Interactive Graphical Visualization Tool for Safety Data Screening

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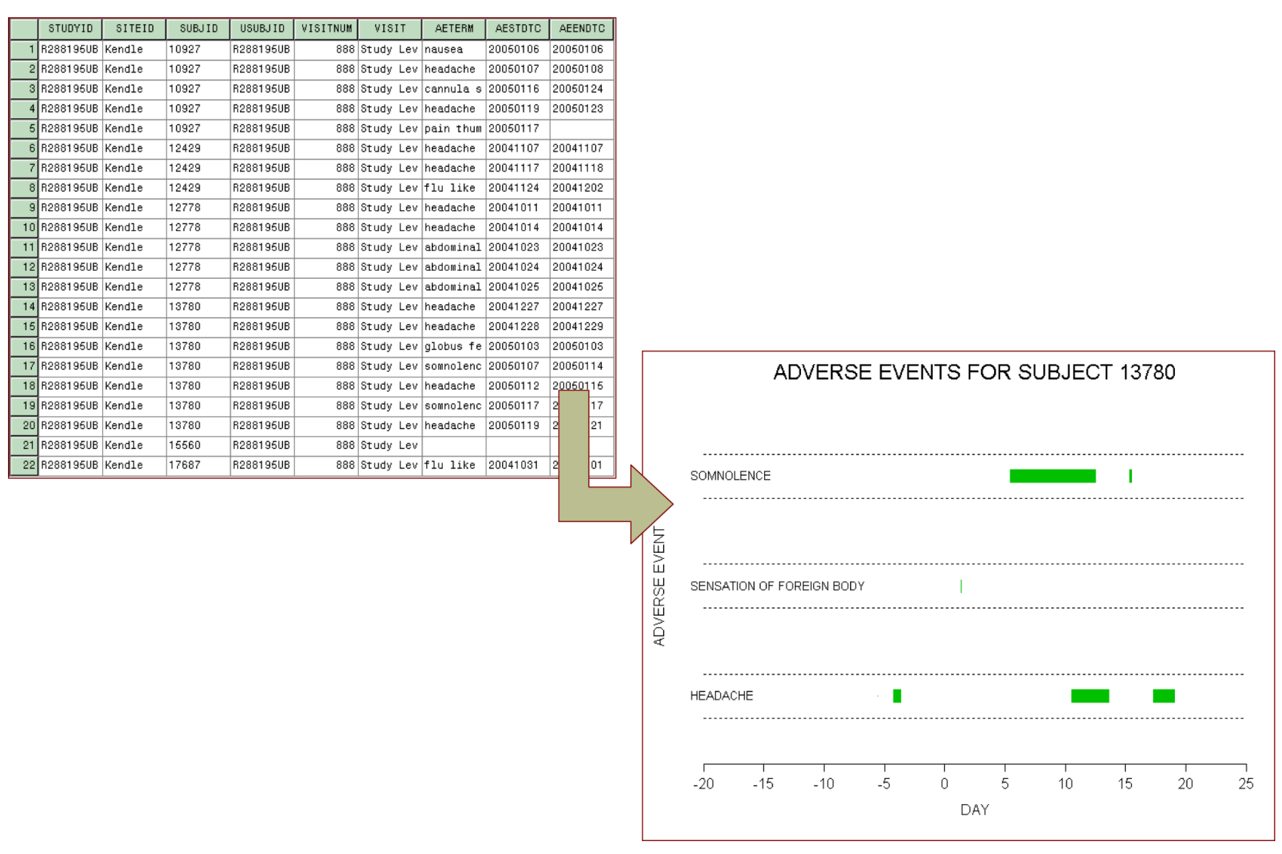
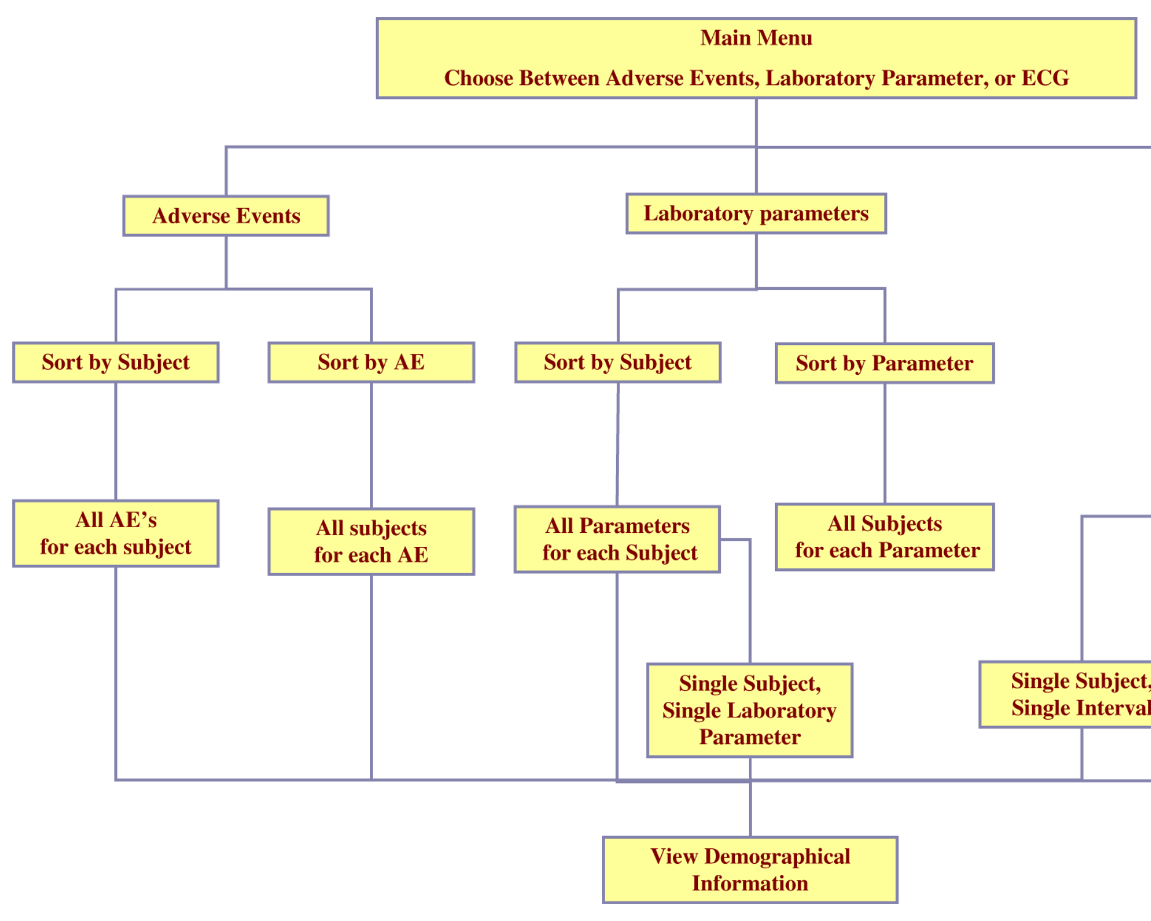
Abstract

