



International Alliance for
Biological Standardization

IABS 3rd Real World Evidence Workshop “Pragmatic Randomized Controlled Vaccine Trials: Toward Global Alignment on Regulatory Framework and Evidence Standards”

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Ethical Considerations for Pragmatic Trials with Vaccines – Stéphanie Morain, Johns
Hopkins Berman Institute of Bioethics

Pragmatic randomized controlled trials offer the opportunity to generate evidence that is more applicable to the real-world needs of patients, clinicians, policymakers, and other health decision-makers. However, the deliberate integration of research into clinical care challenges traditional ethical and regulatory paradigms, which have traditionally viewed research and clinical care as distinct activities, meriting distinct oversight approaches. This presentation will present an overview of some ethical issues presented by the use of pragmatic designs for vaccine trials, including when cluster randomization is (not) appropriate, the ethics of placebo controls when a licensed vaccine exists, informed consent, and early stopping decisions.

