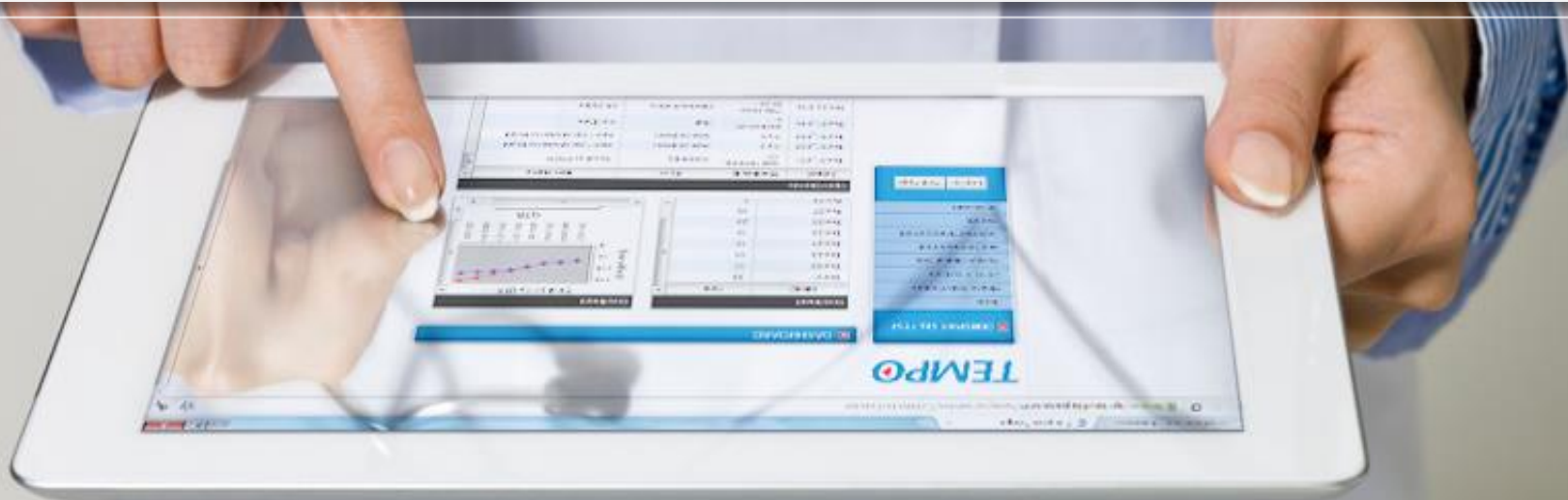


SDTM SV Mapping Challenges



SV Requirements

➤ From SDTM IG 3.2

- The Subject Visits domain consolidates information about the timing of subject visits that is otherwise spread over domains that include the visit variables.
- Populating the Subject Visits dataset will involve derivations
- The SV dataset provides reviewers with a summary of a subject's Visits. Comparison of an individual subject's SV dataset with the TV dataset, which describes the planned Visits for the trial, quickly identifies missed Visits and "extra" Visits. Comparison of the values of SVSTDY and SVENDY to VISIT and/or VISITDY can often highlight departures from the planned timing of Visits.
- Checks implemented accordingly in Pinnacle 21
 - Checks whether all visits are also entered in SV
 - Checks VISIT/VISITNUM values against TV

SV Requirements

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SV	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VISITNUM	Visit Number	Num		Topic	1. Clinical encounter number. (Decimal numbering may be useful for inserting unplanned visits.) 2. Numeric version of VISIT, used for sorting.	Req
VISIT	Visit Name	Char		Synonym Qualifier	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY as a text description of the clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the start of the visit based upon RFSTDTC in Demographics.	Perm
SVSTDTC	Start Date/Time of Visit	Char	ISO 8601	Timing	Start date/time for a Visit.	Exp
SVENDTC	End Date/Time of Visit	Char	ISO 8601	Timing	End date/time of a Visit.	Exp
SVSTDY	Study Day of Start of Visit	Num		Timing	Study day of start of visit relative to the sponsor-defined RFSTDTC.	Perm
SVENDY	Study Day of End of Visit	Num		Timing	Study day of end of visit relative to the sponsor-defined RFSTDTC.	Perm
SVUPDES	Description of Unplanned Visit	Char		Synonym Qualifier	Description of what happened to the subject during an unplanned visit.	Perm

