

Below you find a table with the proposed slots/topics for the planned "Impact and Change Summary Discussion on the SDTM Implementation Guide v3.3 and SDTM Model v1.7" on our next German CDISC User Network Meeting in Eschborn (Frankfurt) on Sep. 25th 2019.

Volunteers for any of the proposed slots for the F-2-F Meeting on Sep. 25th should please contact Kurt Hellstern in the next monthly User Network Telephone Conferences or via the network mailing list ([deun\[at\]lists.cdisc.org](mailto:deun[at]lists.cdisc.org)).

Block	Index	Topic	Presenter(s)
A) Removed Domains + CT	A-1	<p>Domains removed:</p> <ul style="list-style-type: none"> • POOLDEF • TX • APDM • APRELSUB • MO (decommissioned) <p>Codelists dropped:</p> <ul style="list-style-type: none"> • FATEST/FATESTCD • QSTEST/QSTESTCD • MOTEST/MOTESTCD 	e.g. John Doe
B) New Domains	B-1	<p>"Disease Milestone"</p> <p>Section 5: Special Purpose</p> <ul style="list-style-type: none"> • SM – Subject Disease Milestones <p>Section 7: Trial Design Model</p> <ul style="list-style-type: none"> • TM – Trial Disease Milestones 	
	B-2	<p>Section 6.1: Interventions</p> <ul style="list-style-type: none"> • ML – Meal Data • AG – Procedure Agents <p>Section 6.3.13: Findings (Questionnaires, Ratings, and Scales)</p> <ul style="list-style-type: none"> • FT – Functional Tests 	
	B-3	<p>Section 6.3.10: Findings I (Morphology/Physiology Domains Subgroup)</p> <ul style="list-style-type: none"> • CV – Cardiovascular System Findings • MK – Musculoskeletal System Findings • NV – Nervous System Findings 	
	B-4	<p>Section 6.3.10: Findings II (Morphology/Physiology Domains Subgroup)</p> <ul style="list-style-type: none"> • RE – Respiratory System Findings • UR – Urinary System Findings • OE – Ophthalmic Examinations 	
	B-5	<p>New SDTM-IG Section 9: Study References</p> <ul style="list-style-type: none"> • DI – Device Identifiers* (IG Medical Devices) • OI – Non-Host Organism Identifiers (SEND) • PB – Pharmacogenomic/Genetic Biomarker Identifiers* (IG PGx) 	
C) Changes	C-1	<p>Variable Level</p> <ul style="list-style-type: none"> • 79 changes/updates on variable label • Impact on P21 Validation • 3 Variable Type Changes (e.g. EXDOSTOT from Char to Num) 	
	C-2	<p>Controlled Terminology</p> <ul style="list-style-type: none"> • 51 changes/updates on CT specifications <p>Guidance on EPOCH</p>	
	C-3	<p>Extended Use of RS</p>	

* DI and PB domains are referenced from the SDTMIG-MD (SDTM-IG for Medical Devices) and SDTMIG-PGx (SDTM-IG for Pharmacogenomic/Genetics)

