



Trial Design Datasets

An Example for TA and TV

CDISC DACH User Network

20-Feb-2018



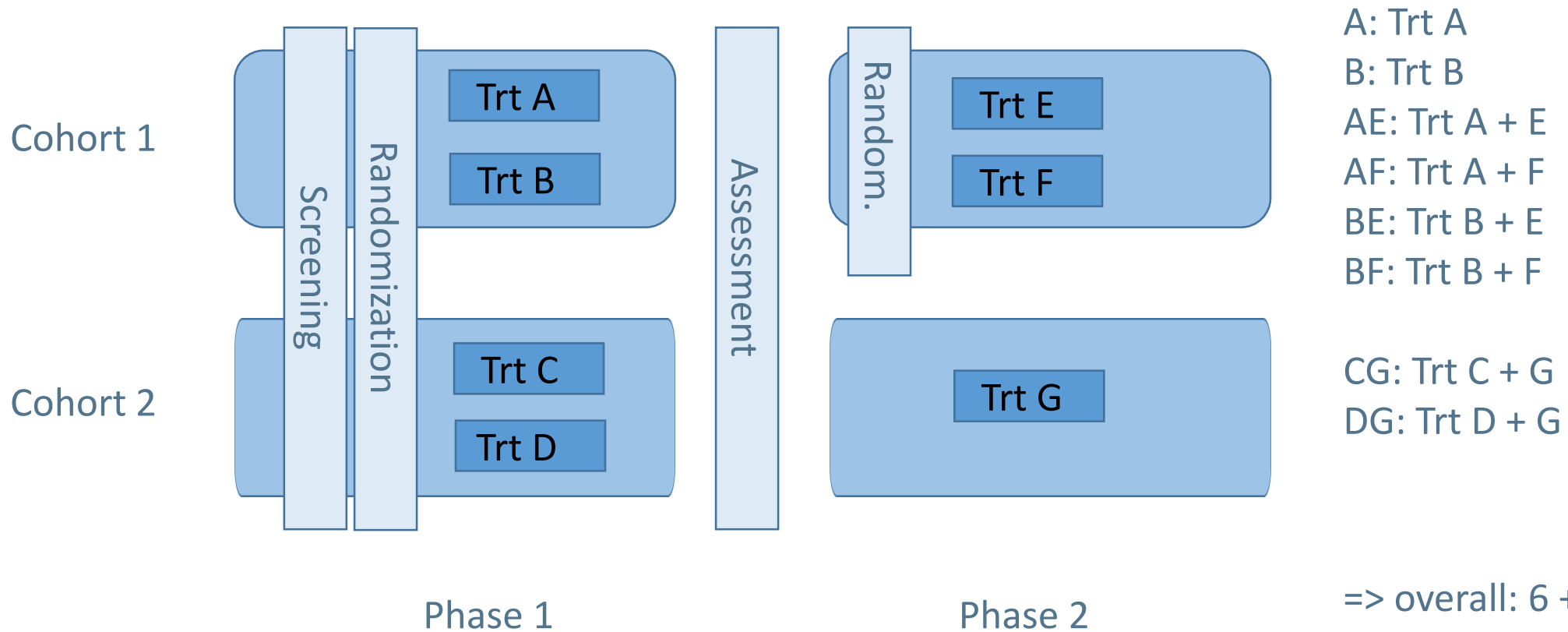
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Study Design



Visit Schedule (per treatment cycle)



Phase 1

Trt A, C: Days 1, 5, 15

Trt B: Days 1, 15

Trt D: Days 1, 3, 5, 8, 15

Phase 2

Trt E, F: Days 1, 5, 15

Trt G: Days 1, 15

=> Planned Visit Description per ARM/ARMCD

First Version

STUDYID	DOMAIN	VISITNUM	VISIT	VISITDY	ARMCD	ARM	TVSTRL	TVENRL
ABC	TV	100	SCREENING	-28	A	Trt A		
ABC	TV	101	PHASE 1: CYCLE 1 DAY 1	1	A	Trt A		
ABC	TV	105	PHASE 1: CYCLE 1 DAY 5	5	A	Trt A		
ABC	TV	115	PHASE 1: CYCLE 1 DAY 15	15	A	Trt A		
ABC	TV	201	PHASE 1: CYCLE 2 DAY 1		A	Trt A		
ABC	TV	205	PHASE 1: CYCLE 2 DAY 5		A	Trt A		
ABC	TV	215	PHASE 1: CYCLE 2 DAY 15		A	Trt A		
ABC	TV	301	PHASE 1: CYCLE 3 DAY 1		A	Trt A		
ABC	TV	305	PHASE 1: CYCLE 3 DAY 5		A	Trt A		
ABC	TV	315	PHASE 1: CYCLE 3 DAY 15		A	Trt A		
ABC	TV		...		A	Trt A		
ABC	TV	9900	PHASE 1 TREATMENT DISCONTINUATION		A	Trt A		
ABC	TV		...		A	Trt A		
ABC	TV	100	SCREENING	-28	B	Trt B		
ABC	TV	101	PHASE 1: CYCLE 1 DAY 1	1	B	Trt B		
ABC	TV	115	PHASE 1: CYCLE 1 DAY 15	15	B	Trt B		
ABC	TV	201	PHASE 1: CYCLE 2 DAY 1		B	Trt B		
ABC	TV	215	PHASE 1: CYCLE 2 DAY 15		B	Trt B		
ABC	TV	301	PHASE 1: CYCLE 3 DAY 1		B	Trt B		
ABC	TV	315	PHASE 1: CYCLE 3 DAY 15		B	Trt B		
ABC	TV		...		B	Trt B		
ABC	TV	9900	PHASE 1 TREATMENT DISCONTINUATION		B	Trt B		
ABC	TV		...		B	Trt B		

