

Monitoring and Navigating Changes in Usual Care

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Patient Centered Outcomes Core



**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Pop Quiz!

- Let's say you're running a pragmatic trial enrolling from five health systems. In Year 3 of the study:
 - One switches to a new EHR platform
 - One merges with another health system
 - One starts a value-based care initiative
 - One gets bought by a private equity group, and
 - One decides to stop seeing patients on Fridays

Do you....?

- A. Close your office door, turn off the lights, and cry
- B. Reframe the study as a natural experiment
- C. Pretend you don't notice and keep collecting data
- D. Email the NIH program officer in all caps

Last but not least...

- How NIH Collaboratory Trials are documenting and monitoring usual care
- Considerations for interim data pulls and futility decisions
- Impacts of an evolving healthcare setting and shifts in ePCT approaches needed



Our closers...



Rachel Winer
STEP-2



Christine Goertz
IMPACT-LBP



Rich Platt
INSPIRE

Discussion Questions

Defining and Documenting

- What strategies have you used or will you use to define and document “usual care” in your trial? How much variation did you observe across sites?

Burden

- How do you balance the need to describe/monitor usual care rigorously while not overburdening sites with more data collection?

Interim data

- Were there any situations where interim data changed your perspective on trial feasibility, sample size, or analytic strategy?

Discussion Questions

Policy changes

- We live in a very dynamic policy environment. Was your trial affected by – or do you anticipate it will be affected by – evolving care models, reimbursement shifts, or policy changes? How did you respond?

Funders and Reviewers

- What should funders and peer reviewers understand better about how pragmatic trials are affected by real-world conditions?

Advice

- If you could give a junior investigator one piece of advice about planning for usual care or healthcare evolution, what would it be?