

## QUICK REFERENCE GUIDE

### *Study Design*

#### **RESOURCES FOR DATA STANDARDS**

NIH CDE (National Institutes of Health Common Data Elements) Repository

[cde.nlm.nih.gov/cde/search](https://cde.nlm.nih.gov/cde/search)

PROMIS® (Patient-Reported Outcomes Measurement Information System)

[bit.ly/PROMIS-resource](https://bit.ly/PROMIS-resource)

National Cancer Institute Thesaurus

[bit.ly/NCI-term-browser](https://bit.ly/NCI-term-browser)

CDISC (Clinical Data Interchange Standards Consortium)

[cdisc.org](https://cdisc.org)

#### **GUIDELINES FOR INCLUDING SPECIAL POPULATIONS**

**Guidelines for working with children**

[bit.ly/working-with-children-guidelines](https://bit.ly/working-with-children-guidelines)

**Guidelines for working with other vulnerable populations**

[bit.ly/vulnerable-populations-guidelines](https://bit.ly/vulnerable-populations-guidelines)

**Guidelines for creating research engagement, recruitment and retention**

[bit.ly/guidelines-research-engagement](https://bit.ly/guidelines-research-engagement)

### *Governance*

#### **RELEVANT FDA GUIDANCE**

Rare Diseases: Natural History Studies for Drug Development Guidance for Industry

[bit.ly/natural-history-studies](https://bit.ly/natural-history-studies)

Rare Diseases: Common Issues in Drug Development Guidance for Industry

[bit.ly/common-issues-drug-development](https://bit.ly/common-issues-drug-development)

Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry

[bit.ly/diversity-clinical-trials](https://bit.ly/diversity-clinical-trials)

### *Partnerships and Collaborative Engagement*

#### **AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)**

*These guides serve as reference handbooks for providing best practices to guide design, operation, analysis, and evaluation of patient registries.*

**2nd Edition:** [bit.ly/AHRQ-2nd-edition](https://bit.ly/AHRQ-2nd-edition)

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