Welcome to the Real World Data SIG!

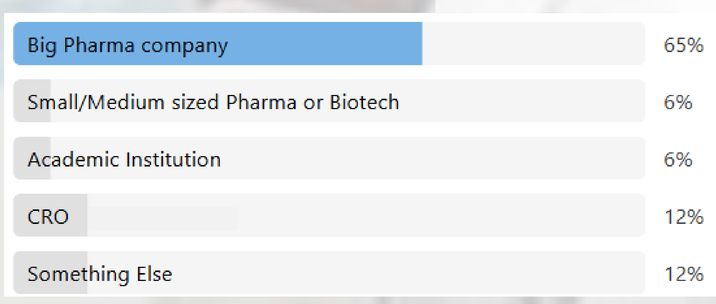
Our Purpose: To increase collaboration and enhance awareness of strategies and methodologies applied in the utilization of Real World Data in the pharmaceutical industry.

Our objectives include:

- Facilitate sharing of case studies and experiences in this area
- Collate and summarise publications, articles, presentations, training
- Identify emerging news and trends
- Organise and/or participate in workshops related to RWD
- Collaborate with key stakeholder groups (EFSPI/PSI, EFPIA, ISPOR, regulatory and academia)
- Provide comments on RWD related guidelines, e.g. country-specific methods guidelines, FDA methods guidelines, ISPOR etc.
- Develop/highlight best practices and recommendations
- Influence industry practice and acceptance of approaches by regulators and other stakeholders

A global SIG team…

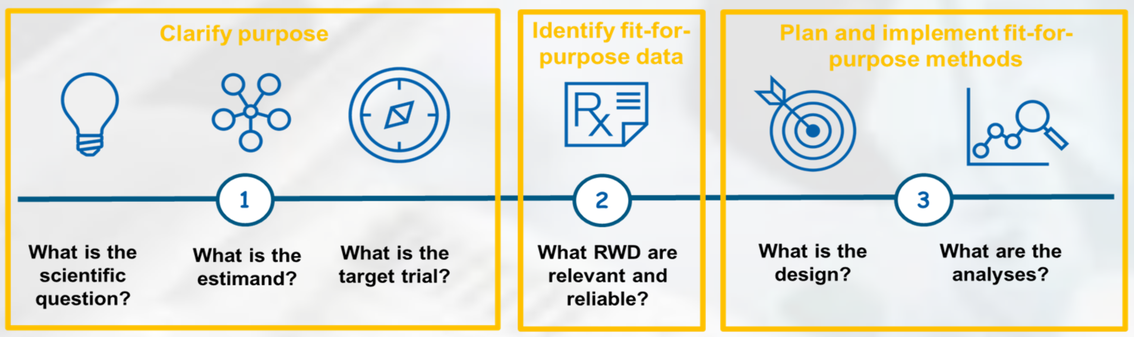
… collaborating across institutions



Data re-use: an (imperfect) analogy!

(Source: PSI Regulatory Hot Topics Session, 18 June 2024, Josie Wolfram).

Workflow transforming RWD into RWE (credits Rima Izem, 17 June SIG session)



Discussion Topics

- RWD quality – how to evaluate reliability and relevance?
- Best practices for hybrid designs incorporating evidence from clinical trial and real-world elements
- Target Trial Emulation vs Estimand frameworks
- Bayesian?
- Consistencies across the various guidances out there

Welcome your thoughts on RWD on a post-it!

Our blog and more information can be found at: https://psiweb.org/sigs-special-interest-groups/rwd-sig

SCAN ME

Compiled by Elizabeth Merrall & Helen Broadhurst on behalf of the SIG