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.

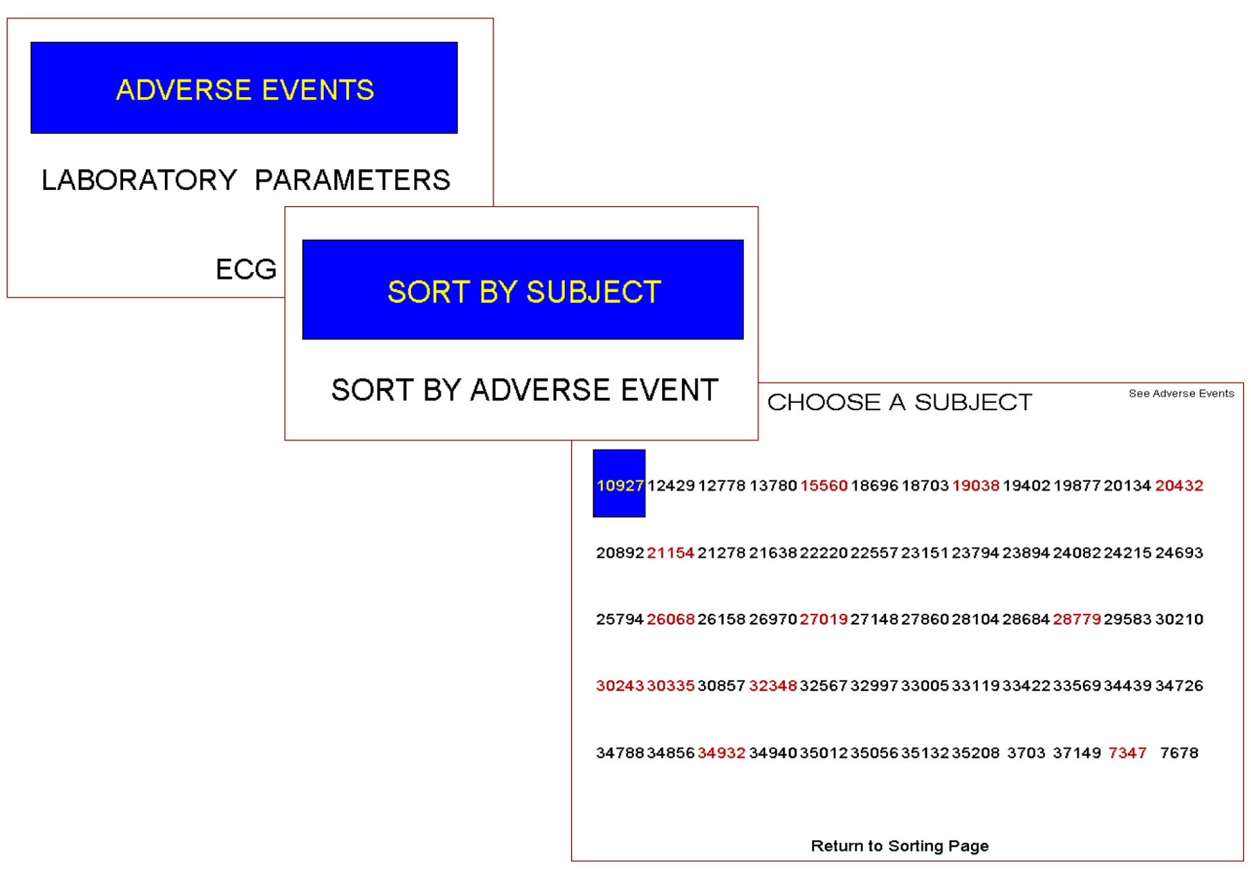


	STUDYID	SITEID	SUBJID	USUBJID	VISITNUM	VISIT	AETERM	AESTDTC	AEENDTC
1	R288195UB	Kendle	10927	R288195UB	888	Study Lev	nausea	20050106	20050106
2	R288195UB	Kendle	10927	R288195UB	888	Study Lev	headache	20050107	20050108
3	R288195UB	Kendle	10927	R288195UB	888	Study Lev	cannula s	20050116	20050124
4	R288195UB	Kendle	10927	R288195UB	888	Study Lev	headache	20050119	20050123
5	R288195UB	Kendle	10927	R288195UB	888	Study Lev	pain thum	20050117	
6	R288195UB	Kendle	12429	R288195UB	888	Study Lev	headache	20041107	20041107
7	R288195UB	Kendle	12429	R288195UB	888	Study Lev	headache	20041117	20041118
8	R288195UB	Kendle	12429	R288195UB	888	Study Lev	flu like	20041124	20041202
9	R288195UB	Kendle	12778	R288195UB	888	Study Lev	headache	20041011	20041011
10	R288195UB	Kendle	12778	R288195UB	888	Study Lev	headache	20041014	20041014
11	R288195UB	Kendle	12778	R288195UB	888	Study Lev	abdominal	20041023	20041023
