How to - Trial Summary Parameter

CJUG SDTM Team : LISaS 2013-11-08

Preconditions for the Discussion

- CDISC Controlled Terminology: As of 2013-10-04
- SDTM IG: v3.1.3 or v3.1.2
- CDISC Protocol Representation Model (PRM)Toolset: v1.0 - Study Outline Concepts
  - http://www.cdisc.org/content4044
- OpenCDISC Validator: v1.4.1
- PhUSE/FDA Working Group: SDTM Validation Rules Project (2013 FDA/PhUSE CSS March 18-19 Project Breakout Session)
  - http://www.phusewiki.org/wiki/index.php?title=SDTM_Validation_Rules_Project

What's the "Trial Summary Parameter"?

STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
XYZ	TS	1		TITLE	Trial Title	A 24 Week Study of Oral Gabapentin vs. Placebo as add-on Treatment to Phenytoin in Subjects with Epilepsy due to Neurofibromatosis				
XYZ	TS	1		TPHASE	Trial Phase Classification	Phase II Trial		C15601	CDISC	2011-06-10
XYZ	TS	1		TTYPE	Trial Type	EFFICACY		C49666	CDISC	2011-06-10
XYZ	TS	2		TTYPE	Trial Type	SAFETY		C49667	CDISC	2011-06-10
XYZ	TS	1		PLANSUB	Planned Number of Subjects	300				
XYZ	TS	1		OBJPRIM	Trial Primary Objective	Reduction in the 3-month seizure frequency from baseline				
XYZ	TS	1		OBJSEC	Trial Secondary Objective	Percent reduction in the 3-month seizure frequency from baseline				
XYZ	TS	2		OBJSEC	Trial Secondary Objective	Reduction in the 3-month tonic-clonic seizure frequency from baseline				

In the CDISC Controlled Terminology …

- The number of parameters: **47**

Added on to Existing Treatments	Trial Phase Classification	Planned Country of Investigational Sites
Planned Maximum Age of Subjects	Trial Type	Healthy Subject Indicator
Planned Minimum Age of Subjects	Current Therapy or Treatment	Intervention Model
Age Span	Trial Primary Objective	Intervention Type
Dose per Administration	Trial Secondary Objective	Planned Number of Arms
Trial Length	Clinical Study Sponsor	Exploratory Outcome Measure
Planned Number of Subjects	Comparative Treatment Name	Primary Outcome Measure
Trial is Randomized	Dose Units	Secondary Outcome Measure
Route of Administration	Dosing Frequency	Pharmacological Class of Invest. Therapy
Sex of Participants	Trial Indication	Randomization Quotient
Study Stop Rules	Investigational Therapy or Treatment	Registry Identifier
Trial Blinding Schema	Actual Number of Subjects	Stable Disease Minimum Duration
Control Type	Adaptive Design	Study End Date
Diagnosis Group	Confirmed Response Minimum Duration	Study Start Date
Trial Indication Type	Data Cutoff Description	Study Type
Trial Title	Data Cutoff Date	

