC HEALTH RECORDS

Key Products

- Publication with recommendations for enhancing the use of EHR systems for pragmatic embedded research (Richesson et al. 2021)
- Assessing Data Quality Guidance Document
- Living Textbook chapters on using real-world data and EHR-based phenotyping



Major Achievements

- Developed data and resource sharing materials to help Demonstration Projects identify their sharing plans and promote posting of materials at closeout
- Established the Collaboratory's Distributed Research Network and executed data queries
- Presented a workshop series on advances in digital health, EHRs, and ePCTs



ETHICS & REGULATORY

Key Products

- Published foundational scholarship and research regarding an array of ethics and regulatory issues in ePCTs in the peer-reviewed literature, with 34 articles to date
- Drafted a Data Monitoring Committee Charter and Points to Consider in Data Monitoring for ePCTs



Major Achievements

- Consulted on the ethical and regulatory issues associated with each Demonstration Project at its outset
- Organized national workshops on the ethical and regulatory aspects of ePCTs
- Conducted substantial empirical research on stakeholder perspectives on ePCTs



HEALTH CARE SYSTEMS INTERACTIONS

Key Products

- Case studies on accounting for healthcare systems' quality improvement activities during ePCTs (Tuzzio et al. 2021)
- Publication on minimizing the burden of pragmatic research on healthcare systems (Larson et al. 2016)
- Guide to research partnerships for ePCTs (Johnson et al. 2014)



Major Achievements

- Led workshop on disseminating, implementing, and sustaining evidence-based practices (featuring *Swimming With the Sharks*)
- Created and maintained a comprehensive issues tracker with challenges and resolutions shared by Demonstration Projects
- Shared lessons about building and sustaining trusting partnerships between research teams, health system leaders, clinicians, and staff



PATIENT-CENTERED OUTCOMES

Key Products

- Roundtable report on capturing patient-reported health data
- Contributed to Users Guide for Integrating Patient-Reported Outcomes in Electronic Health Records
- Patient-Reported Outcomes Living Textbook chapter



Major Achievements

- Conducted surveys and interviews on cultural/linguistic adaptation and acceptability/burden of PROs
- Led a workshop to help clinicians implement NIH PROMIS
- Consulted with Demonstration Projects to inform the selection and collection of PROs
- Convened a policy meeting in Washington, DC, to discuss barriers and opportunities for getting PROs into the EHR