VISIT NUMBER OF UNSCHEDULED VISITS
-SV VS OTHER DOMAIN-

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AGENDA

- What is VISIT/VISITNUM?
- VISIT/VISITNUM numbering method
- Unscheduled in SV numbering
- Cause for concern
- Various ideas
- Summary

WHAT IS VISIT/VISITNUM?

- How is VISIT/VISITNUM defined?

> Quote SDTM v1.2/v1.3 :
> 2.2.9. THE SUBJECT VISITS TABLE

VISIT :

Protocol-defined description of clinical encounter or description of unplanned visit. May be used in addition to VISITNUM and/or VISITDY as a text description of the clinical encounter.

WHAT IS VISIT/VISITNUM?

○ How is VISIT/VISITNUM defined?

> Quote SDTM v1.2/v1.3 :
> 2.2.9. THE SUBJECT VISITS TABLE

VISITNUM

Clinical encounter number. (Decimal numbering may be useful for inserting unplanned visits.)
Numeric version of VISIT, used for sorting.

WHAT IS VISIT/VISITNUM?

> Quote SDTMIG v3.1.2/v3.1.3 : CDISC Notes

VISIT :

1.Protocol-defined description of clinical encounter.

2. May be used in addition to VISITNUM and/or VISITDY.

VISITNUM

1. Clinical encounter number.

2. Numeric version of VISIT, used for sorting.

Other descriptions...

> Quote SDTM IG v3.1.2/v3.1.3 : 4.1.4.5

Values of VISITNUM are used for sorting and should, wherever possible, match the planned chronological order of visits.

WHAT IS VISIT/VISITNUM?

Other descriptions...

> Quote SDTM IG v3.1.2/v3.1.3 : 4.1.4.5

Occasionally, a protocol will define a planned visit whose timing is unpredictable (e.g., one planned in response to an adverse event, a threshold test value, or a disease event), and completely chronological values of VISITNUM may not be possible in such a case.

WHAT IS VISIT/VISITNUM?

Other descriptions…

Quote SDTM IG v3.1.2/v3.1.3 : 4.1.4.5

There should be a one-to-one relationship between values of VISIT and VISITNUM.

VISIT/VISITNUM NUMBERING METHOD

And more …

> Quote SDTM IG v3.1.2/v3.1.3 : 4.1.4.5

VISITNUM should generally be populated, even for unplanned visits, as it is expected in many Findings domains, as described above.

VISIT/VISITNUM NUMBERING METHOD

And more …

Quote SDTM IG v3.1.2/v3.1.3 : 4.1.4.5

The easiest method of populating VISITNUM for unplanned visits is to assign the same value (e.g., 99) to all unplanned visits, but this method provides no differentiation between the unplanned visits and does not provide chronological sorting.

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VISIT/VISITNUM NUMBERING METHOD

And more …

> Quote SDTM IG v3.1.2/v3.1.3 : 4.1.4.5

Methods that provide a one-to-one relationship between visits and values of VISITNUM, that are consistent across domains, and that assign VISITNUM values that sort chronologically require more work and must be applied after all of a subject's unplanned visits are known.

VISIT/VISITNUM NUMBERING METHOD

Quote SDTM IG v3.1.2/v3.1.3 : 4.1.4.5

USBJID	VISIT	VISITNUM	VISITDY	LBDY
001	Week1	2	7	7
001	Week2	3	14	13
001	Week2 Unscheduled	3.1		17

VISITDY becomes Null because unscheduled Visit is not defined by Planned Visit.

Unscheduled Visit is set with the decimal point as a value during not a value uniform 99 but planned visit according to the description of SDTM1.3.

Other descriptions…

Quote FDA:UCM312964
Study Data Specifications Version 2.0
:2.5 General Considerations for all Datasets

- For unscheduled visits or measurements, numbers are often assigned values between two protocol-scheduled visits. These numbers should be distinct from other visit numbers but retain the chronological order (e.g. two unscheduled visits between visit 3 and visit 4 might be 3.1 and 3.2). The character form of the visit identifier may be UNSCHEDULED or a similar term.

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VISIT/VISITNUM NUMBERING METHOD

In fact …

USBJID	VISIT	VISITNUM	VISITDY	LBDY
001	Week1	2	7	7
001	Week2	3	14	13
001	Unscheduled 3.1	3.1		17
001	Unscheduled 3.2	3.2		18
001	Week3	4	21	20

Now, it is main issue

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UNSCHEDULED IN SV NUMBERING

In fact, VISIT exists independently in each domain. When the test etc. are not done by planned VISIT, Unscheduled VISIT is generated in every case.

VS
V1:2013/01/11
U:2013/01/13
V2:2013/01/18

LB
V1:2013/01/11
U:2013/01/12
V2:2013/01/18

EG
V1:2013/01/11
U:2013/01/14
V2:2013/01/18

Planned Visit V1 and V2 are the same days.
But unscheduled VISIT takes a different date in each domain.

