SEND 3.1 FOCID Visualization and Validation

Tania Smith and Eli Miller; Covance Laboratories Inc., Madison, Wisconsin

Abstract

FOCID (Focus of Study-Specific Interest) in SEND 3.1 opens the door for more complex spatial, time series, and linked data analysis. Proper implementation of FOCID provides the ability to identify how a compound affects a specific focus area and can improve the ability to evaluate an investigative drug's safety. This poster investigates (1) the details of FOCID, (2) how FOCID can be used to facilitate visual analysis of SEND datasets and (3) methods of validating the use of FOCID. Visualization topics will include analyzing a compound's spatial effect, its effects over time on a focus area and cross-domain analysis. Validation topics include discussion on current published business, validation, and conformance rules. Understanding the intended use of FOCID and implementing strategies to take advantage of its presence will not only ensure usability of this new SEND feature, but also boost your ability to effectively trace effects across multiple data types.

Details of FOCID

When a study has a specific area of interest, such as an injection site, these findings are made in different areas of study oversight and often represented in different nomenclature based on the area where the datatype was captured. Often the terminology used has meaning to the responsible parties collecting or referencing the data. FOCID promotes and facilitates consistency for all records across general observation class domains pertaining to each focus area to be grouped together via a single variable, allowing a data reviewer to evaluate all findings with ease.

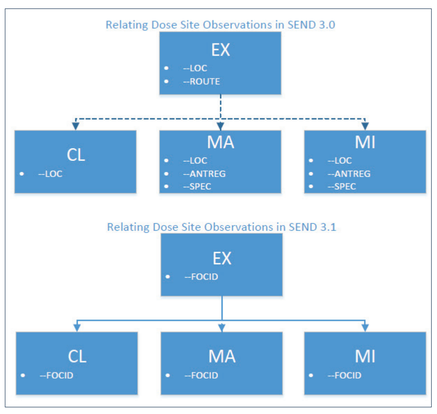

Figure 1. Mapping of findings across domains in SEND 3.0 (top) versus SEND 3.1 (bottom).

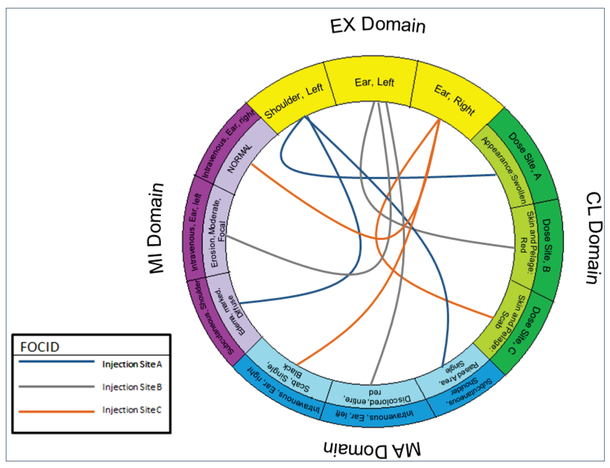

Figure 2. Relationships between findings in the EX, CL, MI and MA domains using FOCID.

Visualization Using FOCID

Certain visualizations between areas are less meaningful without a clarification based on what exactly is the focus on an observation. More complex study designs, specifically dermal studies, can be effectively visualized knowing the observations are specifically treatment-related. The visualizations here were made using ggplot2.

- **Site vs Site [Figure 3]**
  The visualization shows dose site analysis for a single subject. The sunburst chart shown demonstrates overall dose site clinical observations in the innermost circle, observations broken down by dose site in the second circle and observations broken down by dose site and result in the outermost circle. This offers a reviewer a snapshot of a treatments effect on multiple dose sites.
- **Site over Time [Figure 4]**
  This example is a histogram of the Clinical Observations of a single subject, colored based on the FOCID of the observation. The vertical line on days 1, 8 and 15 represent the different dose routes at each area.
- **Site vs Group [Figure 5]**
  This example is a comparison of the summary statistics across groups for a single dose site.

Validation of FOCID

FOCID does not have any controlled terminology requirement, nor do many of the variables that are correlated to it, such as location and anatomical region. There are no currently published business or validator rules for the use of this variable as well. Per the SENDIG v3.1 (p.53), "the value in this variable should have inherent semantic value." The validation of this variable should be focused on ensuring the same meaningful value is applied consistently per site of interest throughout the study data.

