The Define-XML standard is based on the CDISC Operational Data Model (ODM)-XML schema. ODM is a vendor-neutral, platform-independent format for the interchange and archiving of clinical study data. The model includes the clinical data along with its associated metadata, administrative data, reference data, and audit information. All of the information that needs to be shared among different software systems during setup, operation, analysis, and submission, or for long-term retention as part of an archive, is included in the model. ODM has been embraced by a broad range of clinical development organizations, and a number of vendors provide software applications and tools that use ODM. The current version of the ODM standard is available at http://www.cdisc.org/odm and the version of ODM supported for a specific version of the Define-XML is identified in the Define-XML schema.

One of the features of the ODM is a standardized mechanism for defining schema extensions to provide the functionality needed to support interchange requirements for specialized uses. To address the specific needs of data transmission in support of regulatory submissions, CDISC has developed the Define-XML model, which is implemented as a set of extensions to the base ODM schema. These extensions follow the guidelines for Vendor Extensions provided in the ODM specification and comply with the W3C XML Schema Version 1.0 specification. The XML schema files for the Define-XML standard are available online at http://www.cdisc.org/define-xml.

Although this document is intended to be understandable to readers with minimal technical knowledge of the ODM and XML, knowledge of this document alone is not a substitute for knowledge of the ODM nor is it sufficient to produce complete Define-XML documents. This document should be used in close concert with the current version of the ODM specification as well as current versions of the relevant data standards. The ODM specification package is available online at http://www.cdisc.org/odm. Numerous examples of XML fragments appear in this document. Many of these examples are provided as XML files and can be downloaded from the CDISC website (http://www.cdisc.org/define-xml).