## IMPLEMENTATION OF ONCOLOGY SPECIFIC SDTM DOMAINS

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### ABSTRACT

Information regarding tumor lesions and disease response is key in oncology clinical trials to evaluate the primary or secondary endpoint. It’s usually collected by two independent radiologists. Specific oncology domains described in Study Data Tabulation Model Implementation Guide (SDTMIG) 3.2 and SDTMIG V3.2 implement the collection of tumor measures and the evaluation of responsible identification information of the lesion. The SDTMIG describes a process to collect and organize tumor lesion information. This process includes the identification of tumor lesions, the assessment of tumor lesions, and the disease response evaluation.

### ONCOLOGY SPECIFIC SDTM DOMAINS

Each of the figures in this paper is an illustration of data coming from one patient. In order to simplify the figures and make them easier to understand, each was designed to include all variables, which is why the variables are not named. The purpose of the figures is to demonstrate a way of implementing what is described in SDTMIG 3.2.

#### TU DOMAIN

#### GENERAL INFORMATION

**TU** is the Tu Domain. For example, the clinical trial study team can decide that if two or more measurable lesions are split up or merged, and new lesions is captured in the tumor results domain (TR).

**TUMIDENT**

Identification information of the lesion is collected in the Tu domain. Each identified tumor lesion is repeatedly measured or assessed at subsequent time points.

#### NEW: SPLIT AND MERGED LESIONS

**TUMOR RESPONSE**

The anatomic location characterizes the Tu domain. Additional anatomical location qualifies (FATI, TURI, TURM) might also be used in the database and are shown on Figure 6.

**TUMOR RESPONSE CD**

Each record in Tu corresponds to the identification of tle lesion (the example: TURRIDS = TUMRIDS).

**TUMOR RESPONSE**

The result of the identification corresponding to the identification of the identified tumor.

**TUMOR RESPONSE**

The date on which the imaging/physical exam was done. Remark: TUDTC is not a time variable.

### NEW LESIONS

**TUMOR RESPONSE**

New lesions represent progressive disease and the identification information is collected in the Tu domain at the visit where the lesion was diagnosed.

**New lesion**

Is split or merged lesion? A tumor lesion which was identified at baseline, might split into one or more distinct tumor lesions during the clinical trial or join or lose some distinct lesion. This information can be captured in either the Tu or the Tr domain. The follow up of each of these lesions can be captured individually.

### RESULTS OF THE INVESTIGATOR AND INDEPENDENT ASSESSORS

**Measurement 1**

In Figure 7, this consists of an indication of the assessor and an identification number of the tumor lesion. If two or more lesion identifications are included on one page, a unique identifier can be assigned in the Tu domain.

**Measurement 2**

In Figure 8, the Tu lesion was measured in 2 perpendicular dimensions. In Figure 9, the Tu lesion 2-dimensional measurement is reflected in TURRIDS and TURRIDS for the accessible tumor lesion TURRIDS. For the Tu lesion TURRIDS, this value is assigned in the Tu domain. This information is updated at subsequent time points. The follow up of each of these lesions, lesion that are split or merged, and new lesions is captured in the Tu domain.

**RESULTS OF THE INVESTIGATOR AND INDEPENDENT ASSESSORS**

In this example Cheson criteria 2007 has been used.

### CONCLUSION

With the increase of clinical trials in oncology and the accumulated collection of complete data, new domains have been developed using CDISC to select the information about tumors in a more structured and standardized way. These ‘Tumor Response’ tables and the ‘Tumor Response Additional’ tables will be completed in order to set up clinical databases consistently and with a high standard of quality.

### REFERENCES

1. Study Data Tabulation Model Implementation Guide: Oncologic Clinical Trials, Volume 2, 2, CDISC Submission Data Standards Team (November 26, 2013)
2. Study Data Tabulation Model, Version 1.4, CDISC Submission Data Standards Team (November 26, 2013)
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### CONTACT INFORMATION

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