UNSCHEDULED IN SV NUMBERING

- As for VISITNUM, Unscheduled VISITNUM of each domain is set according to the above-mentioned rule.

DOMAIN	VSDTC	VISIT	VISITNUM
VS	2013-01-11	VISIT 1	1
VS	2013-01-13	Unscheduled 1.1	1.1
VS	2013-01-18	VISIT 2	2

DOMAIN	VSDTC	VISIT	VISITNUM
LB	2013-01-11	VISIT 1	1
LB	2013-01-12	Unscheduled 1.1	1.1
LB	2013-01-18	VISIT 2	2

DOMAIN	VSDTC	VISIT	VISITNUM
EG	2013-01-11	VISIT 1	1
EG	2013-01-14	Unscheduled 1.1	1.1
EG	2013-01-18	VISIT 2	2

UNSCHEDULED IN SV NUMBERING

- Now, there is a domain named SV(Subject Visit) in Special-Purpose domain of SDTM.

- This domain collects and integrates each subject Visit, and shows the outline.

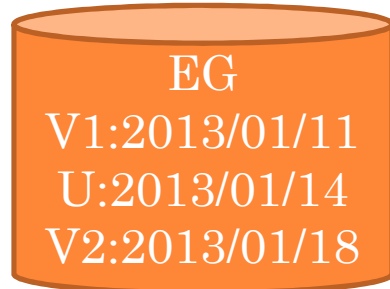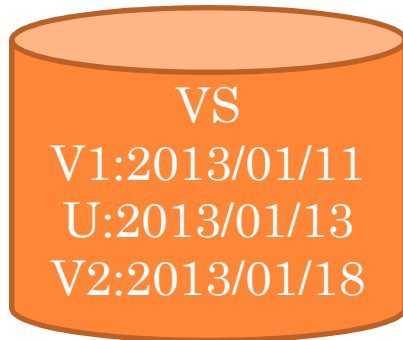- The rule of current Visit is applied to collected Visit.
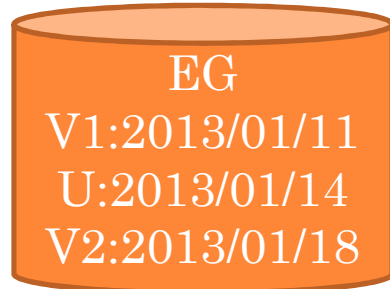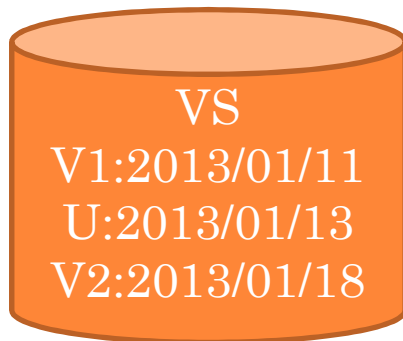
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UNSCHEDULED IN SV NUMBERING

VS
V1:2013/01/11
U:2013/01/13
V2:2013/01/18

LB
V1:2013/01/11
U:2013/01/12
V2:2013/01/18

EG
V1:2013/01/11
U:2013/01/14
V2:2013/01/18

SVSTDTC	VISIT	VISITNUM
2013/01/11	Visit 1	1
2013/01/12	Unscheduled 1.1	1.1
2013/01/13	Unscheduled 1.1	1.1
2013/01/14	Unscheduled 1.1	1.1
2013/01/18	Visit 2	2

If it integrates it into SV , <u>different VISIT/VISITNUM comes to Unscheduled Visit at the same date</u>. Therefore, it is necessary to set VISIT/VISITNUM again in SV.

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UNSCHEDULED IN SV NUMBERING

VS
V1:2013/01/11
U:2013/01/13
V2:2013/01/18

LB
V1:2013/01/11
U:2013/01/12
V2:2013/01/18

EG
V1:2013/01/11
U:2013/01/14
V2:2013/01/18

SVSTDTC	VISIT	VISITNUM
2013/01/11	Visit 1	1
2013/01/12	Unscheduled 1.1	1.1
2013/01/13	Unscheduled 1.2	1.2
2013/01/14	Unscheduled 1.3	1.3
2013/01/18	Visit 2	2

If it integrates it into SV , <u>different VISIT/VISITNUM comes to Unscheduled Visit at the same date</u>. Therefore, it is necessary to set VISIT/VISITNUM again in SV.

