**Abstract**

Project: Demonstrating proof-of-concept for the decision-making process by modeling different nonclinical endpoints to custom SDTM findings domains.

The PHUSE Nonclinical Roadmap Group developed a resource that transforms nonclinical data that is not currently modeled in SEND into an SDTM Custom Domain. In this poster, the group demonstrates how the Custom Domain Resource was used to model Micronucleus, Ocular Irritation, and Motor Activity data. The goal was to demonstrate how three different types of nonclinical data can be modeled in SDTM using a streamlined decision-making process.

**Approach**

The Study Data Tabulation model (SDTM) is currently only applicable for collected subject or pool-based data, so the data that we are attempting to model will be subject to this restriction. Endpoints in a nonclinical study may consist of several examinations, each of which has its own result. Each result may constitute its own data type, like numerical or descriptive data. Within each of the selected endpoints for modeling, each result (or data) type must be processed through the decision tree to be appropriately represented by the resulting domain structure.

In the Motor Activity study [data courtesy of PDS], we identified one result type:

- Number of crossed photocell per axis, where the data type is an integer.

In the Micronucleus study [1], we identified two result types:

1. Number of micronucleated erythrocytes per 2000 polychromatic erythrocytes (PCE) examined per animal, where the data type is an integer.
2. Ratio of polychromatic erythrocytes (PCE) to mononuclear erythrocytes (MNE) determined in at least 500 erythrocytes per animal, where the data type is float.

In the Ocular study [2], we identified two result types:

1. The Draize scale for scoring of ocular lesions, where the data type is an integer.
2. The derived weighted sum of all ocular scoring, where the data type is an integer.

**Summary**

The PHUSE Nonclinical Roadmap Group performed a validation of the workflow designed in the decision tree to identify potentially misleading areas within that workflow. The decision tree was used by individuals in the group to create custom SDTM domains for Motor Activity, Micronucleus, and Ocular Irritation data. The outcome was a custom-fitted SDTM domain table for each of the three nonclinical data types, all of which are presented on this poster. Individual experiences in creating these custom domains were discussed among the group, and subsequently, updates were made to the decision-tree to make it more intuitive to use. The decision-tree process presented on this poster has the confidence of the group that it will result in a custom-domain which conforms with the rules of SDTM. The Nonclinical Roadmap Group will gladly accept feedback from the PHUSE community about the execution of the decision tree on other nonclinical data types. A digital version of the three nonclinical custom domain examples can be accessed via the QR code or URL link.

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