Possible methods for validating are:

1. **Validating context:** As there aren't many restrictions on FOCID in the SENDIG, most of the validation would fall to logical checks. Verifying the test/observation in consistent with the focus area is one potential check of data accuracy. Ensuring an optical exam isn't done to an intravenous injection site is an example of a possible check on context using FOCID.
2. **Validating consistency:** FOCID isn't necessarily a dose site however when it is a dose site FOCIDs should be present in the exposure domain. Verifying your FOCIDs are used in a context that is correct and helpful to a reviewer is an opportunity and a challenge for SEND 3.1.
3. **Validating presence:** This is similar to validating context. Depending on the study design, certain studies might require the use of FOCID.

Visualizations using FOCID would be able to catch many of these problems. Most of the checks above are logical checks that would be outliers in observations. Visualizations are a powerful tool to check the logical constancy of FOCID and the observations that use them.

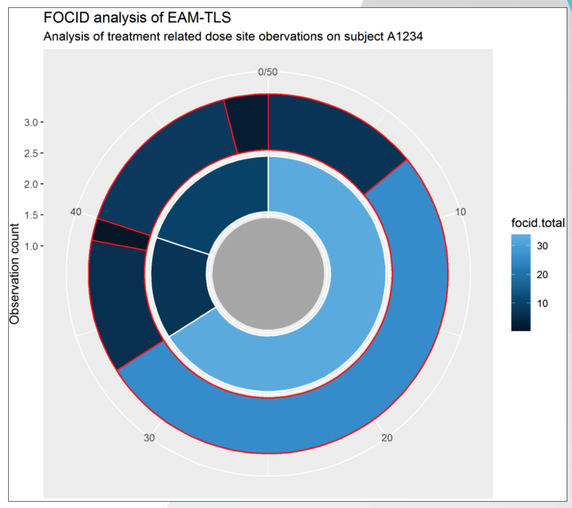

Figure 3. Site vs Site

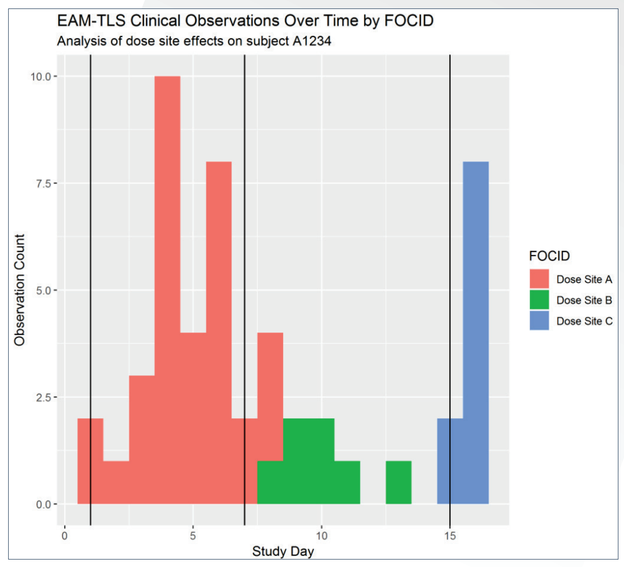

Figure 4. Site over Time

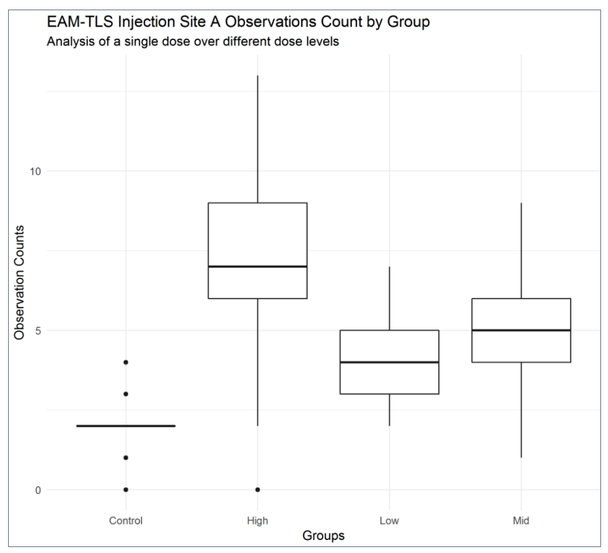

Figure 5. Site vs Group

Conclusion

For studies with multiple areas of focus, such as injection sites, previously a model using a singular element to tie together findings per focus across all domains did not exist. Each domain references each focus area in nomenclature with meaning for parties collecting or evaluating that specific data type. The FOCID variable from SENDIG v 3.1 gives the ability to easily perform cross domain analysis using visualization. Visualization with FOCID can be done in several ways including across groups, over time or multiple dose sites. The successful implementation of FOCID is dependent on consistent terms with semantic meaning.

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