

CDISC SDTM Implementation Guide (Version 3.2)



- CDISC SDTM Implementation Guide (Version 3.2)
 - For concomitant medications, populate CMDECOD with the drug's generic name and populate CMCLAS with the drug class used for the sponsor's analysis and summary tables. If coding to multiple classes, follow **Section 4.1.2.8.1, Multiple Values for an Intervention or Event Topic Variable** or omit CMCLAS.
 - For concomitant medications, supplemental qualifiers (see **Section 8: 8.4, Relating Non-Standard Variables Values to a Parent Domain** and **Appendix C2 - Supplemental Qualifier Name Codes** for more information) may be used to represent additional coding dictionary information, e.g. a drug's ATC codes from the WHO Drug dictionary. However, by knowing the dictionary and version used, the reviewer will be able to obtain additional coding dictionary information.
 - Note: The sponsor is expected to provide the dictionary name and version used to map the terms by utilizing the define.xml external codelist attributes.

Cdisc Implementation Guide

Rachel S Tattersall



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