ABSTRACT

When we do SDTM mapping, we may feel difficult to decide how to map those information which we don’t see frequently. Then we map them to a farfetched domain. However it’s not the best way to catch information when they can go to the specific domains separately. I will share my experience of how to handle the combined information form through one example. And we should be aware that understanding how the study collects the data is important for the mapping.

INTRODUCTION

SDTM provides a standard for organizing and formatting data to streamline processes in collection, management, analysis and reporting [1]. It’s a required standard that we must to follow. However as it has multiple grey areas that are open to interpretation based on study design and analysis intentions [2], we may map the information differently. For some specific case, though there is no absolute right or wrong, we still need to think about if we map them in a better way.

MY UNDERSTANDING OF SDTM

My understanding of SDTM is like a bookshelf to category the data and put them into the different cells. Each cell is like a section of the story. We use these sections to compose a complete story and tell about the clinical trial to FDA. For instance we tell about Demographics in the DM domain, Adverse Event in the AE domain and concomitant medication in the CM domain, etc.. All domains compose the clinical trial and convey the study information. When we hear the story, we always wish the story is constituted by some logical elements rather than chaos. That is to say we don’t wish to see the AE domain contains demographic information or CM domain contains medical history information. So when we do the mapping, good category helps to tell a good story.

BACKGROUND

As other big pharmaceutic companies, we have our data standard office (DSO). For all mapping questions, the data standard office will make decision. When we follow the DSO’s guidance to do in-house studies, the mapping is straightforward. However when we support the out-source studies and see the difference, the work becomes challenge and make us think better.

EXAMPLE

There is an example in one of my studies. In the survival follow-up visit, the eCRF collected survival information, the tumor status, the treatment status and AE, SAE related questions. Our vendor mapped the whole form to the SC domain. It’s simple to map the information to one domain as the eCRF contains too much information. However when we think about these information, we will know they don’t belong to one category and there are more questions than the ones on the eCRF form.

Firstly we need to know:

1) Is this page only collected once?
2) If the patient is "Dead", there is no death date on the page - is this information collected elsewhere?
3) If the items 4, 5, 6 are ticked YES, is the additional information collected on separate pages (e.g. Adverse Event and Concomitant medication).
To answer these questions, we must go through the eCRF pages and know about how the eCRF collects the data.

In this study, there are two pages of the survival follow-up forms. But each line in every page means a visit. If the patient is "Dead", there is another page collects the death information separately (as below indicated).

If items 4, 5, 6 are ticked YES, the additional information is also collected on separate pages (CM/ New Lesion Treatment form and AE form as below).

So based on the information we got, we can decide the first two questions (the survival follow-up date and the survival status) should be mapped to SS (Subject Status) domain (If this page is only collected once, we may consider to map it to DS domain.).

Items 4, 5, 6 won't be mapped since further information will be captured on the separate pages, where the information will be mapped.
For the tumor status, more questions related to the patient’s response needed to be considered, e.g. is it an OVERALL RESPONSE or BEST RESPONSE or is it an EVALUATION OF LESIONS (e.g. TARGET/ NON TARGET / NEW LESION)?

In this study, we have already had the other eCRF forms to collect the Tumor Assessment for TARGET, NON-TARGET, NEW Lesion and OVERALL RESPONSE. If each lesion has already collected the OVERALL RESPONSE and is mapped to the RS domain, we need to map this question to FA domain. Otherwise we need to think about why we collect the “Tumor Status” on the Survival Follow-up Form? After clarifying with the Data Manager, we know the “Tumor Status” is an OVERALL RESPONSE and the same other OVERALL RESPONSE in the treatment cycles. So the data finally goes to RS (Response) domain.

#### 肿瘤评估  
**Tumor Assessment**

<table>
<thead>
<tr>
<th>肿瘤评估（靶病灶）</th>
<th>Target Lesion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>器官编码</strong></td>
<td><strong>部位描述</strong></td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
</tbody>
</table>

#### 肿瘤评估（非靶病灶）  
**Non-Target Lesion**

<table>
<thead>
<tr>
<th>肿瘤评估（非靶病灶）</th>
<th>Non-Target Lesion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>器官编码</strong></td>
<td><strong>部位描述</strong></td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
</tbody>
</table>

#### 肿瘤新病灶  
**New Lesion**

自上次评估以来，是否发现新病灶？是 □ 1 否 □ 0

*如是，请提供病灶发现日期：年/月/日*

病灶部位：
1. ___________________  2. ___________________
3. ___________________  4. ___________________

（请提供编码）
CONCLUSION

When we have different ways to map the data, the better way is classification and putting the same kind of information together. If the information repeats, we don’t need to map them again. However if they are not the duplicated information and belong to some theme, we should put them into the same topic. Therefore understanding how the study collects the data is important for the mapping.

ACKNOWLEDGMENTS

I would like to acknowledge our DSO and SDM, without whom, I would not be here.

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[2] Susan H.M. Boquist, PAREXEL, Billerica, MA Adam J. Sicard, PAREXEL, Durham, NC. “It is a standard, so it is simple, right?”: Misconceptions and Organizational Challenges of Implementing CDISC at a CRO. PharmaSUG 2016 - Paper DS06. Available at http://www.lexjansen.com/pharmasug/2016/DS/PharmaSUG-2016-DS06.pdf

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