

Addressing Barriers to ePCTs Involving Approved Drugs

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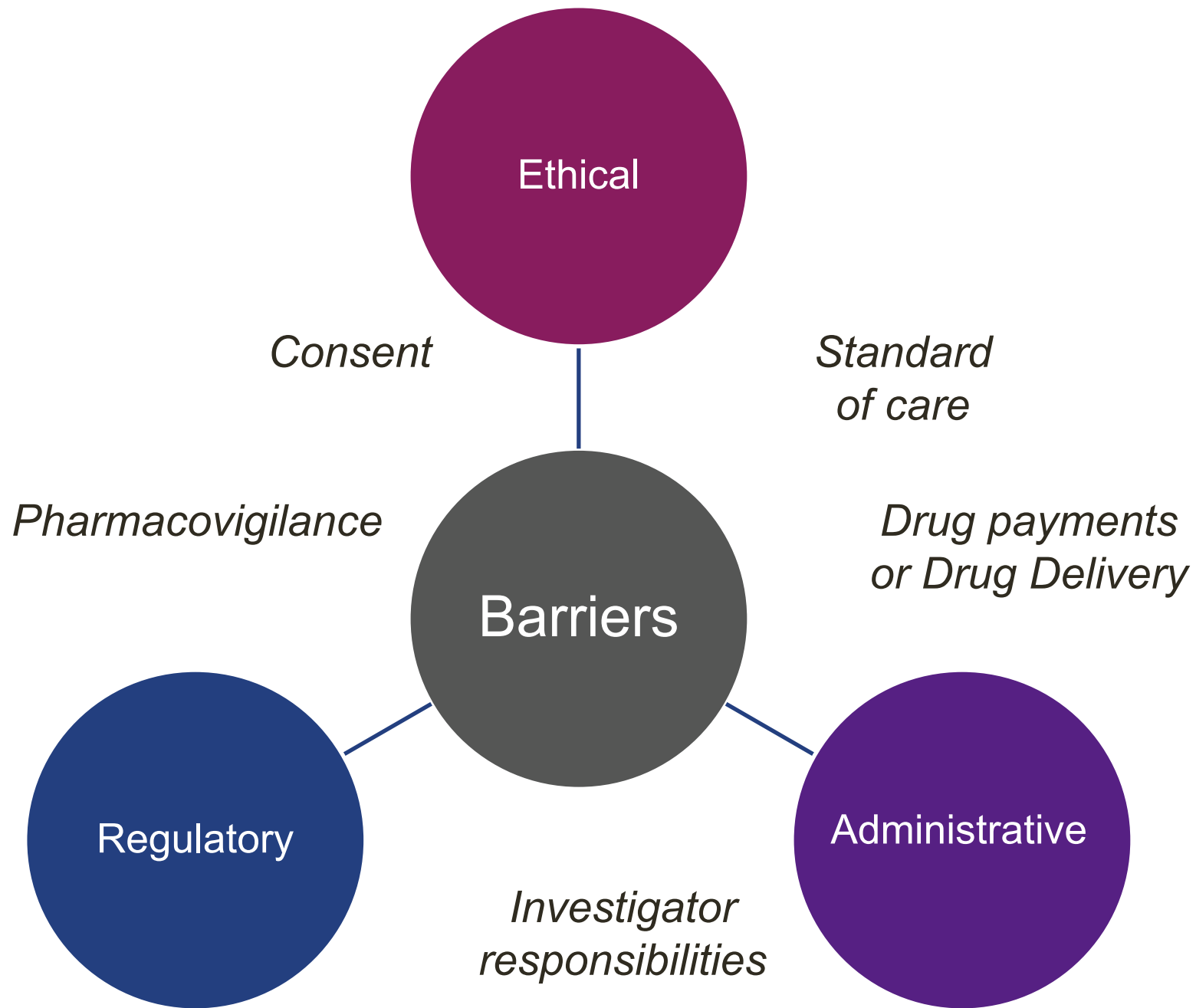
Panelist

- Pearl O'Rourke, MD
 - Harvard Medical School, Retired
- Kevin Bugin, MD
 - Deputy Director of Operations in the Office of New Drugs (OND) in FDA's Center for Drug Evaluation and Research (CDER)
- Leonard Sacks, MD
 - Deputy Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER)
- Tracy Wang, MD
 - Chief of Comparative Clinical Effectiveness Research at the Patient-Centered Outcomes Research Institute (PCORI)

Session Goals

- What are the barriers to conducting ePCTs involving approved drugs, including trials with repurposed drugs and A vs B trials?
 - How might we overcome them?
 - How can the NIH Collaboratory contribute?





Let's discuss...

Scenario 1: No Indication Expansion

- EurekaDrug is indicated for the treatment of hypertension
- UtopiaDrug is indicated for the treatment of hypertension
- BenevolentFunder agrees to fund a comparative effectiveness study to determine which drug has better cardiovascular outcomes (Death, MI, HF, Stroke)

Scenario 2: Seeking Labeling Change

- EurekaDrug is indicated for the treatment of hypertension
- UtopiaDrug is indicated for the treatment of hypertension
- InvestedFunder agrees to fund a comparative effectiveness study to determine which drug has better cardiovascular outcomes (Death, MI, HF, Stroke) and wishes to get an expanded indication for the reduction of CV death, MI and HF.

Let's discuss...benefits/risks

Scenario 1: No Indication Expansion

- EurekaDrug is indicated for the treatment of hypertension
 - Reduces SBP by **10 mmHg**
 - **1%** risk of angioedema
 - **1%** risk of hyperkalemia
- UtopiaDrug is indicated for the treatment of hypertension
 - Reduces SBP by **6 mmHg**
 - **0.3%** risk of angioedema
 - **0.3%** risk of hyperkalemia

Scenario 2: Seeking Labeling Change

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Questions



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