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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Organization:
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E-mail:
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