Background and Purpose

Relationship to Other CDISC Standards

How to Read this Document

ReportingEvent

Common Components
- NestedList
- AnalysisOutputCategorization
- ReferenceDocument
  - DocumentReference
- TerminologyExtension
  - ExtensibleTerminologyTerm
- AnalysisOutputProgrammingCode

Analysis Components
- WhereClause
  - WhereClauseCondition
  - WhereClauseCompoundExpression
- AnalysisSet
- DataSubset
- GroupingFactor
  - SubjectGroupingFactor
  - DataGroupingFactor
- AnalysisMethod
  - Operation
  - AnalysisProgrammingCodeTemplate
- Analysis
  - OperationResult

Output Components
- GlobalDisplaySection
- Output
  - OutputDisplay

Common Safety Displays
- Summary of Demographics
- Overall Summary of Treatment-Emergent Adverse Events
- Summary of TEAE by System Organ Class and Preferred Term
- Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs
- Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>

FDA STF
- Table 2: Baseline Demographic and Clinical Characteristics, Safety Population

Glossary and Abbreviations

Representations and Warranties, Limitations of Liability, and Disclaimers