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

PROMIS® (Patient-Reported Outcomes Measurement Information System)
bit.ly/PROMIS-resource

National Cancer Institute Thesaurus
bit.ly/NCI-term-browser

CDISC (Clinical Data Interchange Standards Consortium)
cdisc.org

GUIDELINES FOR INCLUDING SPECIAL POPULATIONS
Guidelines for working with children

Guidelines for working with other vulnerable populations
bit.ly/vulnerable-populations-guidelines

Guidelines for creating research engagement, recruitment and retention
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

Rare Diseases: Common Issues in Drug Development Guidance for Industry
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

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.