12	R288195UB	Kendle	12778	R288195UB	888	Study Lev	abdominal	20041024	20041024
13	R288195UB	Kendle	12778	R288195UB	888	Study Lev	abdominal	20041025	20041025
14	R288195UB	Kendle	13780	R288195UB	888	Study Lev	headache	20041227	20041227
15	R288195UB	Kendle	13780	R288195UB	888	Study Lev	headache	20041228	20041229
16	R288195UB	Kendle	13780	R288195UB	888	Study Lev	globus fe	20050103	20050103
17	R288195UB	Kendle	13780	R288195UB	888	Study Lev	somnolenc	20050107	20050114
18	R288195UB	Kendle	13780	R288195UB	888	Study Lev	headache	20050112	20050115
19	R288195UB	Kendle	13780	R288195UB	888	Study Lev	somnolenc	20050117	[illegible]
20	R288195UB	Kendle	13780	R288195UB	888	Study Lev	headache	20050119	[illegible]
21	R288195UB	Kendle	15560	R288195UB	888	Study Lev			
22	R288195UB	Kendle	17687	R288195UB	888	Study Lev	flu like	20041031	[illegible]

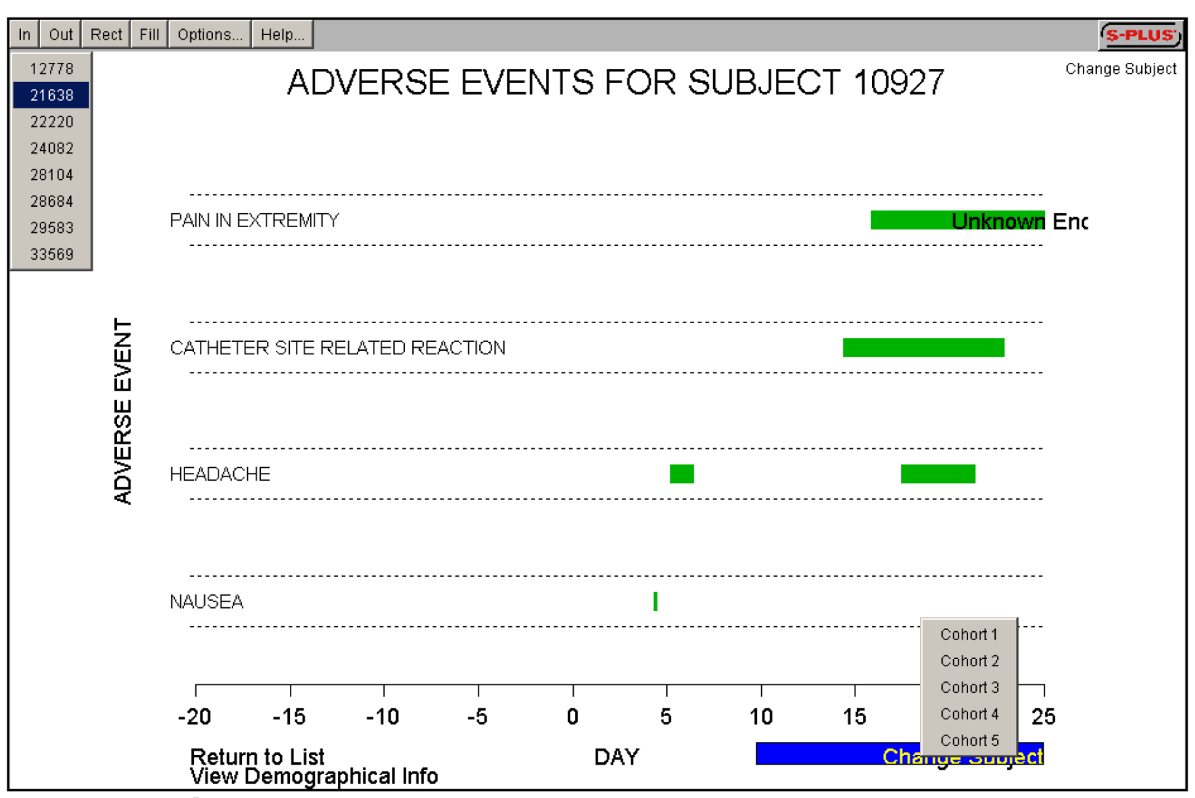
Visualizing Massive Data Sets into Interactive Graphs



