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During the drug development process, extensive patient safety data are collected through clinical trials. Additional safety data are obtained through post-marketing Adverse Event reporting. Exploring and providing pharmacovigilance assessments using such massive data sets is always a challenge. We have developed an interactive graphical visualization tool using S-PLUS to explore safety data (adverse events, vital signs, ECG, liver functions, and different laboratory tests). This tool allows us to link safety data to the population demographics in order to provide a flexible, quick, and effective means to detect and assess any potential safety signals and monitor any drug-related adverse reactions in a sub-population. This new screening capability is developed in-house using S-PLUS Graphlets, and Trellis graphics and provides a powerful web-browsing visualization interface for population and subject-level data screening and evaluation. These tools could easily be enhanced to aid in Exploratory Data Analysis (EDA) prior to model building. Extension of these features to goodness-of-fit plots and other diagnostic graphics generated to evaluate NONMEM models will be highly desirable. The new tool will enable detection of outlier patients and their attributes more readily, thus assisting the modeler in understanding various sources of variability.

ADVERSE EVENTS FOR SUBJECT 13780

Adverse Event	Start Day	End Day	Marker Day
SOMNOLENCE	7	13	14
SENSATION OF FOREIGN BODY	-2	-2	-2
HEADACHE	-4	-3	-3
HEADACHE	11	13	13
HEADACHE	19	19	19

```
graph TD; MM["Main Menu  
Choose Between Adverse Events, Laboratory Parameter, or ECG"] --> AE["Adverse Events"]; MM --> LP["Laboratory parameters"]; MM --> ECL["ECG Levels"]; AE --> SJS_AE["Sort by Subject"]; AE --> SAE_AE["Sort by AE"]; LP --> SJS_LP["Sort by Subject"]; LP --> SLP_LP["Sort by Parameter"]; ECL --> SJS_ECL["Sort by Subject"]; SJS_AE --> AAE_AE["All AE's  
for each subject"]; SAE_AE --> ASAE_AE["All subjects  
for each AE"]; SJS_LP --> AALP_LP["All Parameters  
for each Subject"]; SLP_LP --> ALSLP_LP["All Subjects  
for each Parameter"]; SJS_ECL --> AIE_ECL["All intervals  
for each subject"]; AAE_AE --> SJS_AE_S["Single Subject,  
Single Laboratory  
Parameter"]; ALSLP_LP --> SJS_AE_S; AIE_ECL --> SIE_ECL["Single Subject,  
Single Interval"];
```

The flowchart illustrates the menu structure for the study. It starts with a 'Main Menu' box, which branches into three categories: 'Adverse Events', 'Laboratory parameters', and 'ECG Levels'. Each category further branches into 'Sort by Subject' and 'Sort by [Category]' options. These options lead to 'All [Category]s for each subject' or 'All subjects/parameters/intervals for each [Category]'. Finally, these lead to 'Single Subject, Single Laboratory Parameter' or 'Single Subject, Single Interval' options.

```

graph TD
    AE[ADVERSE EVENTS] --- ECG[ECG]
    LP[LABORATORY PARAMETERS] --- ECG
    ECG --- SBY[Sort by SUBJECT]
    SBY --- SBA[Sort by ADVERSE EVENT]
    SBA --- CS[CHOOSE A SUBJECT]
    CS --- AEList[169357 12429 12778 13780 15560 18696 18703 19038 19402 19877 20134 20432  
20892 21154 21278 21638 22220 22557 23151 23794 23894 24082 24215 24693  
25794 26060 26156 26970 27019 27148 27860 28104 28684 28779 29583 30210  
30243 30335 30857 32348 32567 32997 33005 33119 33422 33569 34439 34726  
34788 34856 34932 34940 35012 35056 35132 35208 3703 37149 7347 7678]
  
```

ADVERSE EVENTS

LABORATORY PARAMETERS

ECG

Sort by SUBJECT

Sort by ADVERSE EVENT

CHOOSE A SUBJECT

See Adverse Events

169357 12429 12778 13780 15560 18696 18703 19038 19402 19877 20134 20432
20892 21154 21278 21638 22220 22557 23151 23794 23894 24082 24215 24693
25794 26060 26156 26970 27019 27148 27860 28104 28684 28779 29583 30210
30243 30335 30857 32348 32567 32997 33005 33119 33422 33569 34439 34726
34788 34856 34932 34940 35012 35056 35132 35208 3703 37149 7347 7678

Return to Sorting Page

ADVERSE EVENT

DAY

Return to List View Demographical Info

Legend:

