

Table 2. Common Data Elements for General and Precision Oncology Clinical Trials

| Clinical Trial Common Data Element Name | Permissible Values or Data Types |
|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Title | String |
| ClinicalTrials.gov Identifier (NCTID) | String |
| ClinicalTrials.gov URL | URL string |
| ClinicalTrials.gov Status | Per accepted lexicon defined by ClinicalTrials.gov |
| Phase | {Phase 1, Phase 2, Phase 3, Phase 4, N/A} |
| Phase I Description | {Dose Escalation, Expansion} |
| Intervention/Treatment/Drugs | From Accepted Intervention/Treatment/Drug Lexicon |
| Selected Biomarkers | From Accepted Biomarker Lexicon |
| Excluded Biomarkers | From Accepted Biomarker Lexicon |
| Germline/Somatic Status of the Selected/Excluded Biomarkers | {Germline, Somatic} |
| Analysis Methods Required for Determining the Biomarker Status | {Tumor-based sequencing, cfDNA sequencing, FISH, CISH, IHC, DNA methylation, Other} |
| Accepted Disease Types | From Accepted Disease Lexicon |
| Excluded Disease Types | From Accepted Disease Lexicon |
| Maximum Age Allowed | Number (positive integer) |
| Minimum Age Allowed | Number (positive integer) |
| Gender(s) Allowed | {Male, Female} |
| Brain or Central Nerve System(CNS) Metastasis Status | {Active Brain/CNS Metastasis Allowed; Treated/Stable Brain/CNS Metastasis Allowed; No Brain/CNS Metastasis Allowed} |
| Prior Therapy Required | {Yes, No} |
| Number of Previous Lines of Therapies Allowed | Number (non-negative integer) |
| Leptomeningeal Disease Allowed | {Yes, No} |
| Measurable/Evaluable Disease Status | {Measurable Disease Required; Measurable/Evaluable Disease Required; No Measurable/Evaluable Disease Required} |
| Performance Status Requirement (ECOG) | {0, 1, 2, 3, 4, 5} |
| Performance Status Requirement (Karnofsky) | {100, 90, 80, 70, 60, 50, 40, 30, 20, 10, 0} |
| Performance Status Requirement (Lansky) | {100, 90, 80, 70, 60, 50, 40, 30, 20, 10, 0} |
| Last Update Date | Date |