VISIT NUMBER OF UNSCHEDULED VISITS

-SV vs Other Domain-
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?**

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

**VISITNUM**
1. Clinical encounter number.
2. Numeric version of VISIT, *used for sorting.*
WHAT IS VISIT/VISITNUM?

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…

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.

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

<table>
<thead>
<tr>
<th>USBJID</th>
<th>VISIT</th>
<th>VISITNUM</th>
<th>VISITDY</th>
<th>LBDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>Week1</td>
<td>2</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>001</td>
<td>Week2</td>
<td>3</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>001</td>
<td>Week2 Unscheduled</td>
<td>3.1</td>
<td>Null</td>
<td>17</td>
</tr>
</tbody>
</table>

**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.
VISIT/VISITNUM NUMBERING METHOD

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.
**VISIT/VISITNUM NUMBERING METHOD**

In fact …

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<td>3</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>001</td>
<td>Unscheduled 3.1</td>
<td>3.1</td>
<td></td>
<td>17</td>
</tr>
<tr>
<td>001</td>
<td>Unscheduled 3.2</td>
<td>3.2</td>
<td></td>
<td>18</td>
</tr>
<tr>
<td>001</td>
<td>Week3</td>
<td>4</td>
<td>21</td>
<td>20</td>
</tr>
</tbody>
</table>
Now, it is main issue
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.

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.

<table>
<thead>
<tr>
<th>DOMAIN</th>
<th>VSDTC</th>
<th>VISIT</th>
<th>VISITNUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>VS</td>
<td>2013-01-11</td>
<td>VISIT 1</td>
<td>1</td>
</tr>
<tr>
<td>VS</td>
<td>2013-01-13</td>
<td>Unscheduled 1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>VS</td>
<td>2013-01-18</td>
<td>VISIT 2</td>
<td>2</td>
</tr>
</tbody>
</table>

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<th>VISITNUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>LB</td>
<td>2013-01-11</td>
<td>VISIT 1</td>
<td>1</td>
</tr>
<tr>
<td>LB</td>
<td>2013-01-12</td>
<td>Unscheduled 1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>LB</td>
<td>2013-01-18</td>
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<tr>
<td>EG</td>
<td>2013-01-14</td>
<td>Unscheduled 1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>EG</td>
<td>2013-01-18</td>
<td>VISIT 2</td>
<td>2</td>
</tr>
</tbody>
</table>
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.
If it integrates it into SV, different VISIT/VISITNUM comes to Unscheduled Visit at the same date. Therefore, it is necessary to set VISIT/VISITNUM again in SV.
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That is,

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

How should we do?
**UNSCHEDULED IN SV NUMBERING**

**Case 1:**
VISIT/VISITNUM of SV is returned.
Each domain create \( \geq \) SV \( \geq \) Each domain

<table>
<thead>
<tr>
<th>SVSTDTC</th>
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<th>VISITNUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013/01/11</td>
<td>Visit 1</td>
<td>1</td>
</tr>
<tr>
<td>2013/01/12</td>
<td>Unscheduled 1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>2013/01/13</td>
<td>Unscheduled 1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>2013/01/14</td>
<td>Unscheduled 1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>2013/01/18</td>
<td>Visit 2</td>
<td>2</td>
</tr>
</tbody>
</table>
**UN_SCHEDULED IN SV NUMBERING**

**Case2:**
VISIT/VISITNUM of SV is **not** returned.
As for unscheduled VISIT/VISITNUM, an independent value is set by all domains.

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<tr>
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<td>1.1</td>
</tr>
<tr>
<td>2013/01/13</td>
<td>Unscheduled 1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>2013/01/14</td>
<td>Unscheduled 1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>2013/01/18</td>
<td>Visit 2</td>
<td>2</td>
</tr>
</tbody>
</table>
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.
 Cause for concern

Case 1:

• 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.
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?
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/studydatastandards/default.htm
Thank You!