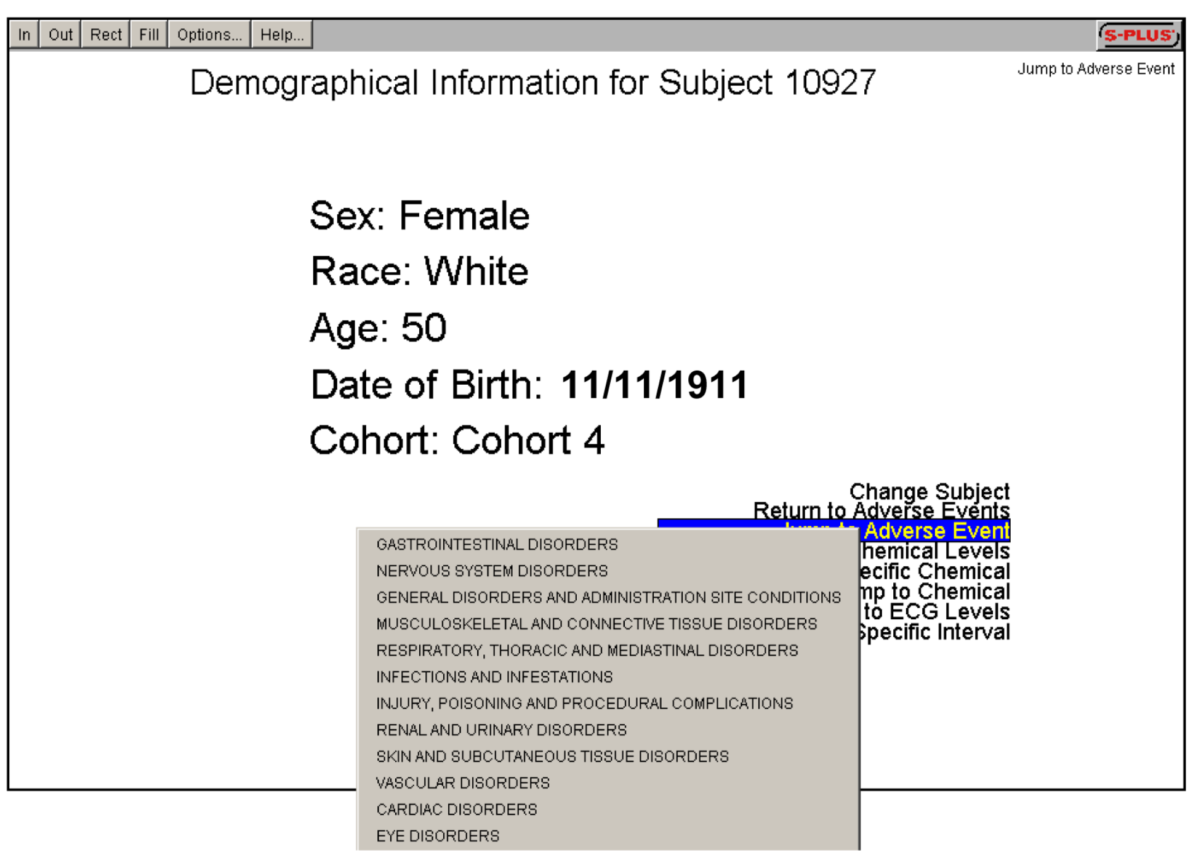
Schematic of the Structure of Data Visualization



Cascading Menus for Adverse Events Sorted by Subject



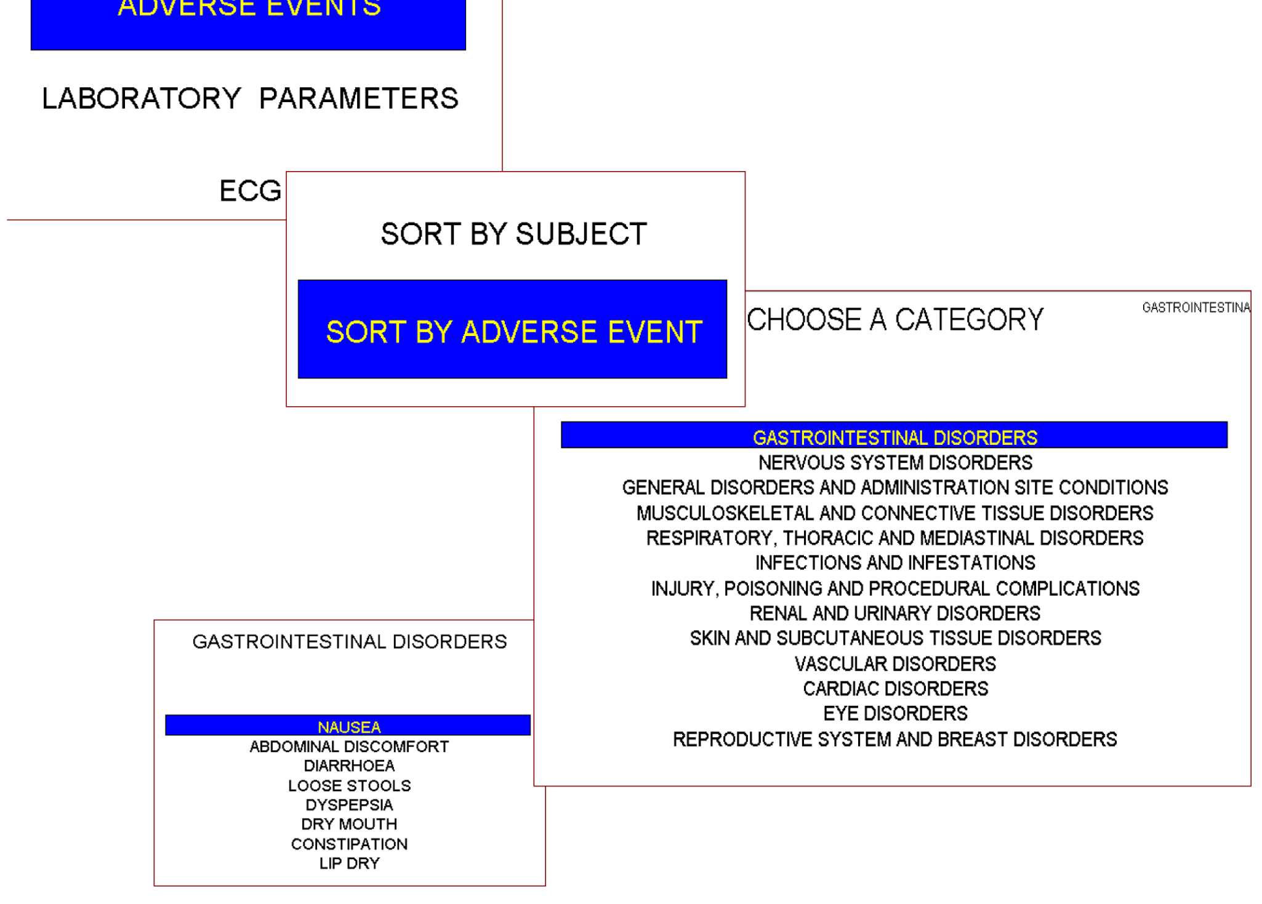
Visualizations for Adverse Events
Sorting by Subject



