

Biostatistics and Study Design: How Do We Generate the Right Evidence to Support Decision-Makers?

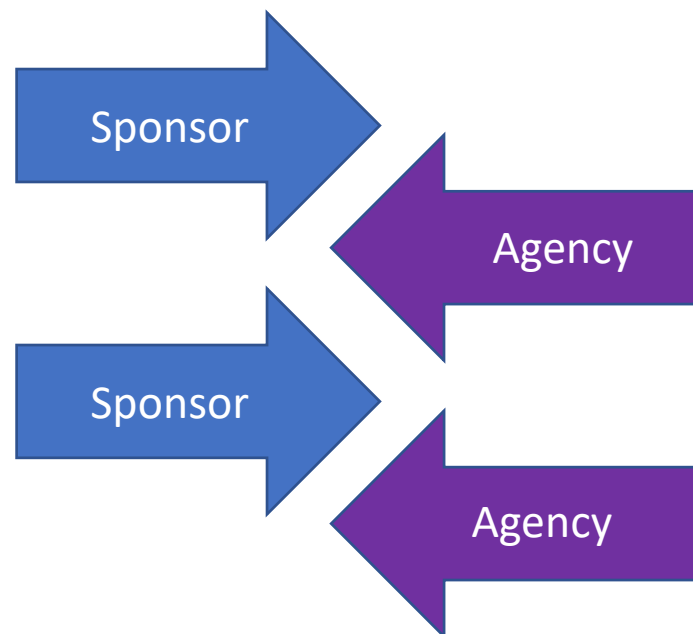
Patrick Heagerty, PhD
Professor, Department of Biostatistics
University of Washington



**NIH PRAGMATIC TRIALS
COLLABORATORY**

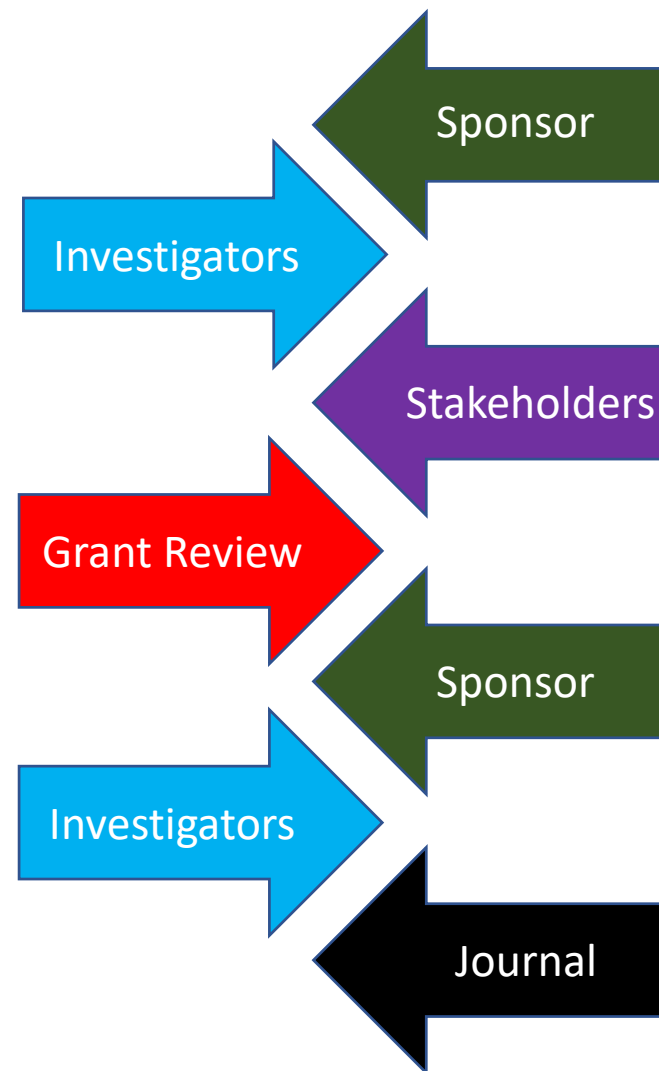
Rethinking Clinical Trials®

Regulatory Decision Process



- Decision maker: Formal engagement throughout
- Strong / uniform guidelines

ePCT Decision Process



Results Consumers