Additions from Pinnacle 21 for SV

- Expects one to one mapping of VISIT and VISITNUM for **all** visits
 - according to SDTM IG this is only needed for planned visits
 - Section 4.14.5 of SDTM IG says:
 - For planned visits:
...
There should be a one-to-one relationship between values of VISIT and VISITNUM.
...
 - Sponsor practices for populating visit variables for unplanned visits may vary across sponsors
...
VISIT may be left null or may be populated with a generic value (e.g., "Unscheduled") for all unplanned visits, or individual values may be assigned to different unplanned visits.
...
- Identifies Unscheduled Visits via the terms „UNSCHED“, „Unsched“, „UNPLAN“ and „Unplan“ (Unsched. /UNSCHED. Used in new version)
 - Should rather use SVUPDES

SV Requirements

- For unscheduled visits or measurements, numbers are often assigned values between two protocol-scheduled visits. These numbers should be distinct from other visit numbers but retain the chronological order (e.g. two unscheduled visits between visit 3 and visit 4 might be 3.1 and 3.2). The character form of the visit identifier may be UNSCHEDULED or a similar term.

(Study Data Specifications V2.0

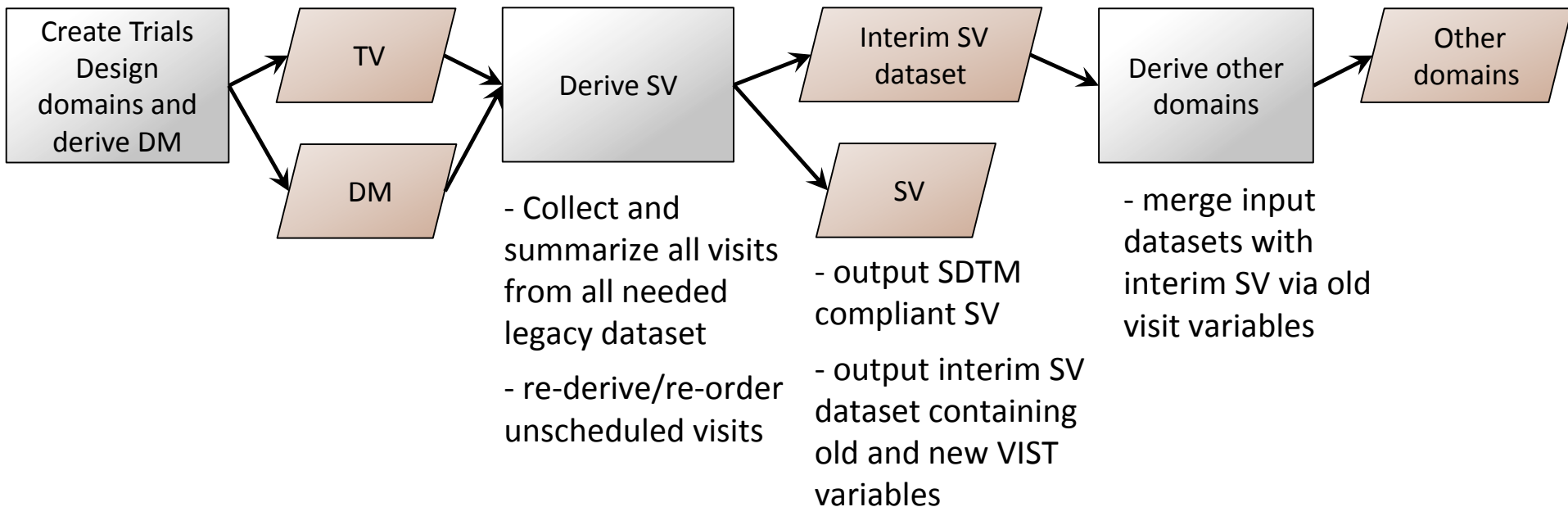
<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM312964.pdf>)