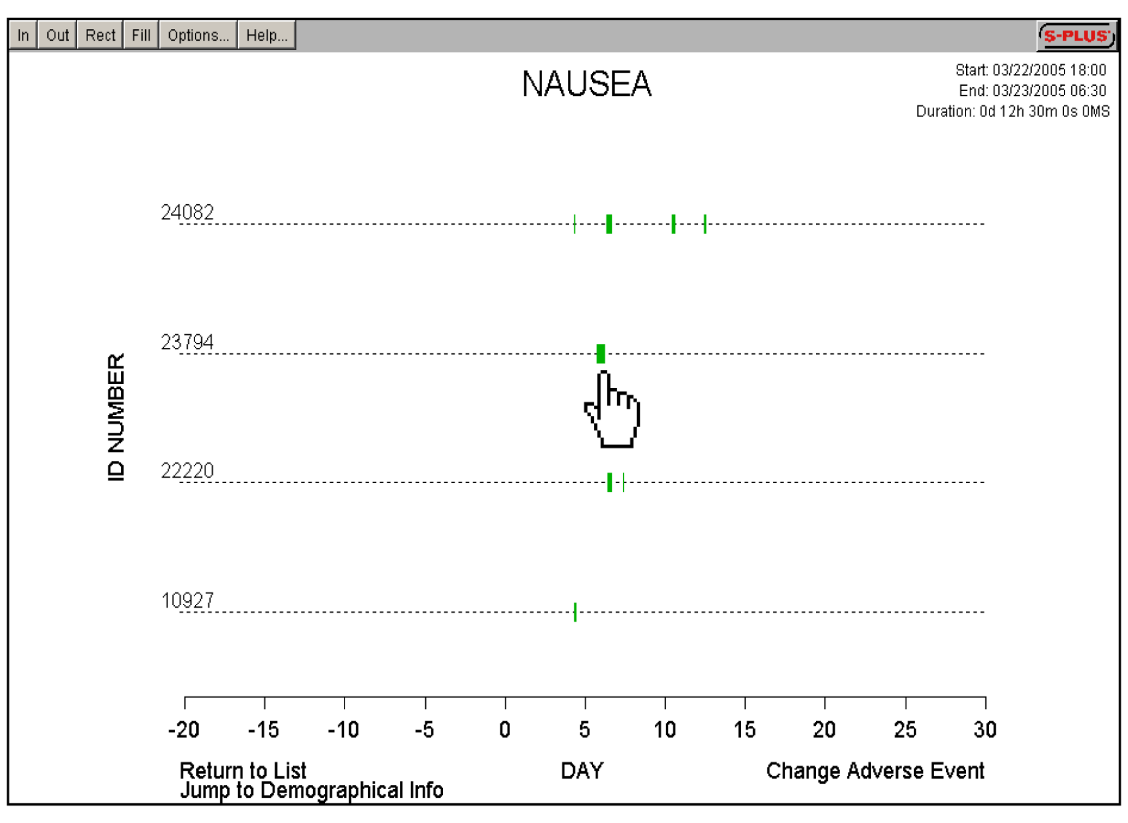
Demographical Information for Subject 10927

