

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 CDSIC-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

Variable	Notes
xxRFTDTC	Dose time, also use to obtain treatment from SE.XPT
xxCVELTM	Convert to numeric and use as main timing variable
xxNOMDY	May need to use in statistical model for Latin Squares

LOGIC

Joins

SE	CV/EG/RE/VS	DM
STUDYID	STUDYID	STUDYID
USUBJID	USUBJID	USUBJID
SESTDTC	xxRFTDTC	

Working with Telemetry Results Data in SEND 3.1 Format



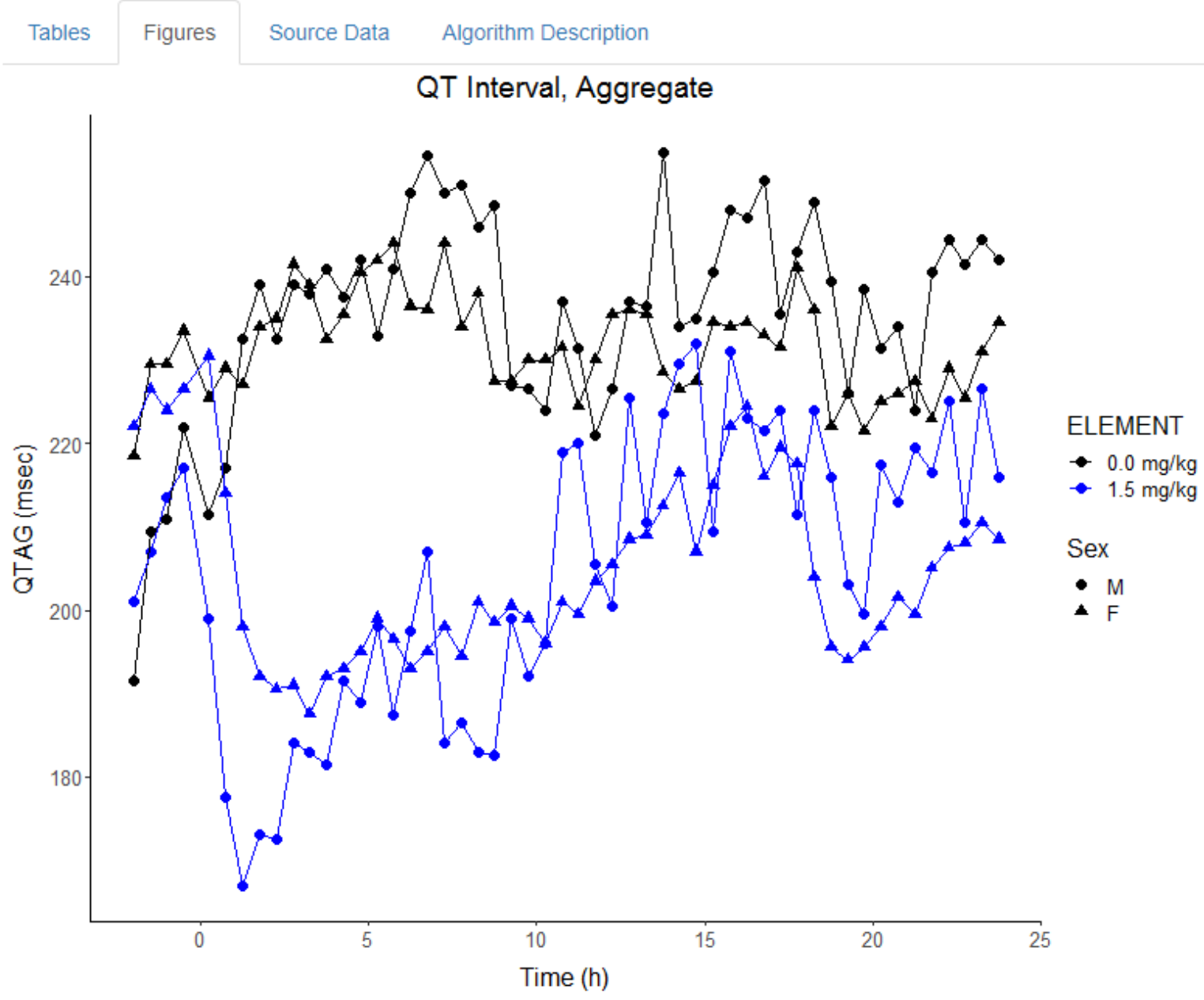
Join datasets for analysis

```
# 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$se[,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

CDISC-SEND Safety Pharmacology Proof-of-Concept Pilot



[Download the Code!](#)





Read CV

```
libname cv xport "&InDir.\cv.xpt";
data cv;
  FORMAT Period bin binstart binend TIME9.
          realtime DATETIME18. dosetime DATETIME20.;
  set cv.cv;

  * Input dosetime as number ;
  dosetime = input(cvrftdtc, B8601DT16.);

  * convert cveltm to a time period;
  call is8601_convert('du', 'du', cveltm, Period);
  if substr(strip(cveltm), 1, 1) = '-' then
    Period = 0 - Period; *manually make negative;

  * obtain real time by adding the period to the dosetime;
  realtime = INTNX('second', dosetime, Period);
run;
libname cv clear;
```

Join datasets for analysis

```
proc sql noprint;
  * assume DM and SE have been imported as WORK datasets;
  CREATE TABLE Temp_CV AS
  (
    SELECT cv.studyid, cv.period, cv.cvstresn AS value,
           cv.bin, cv.cvdY AS day, cv.realtime, cv.dosetime,
           cv.cvtptref AS doselabel, cv.cvnomlbl AS nomlabel,
           dm.sex, dm.subjid, se.etc
    FROM cv LEFT OUTER JOIN dm ON cv.USUBJID=dm.USUBJID
           AND cv.STUDYID=dm.STUDYID
           LEFT OUTER JOIN se ON cv.USUBJID=se.USUBJID AND
           cv.STUDYID=se.STUDYID AND cv.CVRFTDTC=se.SESTDTC
    ) ORDER BY studyid, sex, etc, subjid, realtime;
quit;
```

Use the Safety Pharm Pilot App!



CONCLUSION



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.