- **Not** included in newer versions of the document

SV Mapping Process

- Visits need to be re-derived centrally for SV
 - Bring together all visits spread over various datasets
 - Re-derive/re-order unscheduled visits
- Process option 1:
 - Derive SV first and output interim data
 - merge interim dataset containing old and new Visit names with visit based datasets during their creation
- Process option 2:
 - Derive SV at the end
 - re-output the new visits in all visit based SDTM domains

SV Mapping Process – option 1



USUBJID	VISITO	VISITR	VISITNUM	VISIT	SVSTDTC	SVENDTC
ABC-001-00001	800	1	800	MONTH 18	2010-01-13	2010-01-13
ABC-001-00001	88888	1	800.01	MONTH 18 - UNSCHEDULED 1	2010-02-05	2010-02-05
ABC-001-00001	900	1	900	MONTH 21	2010-04-14	2010-04-14
ABC-001-00001	88888	2.711	900.01	MONTH 21 - UNSCHEDULED 1	2010-04-30	2010-04-30
ABC-001-00001	88888	2.831	900.02	MONTH 21 - UNSCHEDULED 2	2010-05-21	2010-05-21
ABC-001-00001	1000	1	1000	MONTH 24/ET	2010-07-14	2010-07-14

SV Mapping Process – option 1

