

Spring 2019

REPS

Research Ethics and Policy Series



Ethics and innovative trial design

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Traditionally, clinical trials have progressed through a linear sequence from phase 1 (safety, pharmacokinetics, and dosing) to phase 2 (preliminary efficacy) to phase 3 (definitive efficacy). However, factors including a desire to speed times to approval and the need to conduct trials in smaller biomarker-defined patient subgroups have led to a profusion of innovative trial designs. Examples of trial design innovation include seamless designs, basket trials, umbrella trials. Just as these trials offer both methodological advantages and limitations, they also offer both advantages and disadvantages with respect to key elements of ethical research such as favorable benefit-risk balance and informed consent.

Monday, March 4

**Austrian Auditorium, Clinical Research Building
415 Curie Boulevard, University of Pennsylvania
12–1 P.M**

Lunch will be provided for attendees

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