That is,

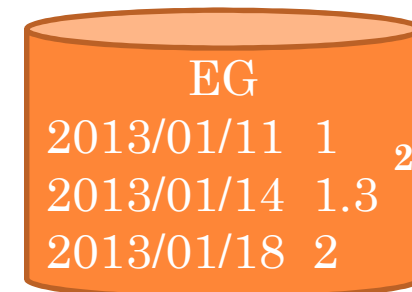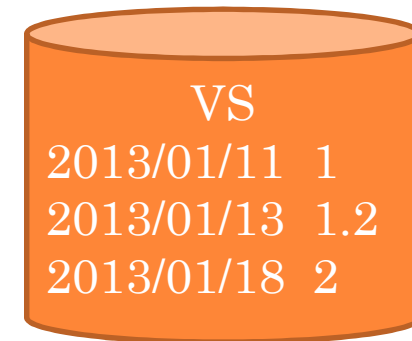Unscheduled VISIT/VISITNUM will take a different value by SV and other domains.

How should we do?

UNSCHEDULED IN SV NUMBERING

Case1:

VISIT/VISITNUM of SV is returned.
Each domain create > SV > Each domain

SVSTDTC	VISIT	VISITNUM
2013/01/11	Visit 1	1
2013/01/12	Unscheduled 1.1	1.1
2013/01/13	Unscheduled 1.2	1.2
2013/01/14	Unscheduled 1.3	1.3
2013/01/18	Visit 2	2

VS
2013/01/11 1
2013/01/13 1.2
2013/01/18 2

LB
2013/01/11 1
2013/01/12 1.1
2013/01/18 2

EG
2013/01/11 1
2013/01/14 1.3
2013/01/18 2

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UNSCHEDULED IN SV NUMBERING

Case2:

VISIT/VISITNUM of SV is not returned.
As for unscheduled VISIT/VISITNUM, an independent value is set by all domains.

SVSTDTC	VISIT	VISITNUM
2013/01/11	Visit 1	1
2013/01/12	Unscheduled 1.1	1.1
2013/01/13	Unscheduled 1.2	1.2
2013/01/14	Unscheduled 1.3	1.3
2013/01/18	Visit 2	2

VS
2013/01/11 1
2013/01/13 1.1
2013/01/18 2

LB
2013/01/11 1
2013/01/12 1.1
2013/01/18 2

EG
2013/01/11 1
2013/01/14 1.1
2013/01/18 2

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CAUSE FOR CONCERN

Case1:

・VISIT/VISITNUM has sequentiality in SV, but It doesn't have sequentiality in each domain. however , unique is kept.

・It is unquestionable for sorting in the domain because it is sorted chronological in SV

・When Visit of each domain is displayed when reviewing, it is likely not to see easily.

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CAUSE FOR CONCERN

Case1:

・Visit is not decided until study end.

・Therefore, It takes time to confirm that SDTM is made while examining it.

・ It is considerably require great care to reflect it from SV in each domain.

・ Should I do there?

CAUSE FOR CONCERN

Case2:

VISIT/VISITNUM is not consistent between each domain and SV.

・ Confusion might happen with SV at the review that brings other domains together.

・But when domain is united and used because it uses the date ,confusion doesn't occur.

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Various ideas

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SV：各ドメインから集めたUnscheduledを、日付順にソートしてVISITNUMをふる

もとのドメイン：ドメインごとに日付順にソートしてVISINUMをふっていました。

Case2

OncologyなどUnscheduled visitを正規visitとほぼ同等に扱う試験でない限り、集計にはUnscheduled visitを使用しないので（=一覧表に出てきますが）、SVと他のドメインでVISIT/VISITNUMが一致しなくても問題ないと思います。

SDTMIGに記載のあるVISITNUM = 99で 一律VISITをUnscheduledにすると、"Duplicated key"となってしまうので、FDAは受け入れない。とglobalのstandardsの人に言われました。

VARIOUS IDEAS

・VISITNUMはSortingのためだけに存在すると考えるなら、ドメイン間の整合性を持たないで処理しても問題ない。

・VISITNUMはドメイン間のデータ連結のために存在すると考えるなら、整合性があったほうが良い。

・そもそもVISITNUMがデータ集計に必要ないなら、全部99でも大丈夫。（例えば、InterimデータでSDTMを作成する場合、VISITNUMを正確につける意味があるのか。とか・・・…）

VARIOUS IDEAS

・基本的にOpenCDISCの「Warning」をどう考えるか（例：気にする or しない）という方針。

・SV以外で連番がバラバラになるのは仕方がない。それにADaM作成の際には複数のSDTMのデータをそのまま引き継がなければならず、SDTMで揃えたところでADaMでまた崩れるから、同一Domain内で綺麗に連番（1.1, 1.2, 1.3…）になることを気にするのは意味がない。

SUMMARY

○ A big problem doesn't occur because it has or has not the correspondence with SV and other domain.

○ Case 1 and Case 2 which is better?

○ I think , there is no correct answer.

○ Decide based on business requirements

○ How does everybody think?

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REFERENCE

- SDTM v1.3 and SDTM IG v3.1.3

http://www.cdisc.org/sdtm

- FDA Study data Specification

http://www.fda.gov/forindustry/datastandards/study
datastandards/default.htm

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