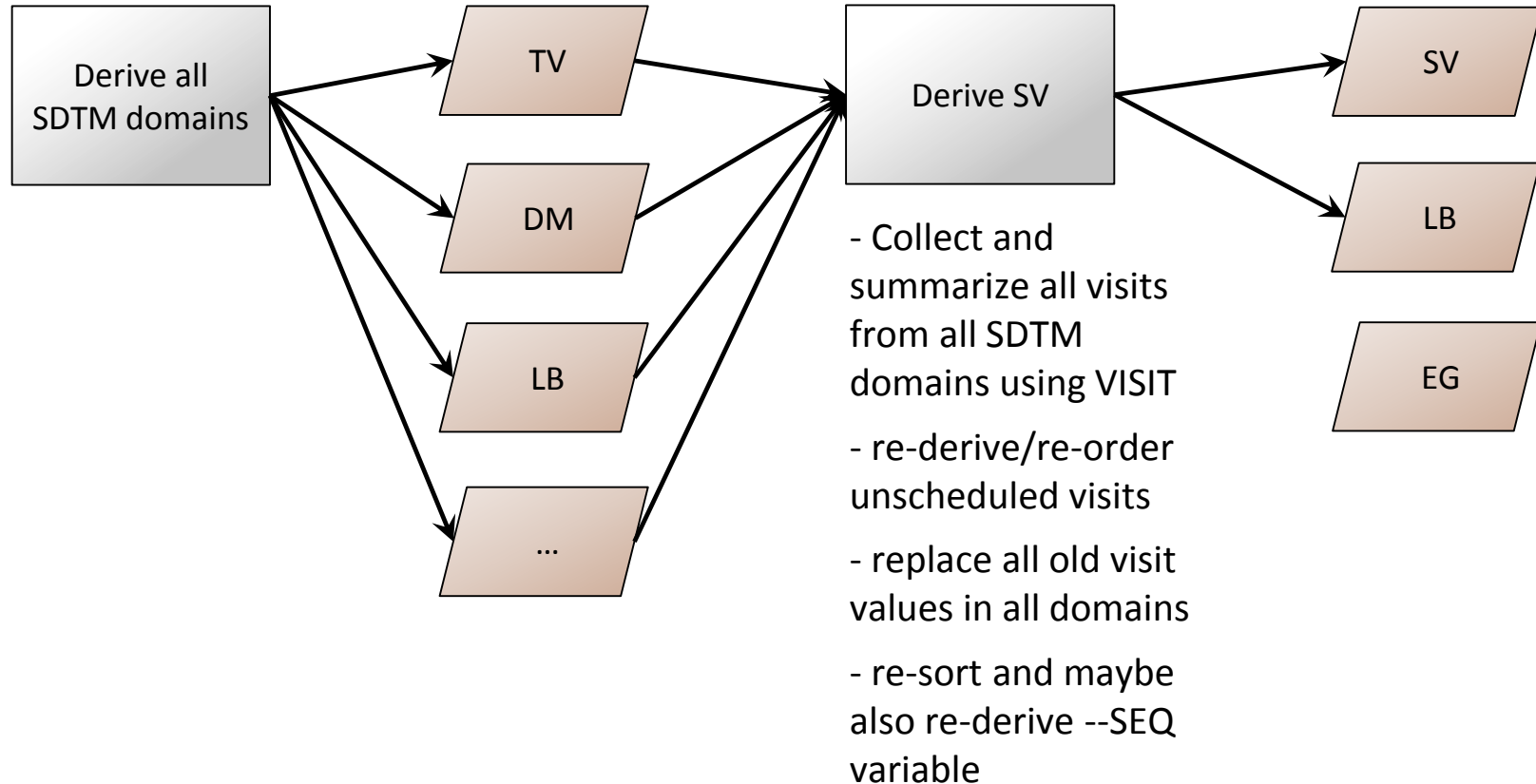
➤ Advantages

- Central derivation of visits
- Re-run of single domains possible at every time
- Simple and reproducible

➤ Disadvantages

- Merge needed in every program creating a domain that uses visits
- In case of greater changes in visit variable structures many programs may need update

SV Mapping Process – option 2



SV Mapping Process – option 2

➤ Advantages

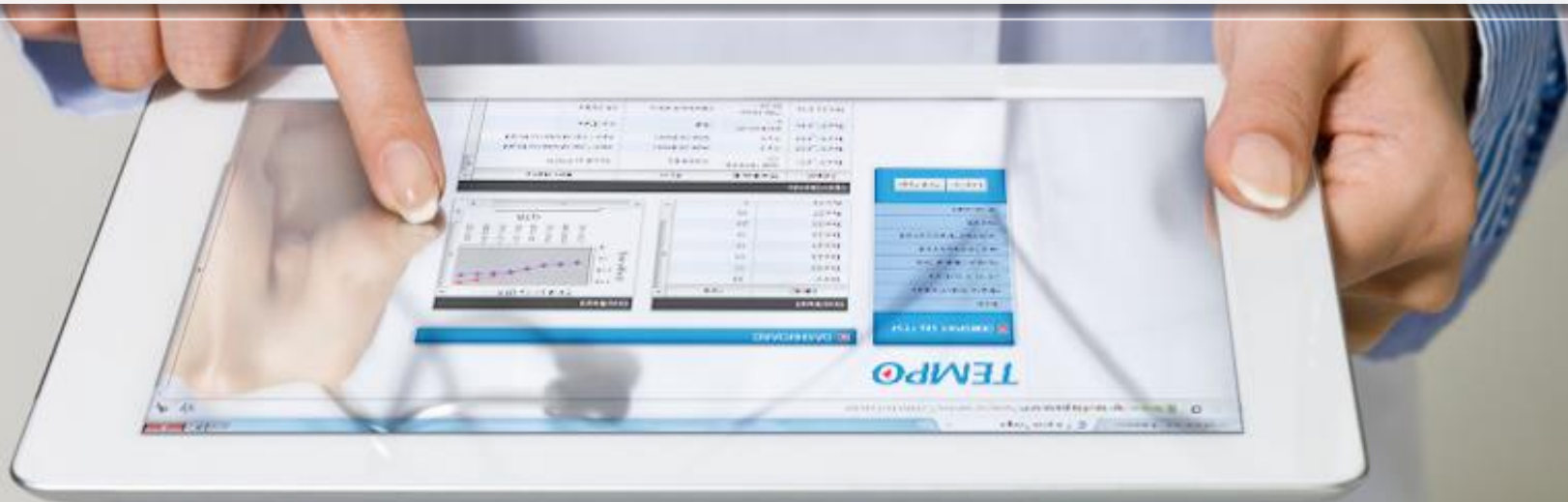
- Central derivation of visits
- One program takes care of all visit derivation
- More generic as based on standardized SDTM data
 - Reusable for all studies

➤ Disadvantages

- Program can be very complex
- Re-sorting of each domain needed, when unscheduled visit values are being changed within the domains
- Re-derivation of --SEQ values might be needed due to new visit values
 - Leads also to re-derivation of SUPP--, CO, RELREC
- Single domains can not be re-run and compared to previous dataset (due to different visit values)



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