Simple Question

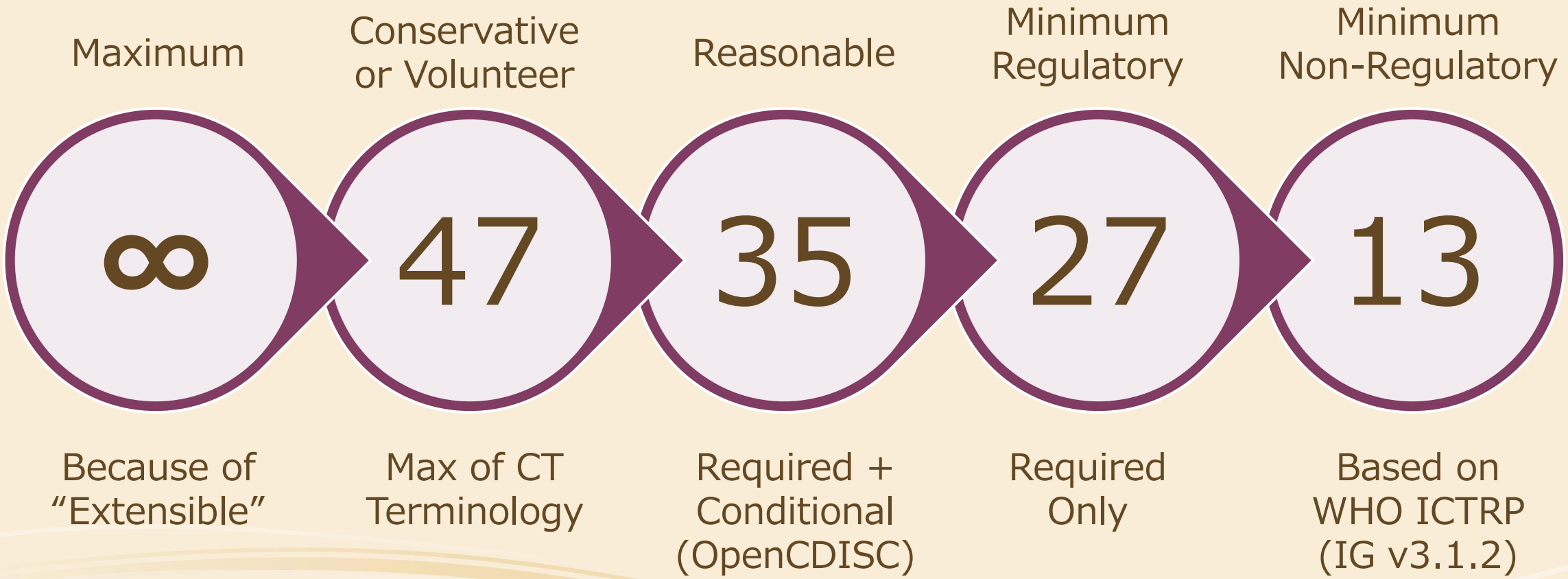
- 47 parameters are way too many.
- Is there guidance on which “Trial Summary Parameters” are supposed to be?
  - How many parameters should we submit?
  - Which one should we submit?

We can refer several documents ...

Documents	Number of Parameters	Note
CDISC Controlled Terminology	47 (Extensible=Yes)	AGESPAN, DOSE, DOSFRQ, DOSU are not found in the IG v3.1.3
SDTM IG v3.1.3 Appendix C3	Total: 43 Required: 27 Conditionally Required: 8 If Applicable: 8	This is consistent with the CDISC PRM Toolset - Study Outline Concepts
SDTM IG v3.1.2*	Appendix C3: 27 Minimum set: 13	Section 7.6.2 Quote; “There is not yet guidance on which Trial Summary parameters are required, but the following minimum recommended set is based on the WHO International Clinical Trial Registry Platform (ICTRP) Registration Data Set: TITLE, INDIC, TCNTRL, RANDOM, TRT, COMPTRT (when applicable), AGESPAN, AGEMIN, AGEMAX, AGEU, SEXPOP, PLANSUB, OBJPRIM, OBJSEC. “; Note that this sentence was removed in the IG v3.1.3.
CDISC PRM Toolset	Same as IG v3.1.3	This is consistent with the SDTM IG v3.1.3 Appendix C3
OpenCDISC Validator	Error: 34	Based on the SDTM IG v3.1.3 and PhUSE/FDA Working Group. However “Randomization Quotient (RANDQT)” is not found.
PhUSE/FDA Working Group	35 (Required: 27+ Conditional: 8)	35 Trial Summary Parameters are required or conditionally required in study data; SDTM IG 3.1.3 – Errors / SDTM IG 3.1.2 – Warnings

*: “Trial Summary Update to the SDTM Implementation Guide: Human Clinical Trials, Feb 6, 2012” is not included.

Summary: The number of Trial Summary Parameters



Note that TS domain is just tabulation dataset. If you create TS domain just before your submission, you may ask reviewers about this question.

Questions?

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