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

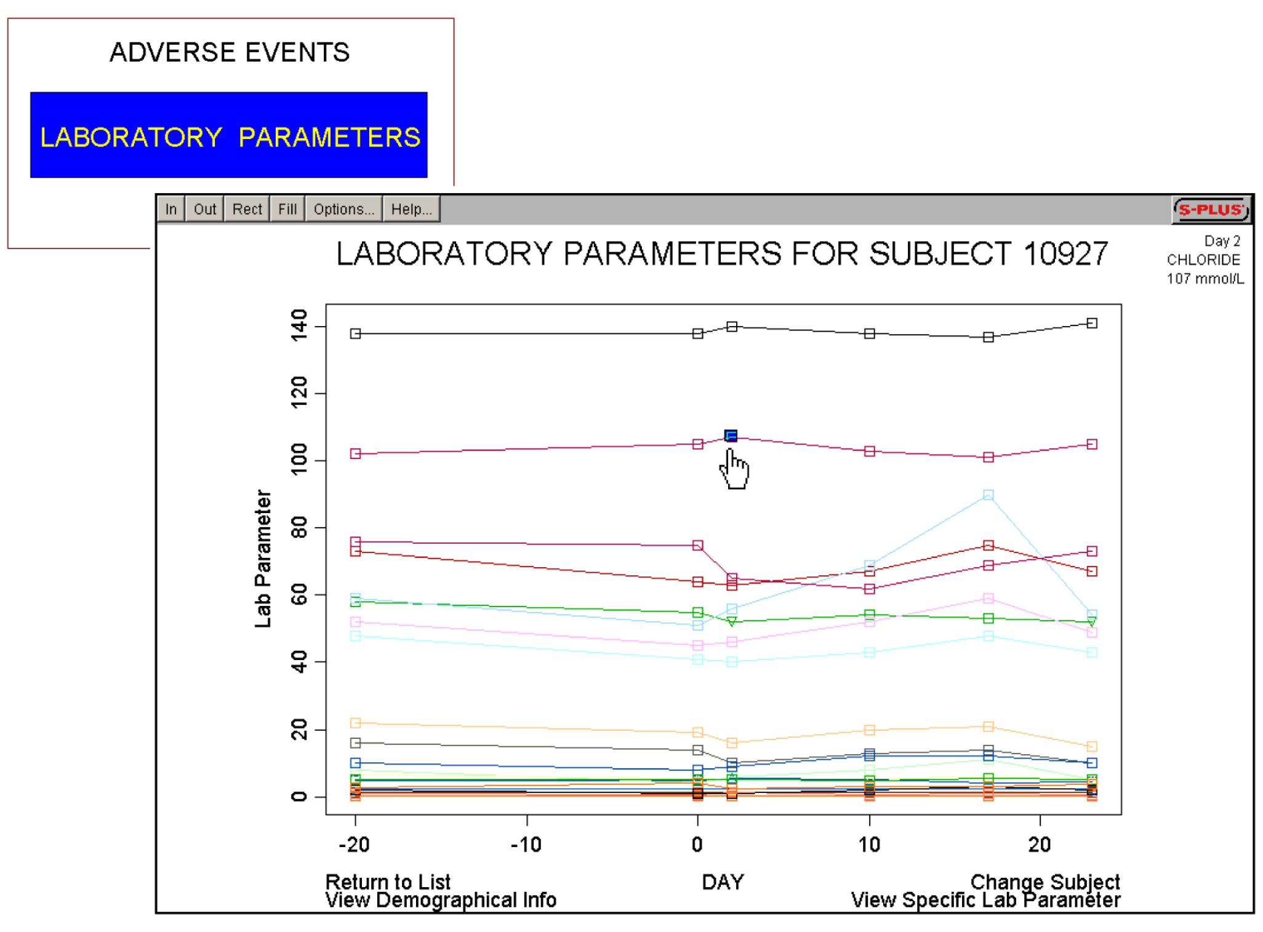
Subject Demographical Information



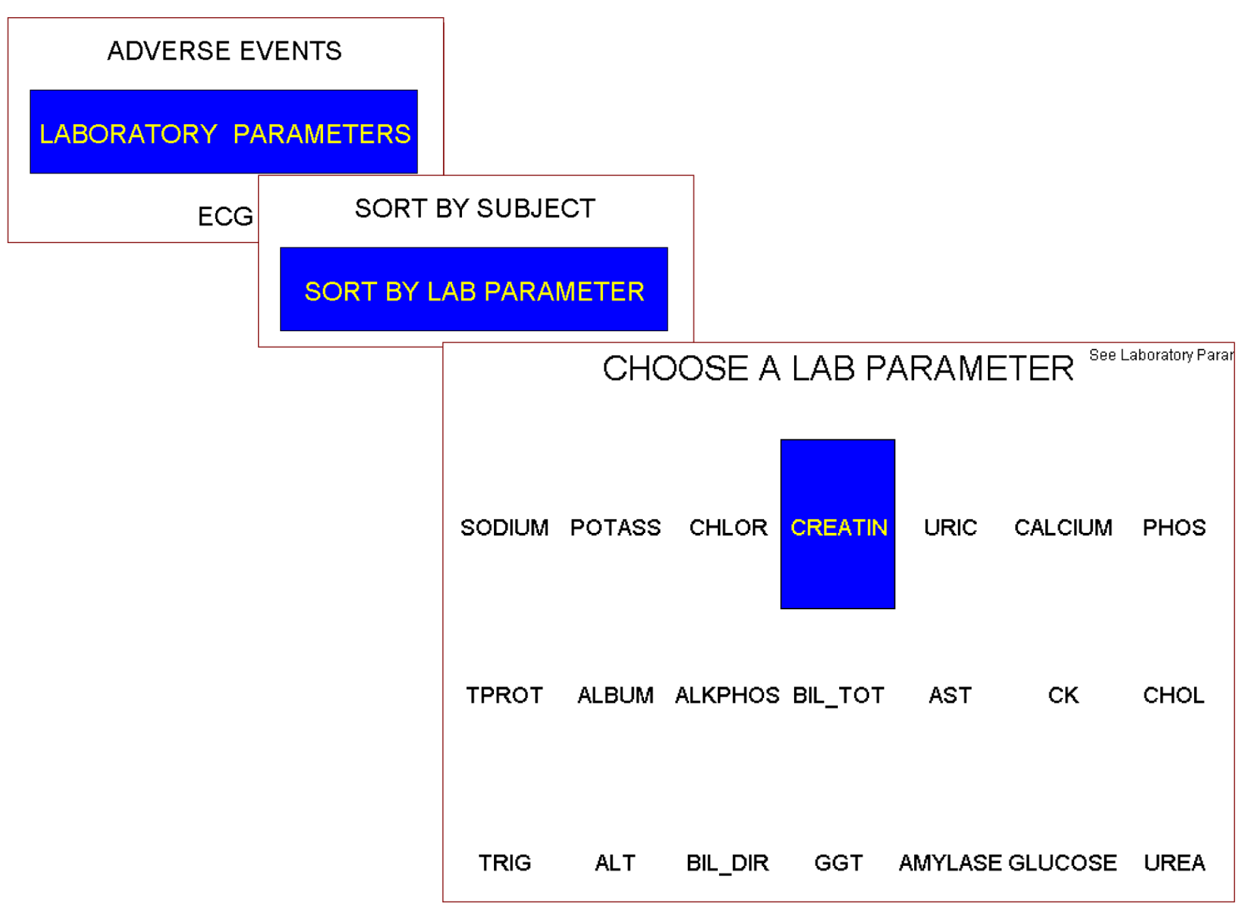
Cascading Menus for Adverse Events Sorted by Event