- Cohort 1
- Cohort 2
- Cohort 3
- Cohort 4
- Cohort 5

Go	Out	Print	Fill	Options...	Help...
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Jump to Adverse Event

Demographical Information for Subject 10927

Sex: Female
 Race: White
 Age: 50
 Date of Birth: 11/11/1911
 Cohort: Cohort 4

[Change Subject](#)
[Return to Adverse Events](#)
[ECG Levels](#)
[Specific Chemical](#)
[ECG Levels](#)
[Specific Interval](#)

GASTROINTESTINAL DISORDERS NERVOUS SYSTEM DISORDERS GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS INFECTIONS AND INFESTATIONS INJURY, POISONING AND PROCEDURAL COMPLICATIONS RENAL AND URINARY DISORDERS SKIN AND SUBCUTANEOUS TISSUE DISORDERS VASCULAR DISORDERS CARDIAC DISORDERS EYE DISORDERS
--

[illegible]

NAUSEA

Start: 03/22/2005 18:00
 End: 03/23/2005 08:30
 Duration: 08:12h 30m 05s 08S

24082

23794

22220

10927

Return to List
 Jump to Demographical Info

DAY

Change Adverse Event

[illegible]

```
graph TD; A[ADVERSE EVENTS] --> B[LABORATORY PARAMETERS]; B --> C[ECG]; B --> D[SORT BY SUBJECT]; D --> E[SORT BY LAB PARAMETER]; E --> F[CHOOSE A LAB PARAMETER]; F --> G[See Laboratory Parameters]; F --> H[SODIUM POTASS CHLOR CREATIN URIC CALCIUM PHOS]; F --> I[TPROT ALBUM ALKPHOS BIL_TOT AST CK CHOL]; F --> J[TRIG ALT BIL_DIR GGT AMYLASE GLUCOSE UREA];
```

ADVERSE EVENTS

LABORATORY PARAMETERS

ECG

SORT BY SUBJECT

SORT BY LAB PARAMETER

CHOOSE A LAB PARAMETER [See Laboratory Parameters](#)

SODIUM POTASS CHLOR **CREATIN** URIC CALCIUM PHOS

TPROT ALBUM ALKPHOS BIL_TOT AST CK CHOL

TRIG ALT BIL_DIR GGT AMYLASE GLUCOSE UREA

CREATININE LEVELS VS. TIME
SUBJECT 18696

Change Subject
Change Lab

CREATININE (umol.)

DATE

View Demogra

Return to Subject 18696
Return to CREATININE

Change Lab Parameter

SODIUM
POTASSIUM
CHLORIDE
CREATININE
URIC ACID
CALCIUM
PHOSPHORUS, INORG.
TOTAL PROTEIN
ALBUMIN
ALKALINE PHOSPHATASE
BILIRUBIN TOTAL
ASPARTATE AMINO TRANSFERASE
CREATINE KINASE
CHOLESTEROL
TRIGLYCERIDES
ALANINE AMINO TRANSFERASE
BILIRUBIN DIRECT
G-GLUTAMYL TRANSFERASE
AMYLASE, SERUM
GLUCOSE
UREA

ADVERSE EVENTS

LABORATORY PARAMETERS

ECG

Return to List

ECG LEVELS FOR SUBJECT 18696

See QTC Interval for Subject 18696

Change Subject

View Demographical Information

The figure displays five stacked ECG waveforms for Subject 18696. The x-axis represents time in minutes, with markers at -4, 0, 4, 8, and 12. The y-axis represents voltage in millivolts (mV), with markers at 0.5, 1.0, 1.5, and 2.0. The waveforms are labeled as follows:

- PR INTERVAL:** Shows the PR interval, which is relatively stable around 1.5 mV until approximately 4 minutes, where it drops sharply to about 0.5 mV and remains low.
- QRS INTERVAL:** Shows the QRS complex, which is relatively stable around 1.5 mV until approximately 4 minutes, where it drops sharply to about 0.5 mV and remains low.
- QT INTERVAL:** Shows the QT interval, which is relatively stable around 1.5 mV until approximately 4 minutes, where it drops sharply to about 0.5 mV and remains low.
- QTc INTERVAL:** Shows the corrected QT interval, which is relatively stable around 1.5 mV until approximately 4 minutes, where it drops sharply to about 0.5 mV and remains low.
- HEART RATE:** Shows the heart rate, which is relatively stable around 1.5 mV until approximately 4 minutes, where it drops sharply to about 0.5 mV and remains low.

Visualizations for QTC Levels