

Abstract

The COVID-19 pandemic caused changes in visit schedules; many missed visits; in some cases, remote visits happened rather than clinic visits; and contingent visit cases arose. It has created chaos in presenting the visit data in Subject Visits (SV domain) but opened doors for the new visit standards such as custom domain Visit Events (VE). So, there was a need to standardize how various visits are numbered and can be displayed chronologically in the SDTM (Study Data Tabulation Model) domains. This paper proposes a method for standardizing and restructuring visit numbers for various visit types such as pre-screening, contingent, planned, unplanned, and follow-up visits, among others, which is entirely novel to the current approach. The real-time challenges of handling the mentioned visits from vendors' data and the possible solutions will also be discussed.

Why Visit number should be Standardized?

01

To enable the industry to maintain and adhere to the same consistent visit number standard.

02

To represent all types of visits chronologically.

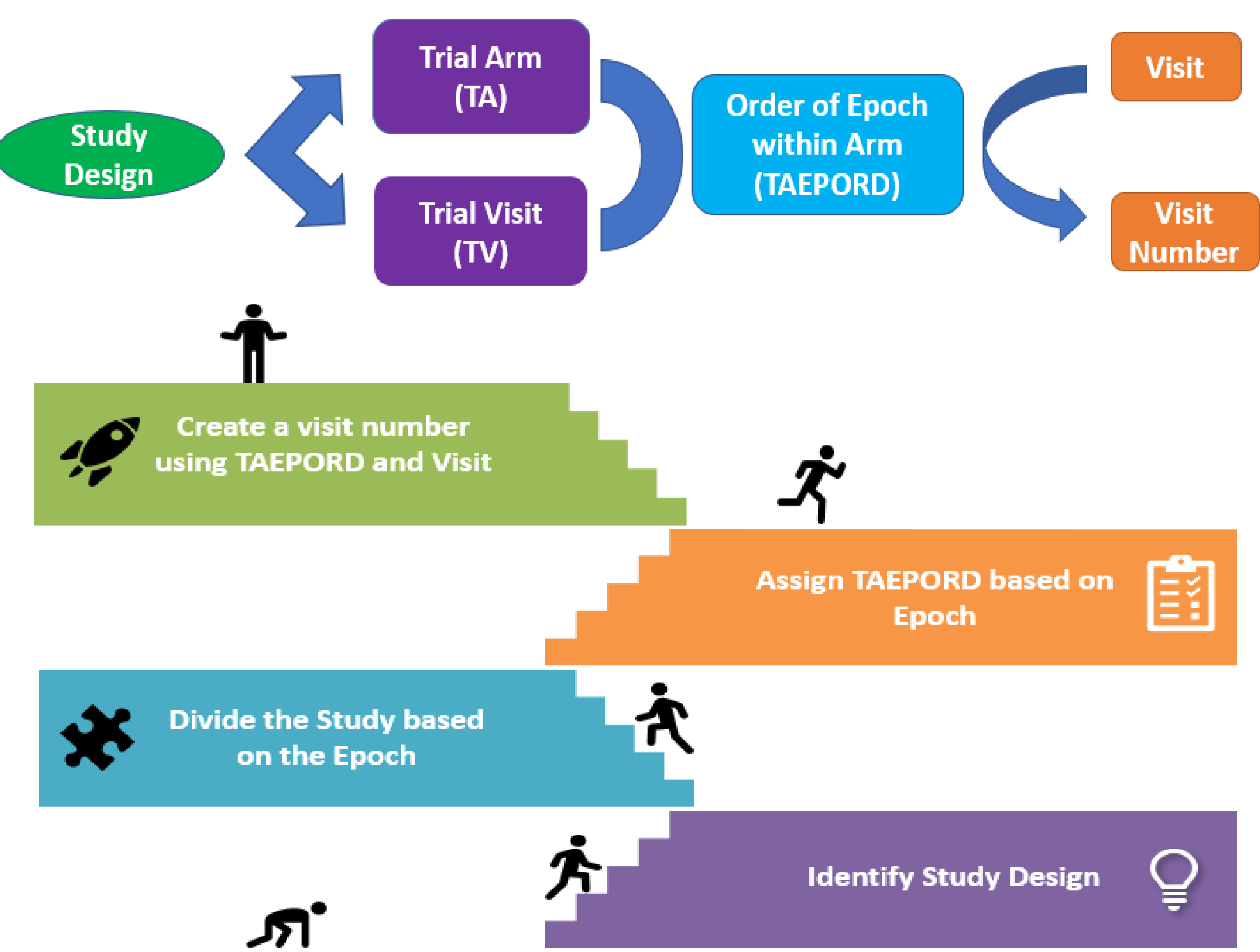
03

To cover all types of visits with a single strategy.

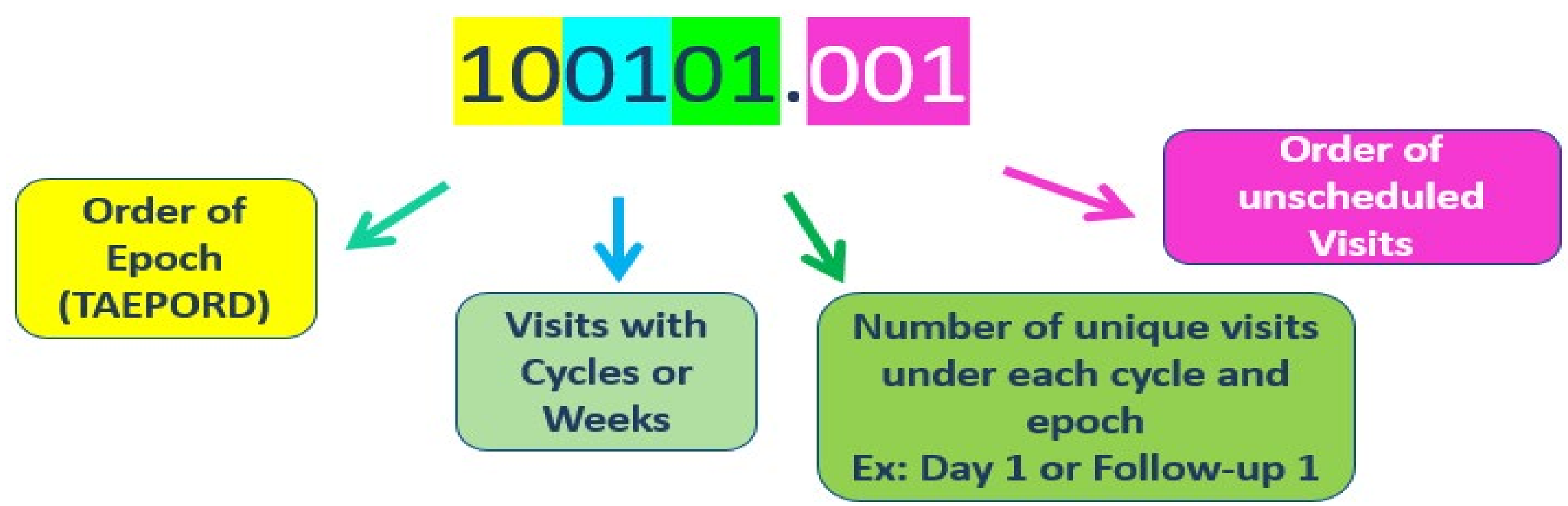
04

To determine the type of visit based on the visit number.

How Visit number can be Standardized?



