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GRAPHICS FOR THE ANALYSIS AND CLINICAL REVIEW OF SAFETY DATA

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Some graphics were created using data available on CTSPedia.org.

Overview

Graphical presentations of safety data are essential for understanding the safety of products in the clinical setting.

- Volume
- Subtlety
- Dimensionality

Overview

Today's discussion will focus on using graphics to depict:

- The Basics
- The Drill Down
- The Full Picture

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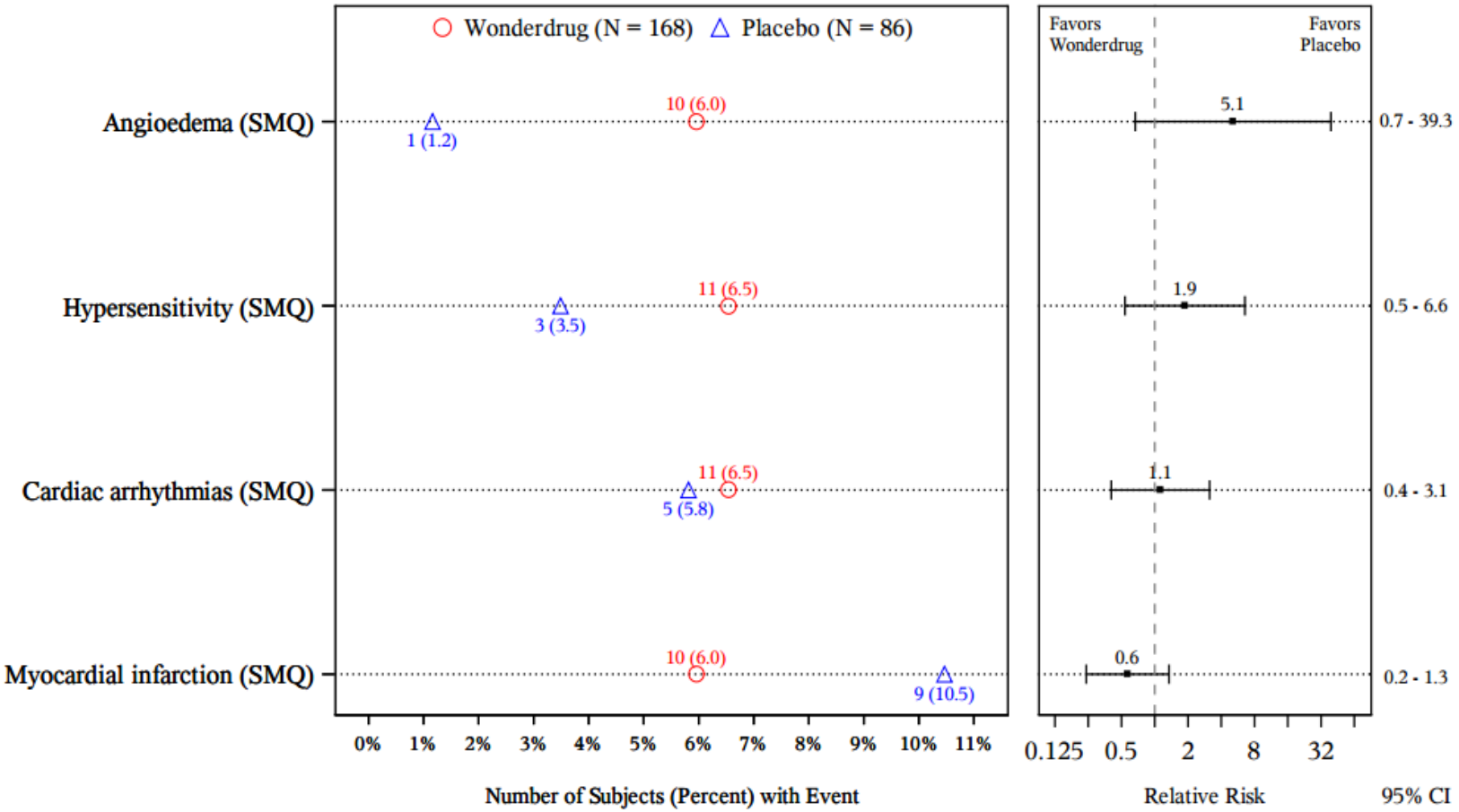
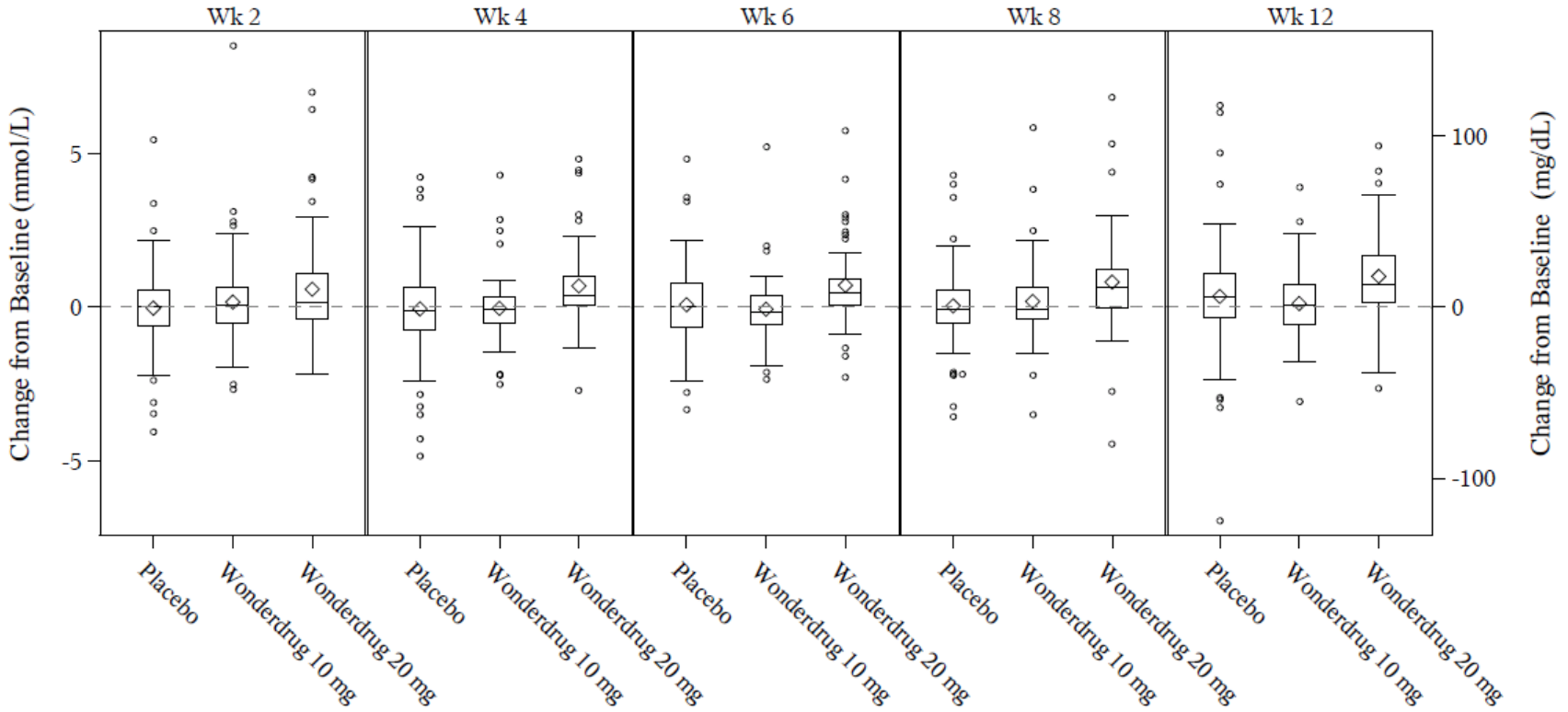
THE BASICS