Visit Schedule (per treatment cycle)



Phase 1

Trt A, C: Days 1, 5, 15 (**21 day cycles**)

Trt B: Days 1, 15 (**28 day cycles**)

Trt D: Days 1, 3, 5, 8, 15 (**21 day cycles**)

Phase 2

Trt E, F: Days 1, 5, 15 (**21 day cycles**)

Trt G: Days 1, 15 (**21 day cycles**)

=> Adapt VISITNUM/VISIT to get correct VISITDY for 28 day cycles

Different Cycle Lengths

STUDYID	DOMAIN	VISITNUM	VISIT	VISITDY	ARMCD	ARM	TVSTRL	TVENRL
ABC	TV	10000	SCREENING	-28	A	Trt A		
ABC	TV	10100	PHASE 1: CYCLE 1 DAY 1	1	A	Trt A		
ABC	TV	10500	PHASE 1: CYCLE 1 DAY 5	5	A	Trt A		
ABC	TV	11500	PHASE 1: CYCLE 1 DAY 15	15	A	Trt A		
ABC	TV	20121	PHASE 1: CYCLE 2 DAY 1	22	A	Trt A		
ABC	TV	20521	PHASE 1: CYCLE 2 DAY 5	26	A	Trt A		
ABC	TV	21521	PHASE 1: CYCLE 2 DAY 15	36	A	Trt A		
ABC	TV	30121	PHASE 1: CYCLE 3 DAY 1	43	A	Trt A		
ABC	TV	30521	PHASE 1: CYCLE 3 DAY 5	47	A	Trt A		
ABC	TV	31521	PHASE 1: CYCLE 3 DAY 15	57	A	Trt A		
ABC	TV		...		A	Trt A		
ABC	TV	990000	PHASE 1 TREATMENT DISCONTINUATION		A	Trt A		
ABC	TV		...		A	Trt A		
ABC	TV	10000	SCREENING	-28	B	Trt B		
ABC	TV	10100	PHASE 1: CYCLE 1 DAY 1	1	B	Trt B		
ABC	TV	11500	PHASE 1: CYCLE 1 DAY 15	15	B	Trt B		
ABC	TV	20128	PHASE 1: CYCLE 2 DAY 1 (28)	29	B	Trt B		
ABC	TV	21528	PHASE 1: CYCLE 2 DAY 15 (28)	43	B	Trt B		
ABC	TV	30128	PHASE 1: CYCLE 3 DAY 1 (28)	57	B	Trt B		
ABC	TV	31528	PHASE 1: CYCLE 3 DAY 15 (28)	71	B	Trt B		
ABC	TV		...		B	Trt B		
ABC	TV	990000	PHASE 1 TREATMENT DISCONTINUATION		B	Trt B		
ABC	TV		...		B	Trt B		

Visit Schedule (per treatment cycle)

Phase 1

Trt A, C: Days 1, 5, 15 (21 day cycles)

Trt B: Days 1, 15 (28 day cycles)

Trt D: Days 1, 3, 5, 8, 15 (21 day cycles)

+ Tumor Assessment Visits every 4 weeks

=> Same VISITNUM/VISIT for all Arms possible?