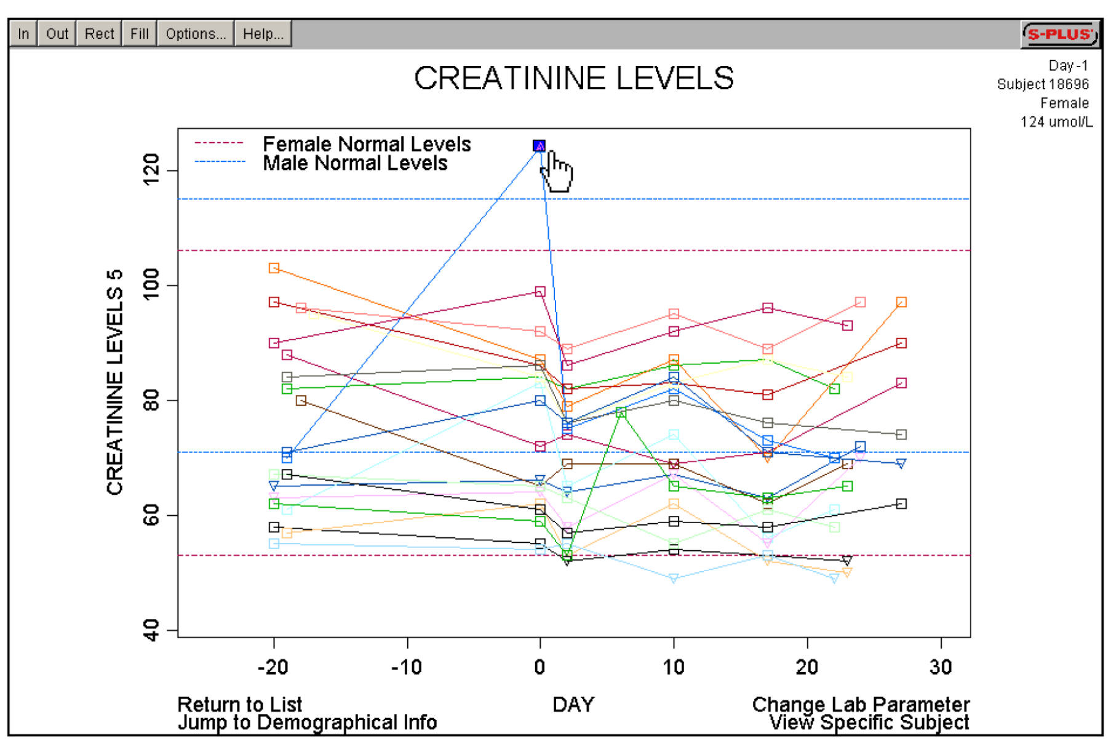
Visualizations for Adverse Events
Sorting by Adverse Events



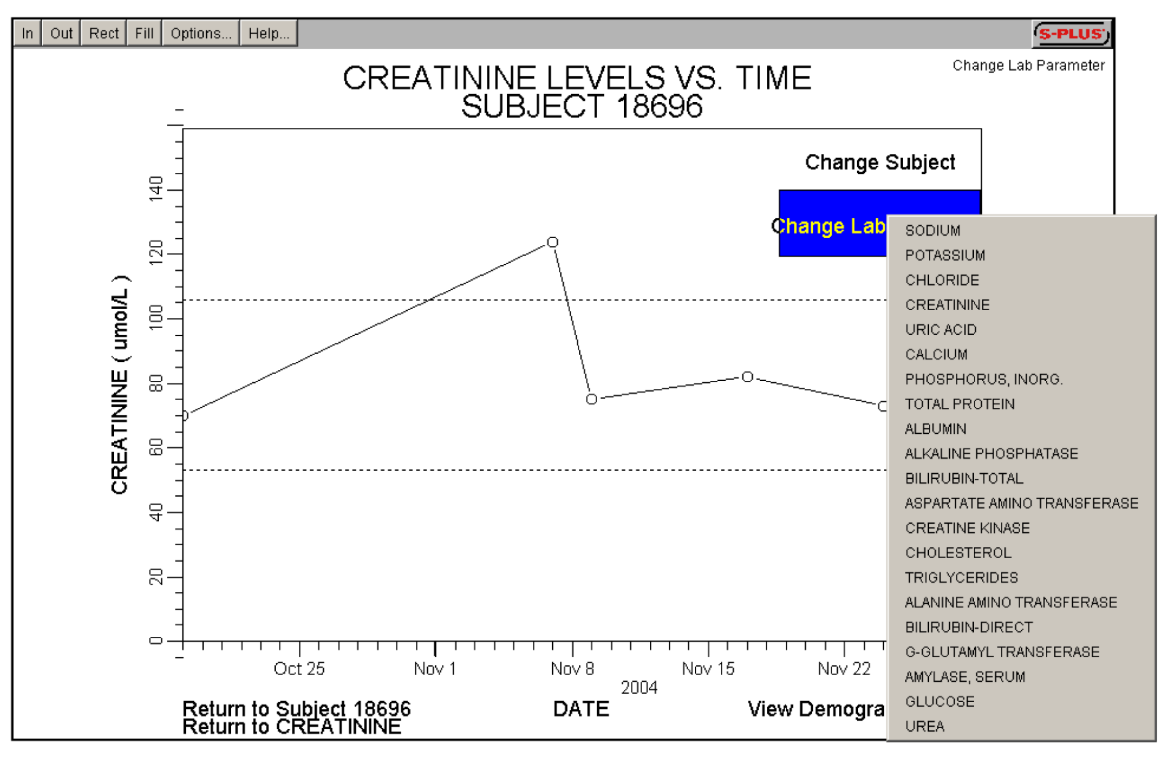
Visualizations for Laboratory Parameters
Sorting by Subject



