



Development Approach on the Sponsor-Defined Extensions of the Model

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Section 1: Why

- ▶ The fundamental principles and standards to follow in the creation of analysis datasets and associated metadata for submission to regulatory authorities (e.g. US Food & Drug Administration)
- ▶ The purpose of ADaM is to provide a framework that enables analysis of the data, while at the same time allowing reviewers and other recipients of the data to have a clear understanding of the data's lineage from collection to analysis to results.

Section 2: How

Section 2: What

- ▶ Roche-defined extensions conform to any rules provided in the ADaM IG.

ADaM extensibility includes:

- ▶ Sponsor-defined analysis datasets – analysis datasets that adhere to the rules of the ADaM data structures – Subject Level Analysis Dataset (ADSL), Basic Data Structure (BDS) and Occurrence Data Structure (OCCDS).

ADaM extensibility includes:

- Derivation rules for how the contents of how each variable should be derived, including those that differ based on the parameter (PARAMCD), i.e. parameter driven derivations.

ADaM extensibility includes:

- Links to the analysis concept for each derivation

ADaM extensibility includes:

- SDTM variables to be included in each analysis dataset

ADaM extensibility includes:

- Sponsor-defined parameter invariant variables required for the analysis

ADaM extensibility includes:

- Sponsor-defined flag variables required for the analysis

ADaM extensibility includes:

- Character variable lengths – defined by the Sponsor, between 1–200 characters.

ADaM extensibility includes:

- Controlled Terminology:
 - Extension of CDISC-defined code lists with sponsor-defined terms.
 - Sponsor-defined code lists.

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