Visit Number Format



Parallel Design Study Schema

TAEPOD						
10	20				30	
SCREENING	TREATMENT				FOLLOW-UP	
Screening	Cycle 1 Day 1	Cycle 3 Day 1	Cycle 5 Day 1	EOT	Follow-Up 1	Follow-Up 2
100001	200101	200301	200501	209999	300001	300002

Trial Arms (TA)						Trial Visits (TV)			
DOMAIN	ARMCD	ARM	TAETORD	ETCD	EPOCH	TAEPOD	TAEPOD	VISITNUM	VISIT
TA	DRG	Drug	1	SCRN	Screening	10	10	100001	Screening
TA	DRG	Drug	2	DRUG	Treatment	20	20	200101	Cycle 1 Day 1
TA	DRG	Drug	3	FU	Follow Up	30	20	200201	Cycle 2 Day 1
TA	PLCB	Placebo	1	SCRN	Screening	10	20	200301	Cycle 3 Day 1
TA	PLCB	Placebo	2	PLCB	Treatment	20	30	300001	Follow-Up1
TA	PLCB	Placebo	3	FU	Follow Up	30	30	300002	Follow-Up2

Crossover Trial Study Schema

TAEPOD						
10	21		22		30	
SCREENING	TREATMENT		FOLLOW-UP			
Screening	Cycle 1 Day 1	Cycle 3 Day 1	Cycle 5 Day 1	Cycle 7 Day 1	Follow-Up 1	Follow-Up 2
100001	210101	210301	220501	220701	300001	300002

Multiple Branches Study Schema

TAEPOD						
10	21		22		30	
SCREENING	DOUBLE BLIND		TREATMENT		OPEN LABEL	
Screening	Week 1 Day 1	Week 2 Day 1	Week 3 Day 1	Week 4 Day 1	Follow-Up 1	Follow-Up 2
100001	210101	210201	220301	220401	300001	300002

TAEPOD						
10	20		31		32	
SCREENING	TREATMENT		SAFETY FOLLOWUP		SAFETY AND EFFICACY FOLLOWUP	
Screening	Day 1	Day 2	SAFETY AND EFFICACY FOLLOWUP 1	SAFETY AND EFFICACY FOLLOWUP 2	SAFETY FOLLOWUP 1	SAFETY FOLLOWUP 2
100001	200001	200002	310001	310002	--	--
Not Responding to Treatment	Screening	Day 1	Day 2	SAFETY AND EFFICACY FOLLOWUP 1	SAFETY AND EFFICACY FOLLOWUP 2	SAFETY FOLLOWUP 1
100001	200001	200002	--	--	320001	320002
Initially Responded to Treatment	Screening	Day 1	Day 2	SAFETY AND EFFICACY FOLLOWUP 1	SAFETY AND EFFICACY FOLLOWUP 2	SAFETY FOLLOWUP 1
100001	200001	200002	310001	310002	320001	320002

Pre-Screening Visit:

EPOCH	TAEPOD	VISIT	VISITNUM
PRE SCREENING	09	Pre-Screening	90000
PRE SCREENING	09	Pre-Screening Unscheduled 1	90000.001
SCREENING	10	Screening	100000

Unscheduled Visit:

EPOCH	TAEPOD	VISIT	VISITNUM
DOUBLE BLIND	20	Week 1 Day 1	200101
DOUBLE BLIND	20	Week 3 Day 1	200301
DOUBLE BLIND	20	Week 5 Day 1	200501
DOUBLE BLIND	20	Week 5 Day 1 Unscheduled 1	200501.001
DOUBLE BLIND	20	Week 5 Day 1 Unscheduled 2	200501.002
DOUBLE BLIND	20	Week 7 Day 1	200701
DOUBLE BLIND	20	End of Double Blind Treatment	209999

Contingent Visit:

EPOCH	TAEPOD	VISIT	VISITNUM
FOLLOWUP	30	FOLLOWUP 1	300001
FOLLOWUP	30	FOLLOWUP 2	300002
Contigent Visit 1	40	COVID Symptoms Day 1_1	400101
Contigent Visit 1	40	COVID Symptoms Day 1_2	400102
Contigent Visit 1	40	COVID Symptoms Day 3_1	400301
Contigent Visit 2	50	Skin Rash Visit 1	500001
Contigent Visit 2	50	Skin Rash Visit 2	500002
Contigent Visit 2	50	Skin Rash Visit 3	500003

Conclusion

Standardizing visit numbers based on the study design could reduce the complexity of presenting visit data and provide direction on how different visits can be numbered and displayed chronologically in the SDTM.

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References

1. <https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-2>