Phase 2

Trt E, F: Days 1, 5, 15 (21 day cycles)

Trt G: Days 1, 15 (21 day cycles)

Additional Assessment Visits I

STUDYID	DOMAIN	VISITNUM	VISIT	VISITDY	ARMCD	ARM	TVSTRL	TVENRL
ABC	TV	10000	SCREENING	-28	A	Trt A		
ABC	TV	10100	PHASE 1: CYCLE 1 DAY 1	1	A	Trt A		
ABC	TV	10500	PHASE 1: CYCLE 1 DAY 5	5	A	Trt A		
ABC	TV	11500	PHASE 1: CYCLE 1 DAY 15	15	A	Trt A		
ABC	TV	20121	PHASE 1: CYCLE 2 DAY 1	22	A	Trt A		
ABC	TV	20521	PHASE 1: CYCLE 2 DAY 5	26	A	Trt A		
ABC	TV	?	ASSESSMENT WEEK 4	28	A	Trt A		
ABC	TV	21521	PHASE 1: CYCLE 2 DAY 15	36	A	Trt A		
ABC	TV	30121	PHASE 1: CYCLE 3 DAY 1	43	A	Trt A		
ABC	TV	30521	PHASE 1: CYCLE 3 DAY 5	47	A	Trt A		
ABC	TV	?	ASSESSMENT WEEK 8	56	A	Trt A		
ABC	TV	31521	PHASE 1: CYCLE 3 DAY 15	57	A	Trt A		
ABC	TV		...		A	Trt A		
ABC	TV	990000	PHASE 1 TREATMENT DISCONTINUATION		A	Trt A		
ABC	TV		...		A	Trt A		
ABC	TV	10000	SCREENING	-28	B	Trt B		
ABC	TV	10100	PHASE 1: CYCLE 1 DAY 1	1	B	Trt B		
ABC	TV	11500	PHASE 1: CYCLE 1 DAY 15	15	B	Trt B		
ABC	TV	?	ASSESSMENT WEEK 4	28	B	Trt B		
ABC	TV	20128	PHASE 1: CYCLE 2 DAY 1 (28)	29	B	Trt B		
ABC	TV	21528	PHASE 1: CYCLE 2 DAY 15 (28)	43	B	Trt B		
ABC	TV	?	ASSESSMENT WEEK 8	56	B	Trt B		
ABC	TV	30128	PHASE 1: CYCLE 3 DAY 1 (28)	57	B	Trt B		
ABC	TV	31528	PHASE 1: CYCLE 3 DAY 15 (28)	71	B	Trt B		
ABC	TV		...		B	Trt B		
ABC	TV	990000	PHASE 1 TREATMENT DISCONTINUATION		B	Trt B		
ABC	TV		...		B	Trt B		

Additional Assessment Visits II

STUDYID	DOMAIN	VISITNUM	VISIT	VISITDY	ARMCD	ARM	TVSTRL	TVENRL
ABC	TV	10000	SCREENING	-28	A	Trt A		
ABC	TV	10100	PHASE 1: CYCLE 1 DAY 1	1	A	Trt A		
ABC	TV	10500	PHASE 1: CYCLE 1 DAY 5	5	A	Trt A		
ABC	TV	11500	PHASE 1: CYCLE 1 DAY 15	15	A	Trt A		
ABC	TV	20121	PHASE 1: CYCLE 2 DAY 1	22	A	Trt A		
ABC	TV	20521	PHASE 1: CYCLE 2 DAY 5	26	A	Trt A		
ABC	TV	21521	PHASE 1: CYCLE 2 DAY 15	36	A	Trt A		
ABC	TV	30121	PHASE 1: CYCLE 3 DAY 1	43	A	Trt A		
ABC	TV	30521	PHASE 1: CYCLE 3 DAY 5	47	A	Trt A		
ABC	TV	31521	PHASE 1: CYCLE 3 DAY 15	57	A	Trt A		
ABC	TV		...		A	Trt A		
ABC	TV	900004	ASSESSMENT WEEK 4	28	A	Trt A		
ABC	TV	900008	ASSESSMENT WEEK 8	56	A	Trt A		
ABC	TV	990000	PHASE 1 TREATMENT DISCONTINUATION		A	Trt A		
ABC	TV		...		A	Trt A		
ABC	TV	10000	SCREENING	-28	B	Trt B		
ABC	TV	10100	PHASE 1: CYCLE 1 DAY 1	1	B	Trt B		
ABC	TV	11500	PHASE 1: CYCLE 1 DAY 15	15	B	Trt B		
ABC	TV	20128	PHASE 1: CYCLE 2 DAY 1 (28)	29	B	Trt B		
ABC	TV	21528	PHASE 1: CYCLE 2 DAY 15 (28)	43	B	Trt B		
ABC	TV	30128	PHASE 1: CYCLE 3 DAY 1 (28)	57	B	Trt B		
ABC	TV	31528	PHASE 1: CYCLE 3 DAY 15 (28)	71	B	Trt B		
ABC	TV		...		B	Trt B		
ABC	TV	900004	ASSESSMENT WEEK 4	28	B	Trt B		
ABC	TV	900008	ASSESSMENT WEEK 8	56	B	Trt B		
ABC	TV	990000	PHASE 1 TREATMENT DISCONTINUATION		B	Trt B		
ABC	TV		...		B	Trt B		

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