Standard plots for adverse events, labs, vital signs and ECGs

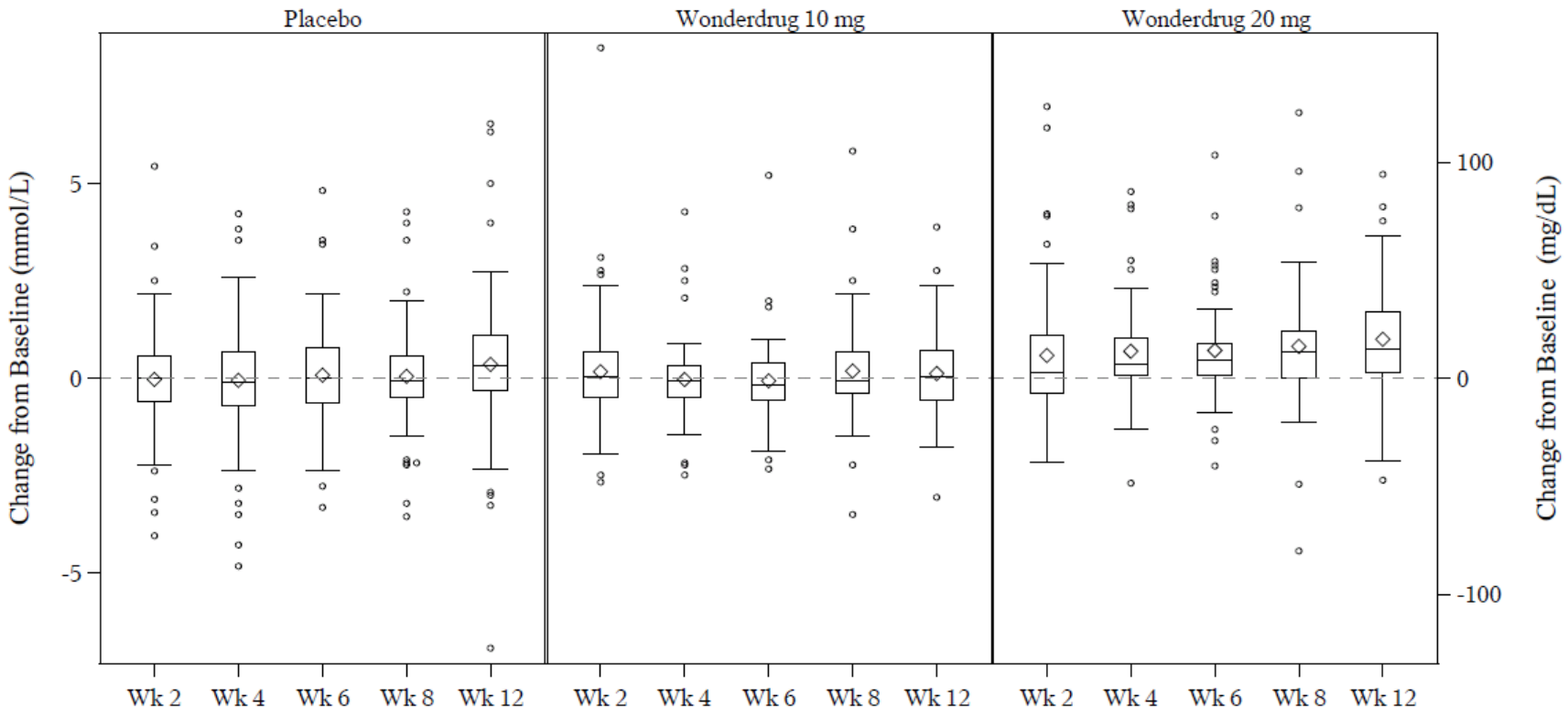
Incidence + Forest Plot for Binary Endpoints



