A Doubly-programmed Analysis of the SEND 3.1 Proof of Concept
Latin Square Design Cardiovascular Safety Pharmacology Pilot Study

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ABSTRACT

The SEND Implementation Guide (IG) version 3.1 includes several new and updated domains for encoding non-clinical ECG, Vital Signs, Cardiovascular, and Respiratory telemetry data for exchange. In 2018, the CDISC-SEND Safety Pharmacology Working Group created a Proof of Concept pilot dataset for a sample Latin Square Design Cardiovascular Safety Pharmacology study. In collaboration with the CDISC-SEND Safety Pharmacology Working Group, the authors used the sample study data within the PhUSE Nonclinical Scripts Project to determine whether the information contained within the domain is sufficient for an analysis. This poster will present the authors’ findings along with helpful code snippets in both R and SAS for working with the new data standards.

### Timing Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>xxRFTDTC</td>
<td>Dose time, also use to obtain treatment from SE.XPT</td>
</tr>
<tr>
<td>xxCVELTM</td>
<td>Convert to numeric and use as main timing variable</td>
</tr>
<tr>
<td>xxNOMDY</td>
<td>May need to use in statistical model for Latin Squares</td>
</tr>
</tbody>
</table>

### Working with Telemetry Results Data in SEND 3.1 Format

**Join datasets for analysis**

```
# Findings domains of interest
DOIs <- c('cv','eg','vs')

# For each domain of interest, merge to add columns:
# SESTDTC and ELEMENT
for (domain in DOIs) {
  elementData <- Data%>%-c('USUBJID','SESTDTC','ELEMENT'))
  Data[[domain]] <- merge(Data[[domain]], elementData, by.x=c('USUBJID',paste0 toupper(domain), 'RFTDTC')), by.y=c('USUBJID','SESTDTC'))
}
```

**R Shiny Web Application**

The authors found that the SEND 3.1 model adequately captures the granularity of telemetry data necessary for analysis and appropriately models the relationships necessary to recreate the dosing model for a Latin Square study design. However, data architects who are modeling data in SEND 3.1 format must take extra care to ensure that the SESTDTC in SE exactly matches the corresponding xxRFTDTC entries in CV/EG/RE/VS to enable a necessary join.

**CONCLUSION**

PASS