

## Theme 1: Scenarios

### When to consider RWD/RWE for reimbursement decisions?

- Lack of data
- Contextualizing
- Using RWE with a caveat

## Theme 2: Collecting RWD

### What RWD to collect?

- Patient characteristics, Intervention, Comparators, Outcomes (effectiveness, patient-reported outcomes, safety, etc.)

### Where to collect?

- Disease registries
- Claims databases
- Electronic medical records
- Health surveys
- Wearables and personal tracking devices

### How to collect?

- Observational studies
- Pragmatic control trials
- Single arm trials

### Who to collect?

- Governance and accountability considerations for country

## Theme 3: From RWD to RWE

### How to use RWD to generate RWE?

- Integrating RWD in economic evaluation
- Using individual patient-level data from real-world sources

### What are the limitations of RWD?

- Confounding
- Selection bias
- Missing data

### What are the statistical methods to analyze RWD?

- Propensity score analyses
- Covariate adjustment
- Instrumental variables
- Imputation for addressing missing data
- Net benefit regression

Fig. 2. Objectives of the REALISE guidance.