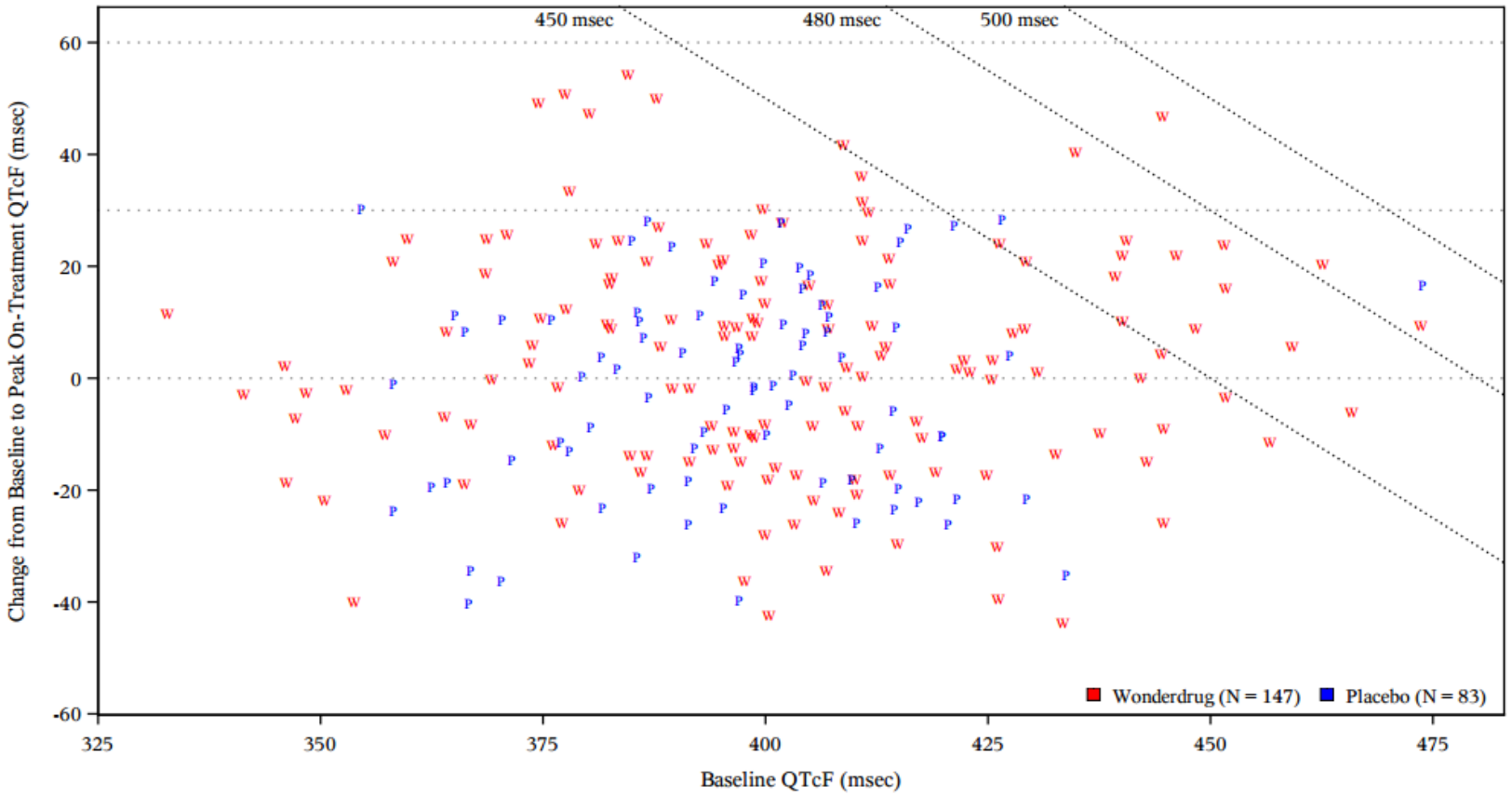
Box Plots for Continuous Endpoints by Visit and Treatment



