TD
Trial Disease Assessments Domain
in
Draft SDTM IG 3.1.4

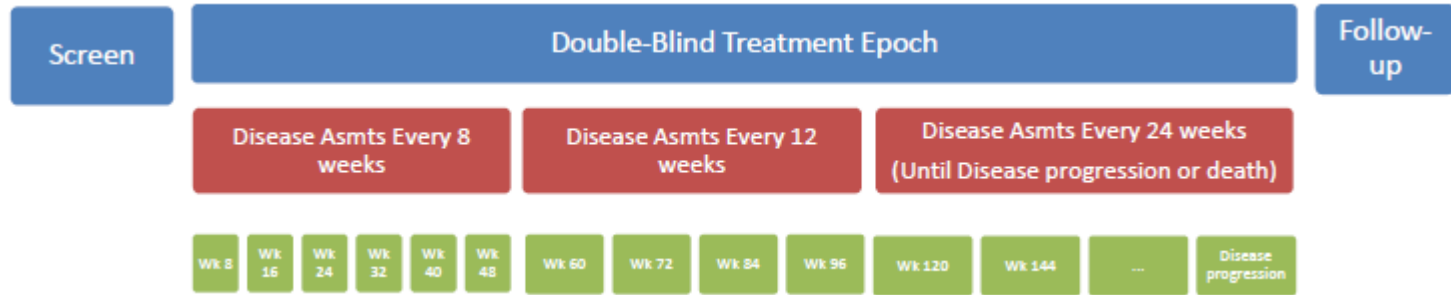**Monika Kawohl**

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TD – Trial Disease Assessments

✔ NEW Trial Design Domain

✔ 1 Record per planned constant assessment period

✔ Use Case – Oncology Trials:
protocol-specified disease assessment schedule
for comparison with act. occurrence of efficacy assessments
to determine compliance with the schedule

✔ To be used by FDA programs that evaluate
possible 'assessment time bias' for efficacy assessments,
in particular for studies with
progression-free survival (PFS) endpoints

Example

Row	STUDYID	DOMAIN	TDORDER	Anchor Variable TDANCVAR	Offset from the Anchor TDSTOFF	------ Planned Assessment Interval----- (Target) TDTGTPRD	Minimum TDMINPRD	Maximum TDMAXPRD	Maximum Number of Actual Assessments TDNUMRPT
1	ABC123	TD	1	ANCH1DT	P0D	P8W	P53D	P9W	6
2	ABC123	TD	2	ANCH2DT	P0D	P12W	P11W	P13W	4
3	ABC123	TD	3	ANCH3DT	P0D	P24W	P20W	P28W	12

Name of variable in ADaM ADSL