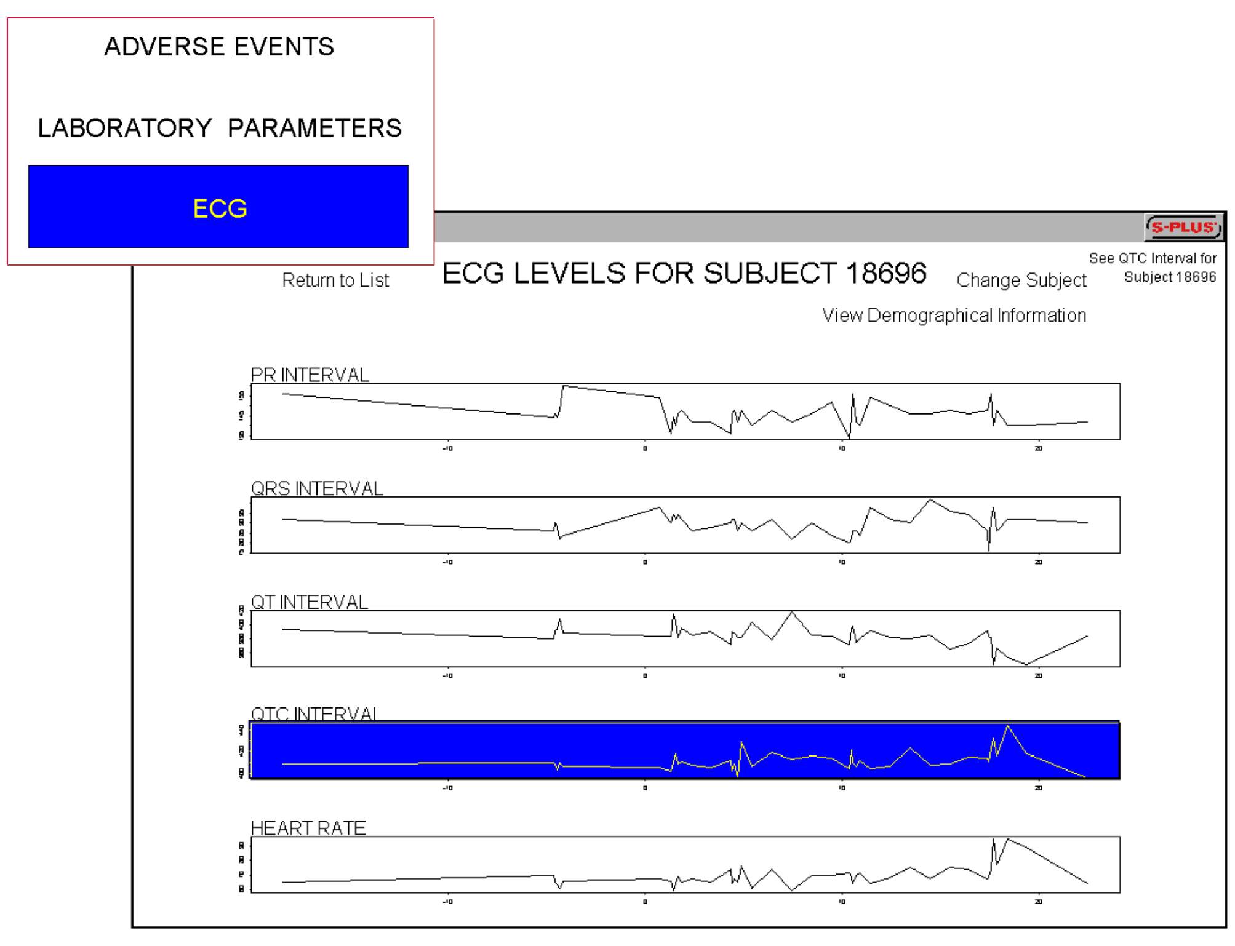
Cascading Menus for Laboratory Parameters
Sorting by Lab Parameter



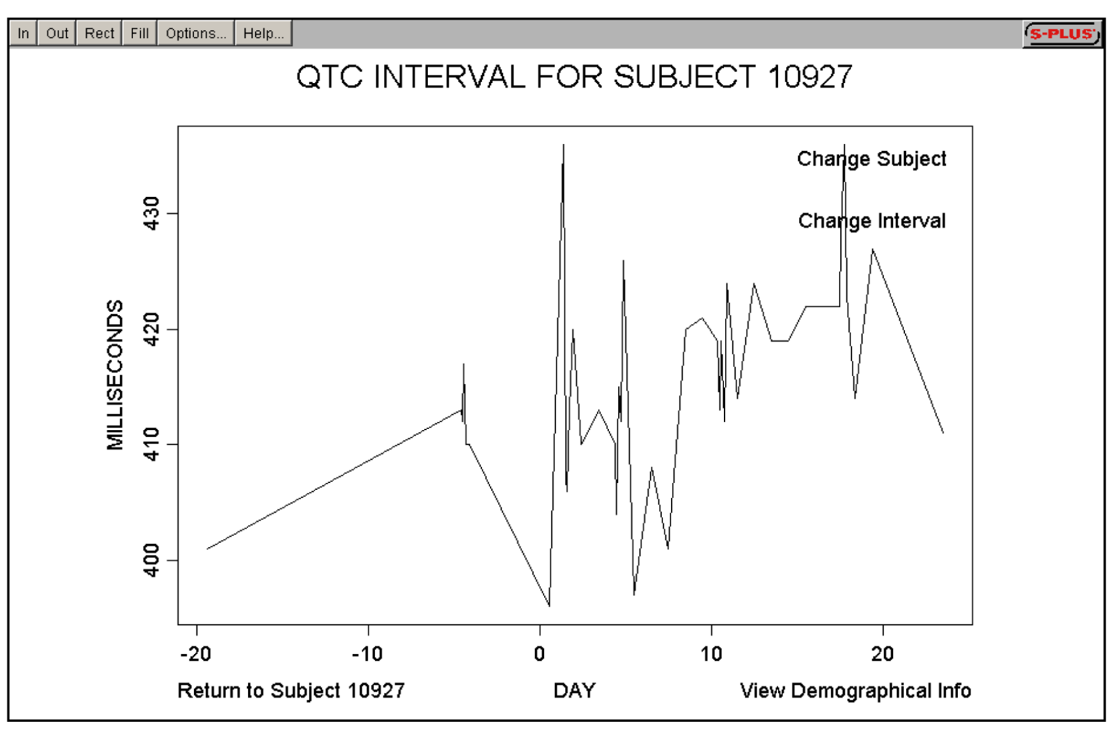
Visualizations for Laboratory Parameters
Sorting by Lab Parameter



Visualizations for Laboratory Parameter for a Subject



Visualizations for ECG Levels
Sorting by Subject



Visualizations for QTC Levels
An Individual Interval

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