Appendix I: Variables to be Included/Excluded for Each Trial

General

The library metadata (VARDEF.CORE) can be referenced to identify the variables which can be excluded from the metadata of the trial (=Perm variables which are not planned to be collected and/or populated). Please note that this CORE might not correspond with the one defined in the CDISC SDTMIG, as sponsors are allowed to 'upgrade' the CORE based on the internal requirements.

- A **Required** variable is any variable that is basic to the identification of a data record (i.e., essential key variables and a topic variable) or is necessary to make the record meaningful. Required variables must always be included in the dataset and cannot be null for any record.
- An **Expected** variable is any variable necessary to make a record useful in the context of a specific domain. Expected variables may contain some null values, but in most cases will not contain null values for every record. When no data has been collected for an expected variable, a null column must still be included in the dataset and a comment must be included in the define.xml to state that data was not collected.
- A **Permissible** variable should be included in a domain as appropriate when planned to be collected or derived. Permissible variables should not be excluded when they contain data.

Permissible Variables to be Included

Permissible variables should be included/submitted for each trial when any of the following conditions are met:

- Data was planned to be collected for this variable and so is available on the annotated CRF (acrf.pdf).
- Data was planned to be collected for this variable through an external data transfer and so is available in the Data Transfer Agreement (DTA).
- Data can be derived/assigned based on other collected data, e.g. when a --DTC has been collected, the corresponding --DY variable can be derived. See below a list of the 'conditionally expected' variables:

When this variable is included	These variables should also be included
--DTC	--DY
--STDTC	--STDY
--ENDTC	--ENDY
--REASND	--STAT
--TPT	--TPTNUM, --ELTM, --TPTREF
VISIT	VISITNUM, VISITDY
CO.IDVAR	CO.RDOMAIN, CO.IDVARVAL
--OCCUR	--PRESP
--ORRESU	--STRESU, --STRESN

- Some data should be available, however the domain/variable where this data is available can vary from trial to trial.

Data to be included	Domain/Variable where data could be available
Exposure Kit numbers with corresponding Batch Lot number	EX.EXREFID with corresponding EX.EXLOT or DAREFID with corresponding DALOT in SUPPDA

- Some variables have been defined by CDISC as Permissible, however should be / have been upgraded to Expected according to FDA Submission Requirements and/or internal process requirements.

Conditions around variables to be included	Variables to be included
Value-Level Metadata nesting requirements	LB: LBCAT, LBSPEC, LBMETHOD QS: QSCAT
Parameters used to determine the AE Seriousness	AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESMIE
Baseline flags in Findings domains in case they can be derived	--BLFL
EPOCH in General Observational Class domains, in case they can be derived	EPOCH
Data collected at a specific VISIT	--DTC (collection date)
Intervention-Events domains	--STDTC
Findings – Findings About domains	--DTC

Version History

Date	Version	Summary of Changes
October 2015	1.0	Initial version