The underlying assumptions, statistical methods, transformations, derivations and imputations performed in the analysis of a clinical study should be communicated clearly and in such a manner that the values and results can be easily replicated. ADaM metadata facilitates this communication by providing specification of details and links between the general description of the analysis (as found in the protocol’s data analysis section, SAP, or the reported analysis methods), the analysis results, the data used in the analysis, and the SDTM domains. The following sections describe in detail the components of the ADaM metadata.

The metadata structures described for the analysis dataset metadata and the analysis variable metadata are based on the Case Report Tabulation Data Definition Specification Standard, version 1.0.0 (CRT-DDS). Refer to that document for additional details.

The examples of metadata included in this document are for illustration only and are not intended to dictate or recommend presentation style, format or process. In addition, the italicized rows included in some of the illustrations are only for reference, as a reminder of the field definitions. It is not intended that this row be included by applicants in metadata.