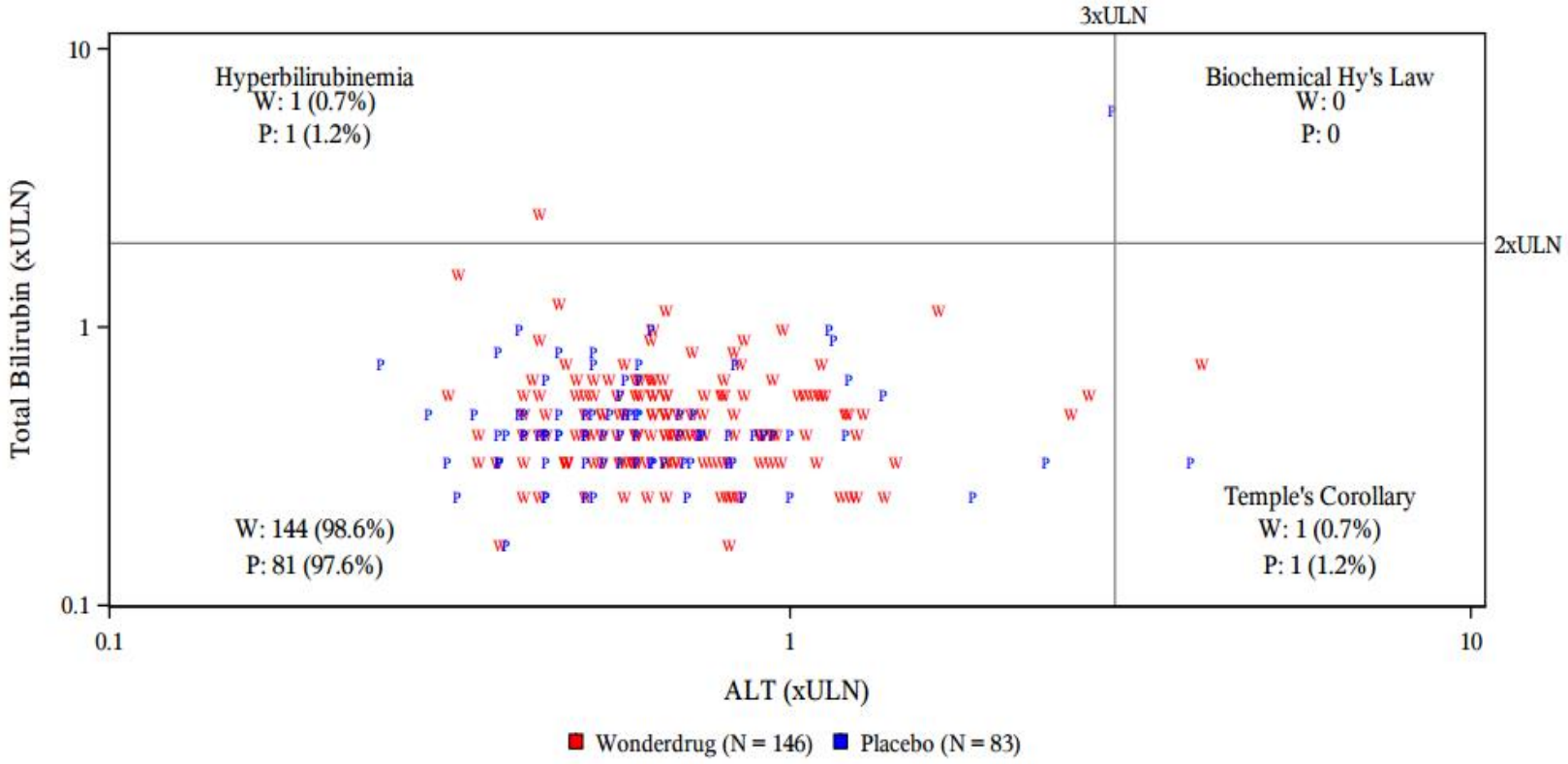
Box Plots for Continuous Endpoints by Treatment and Visit



Scatterplot with Reference Lines for Clinically Important Values



Evaluation of Drug-Induced Liver Injury (eDISH) Plot



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THE DRILL DOWN

Event charts for exploring patterns in events

Event Charts

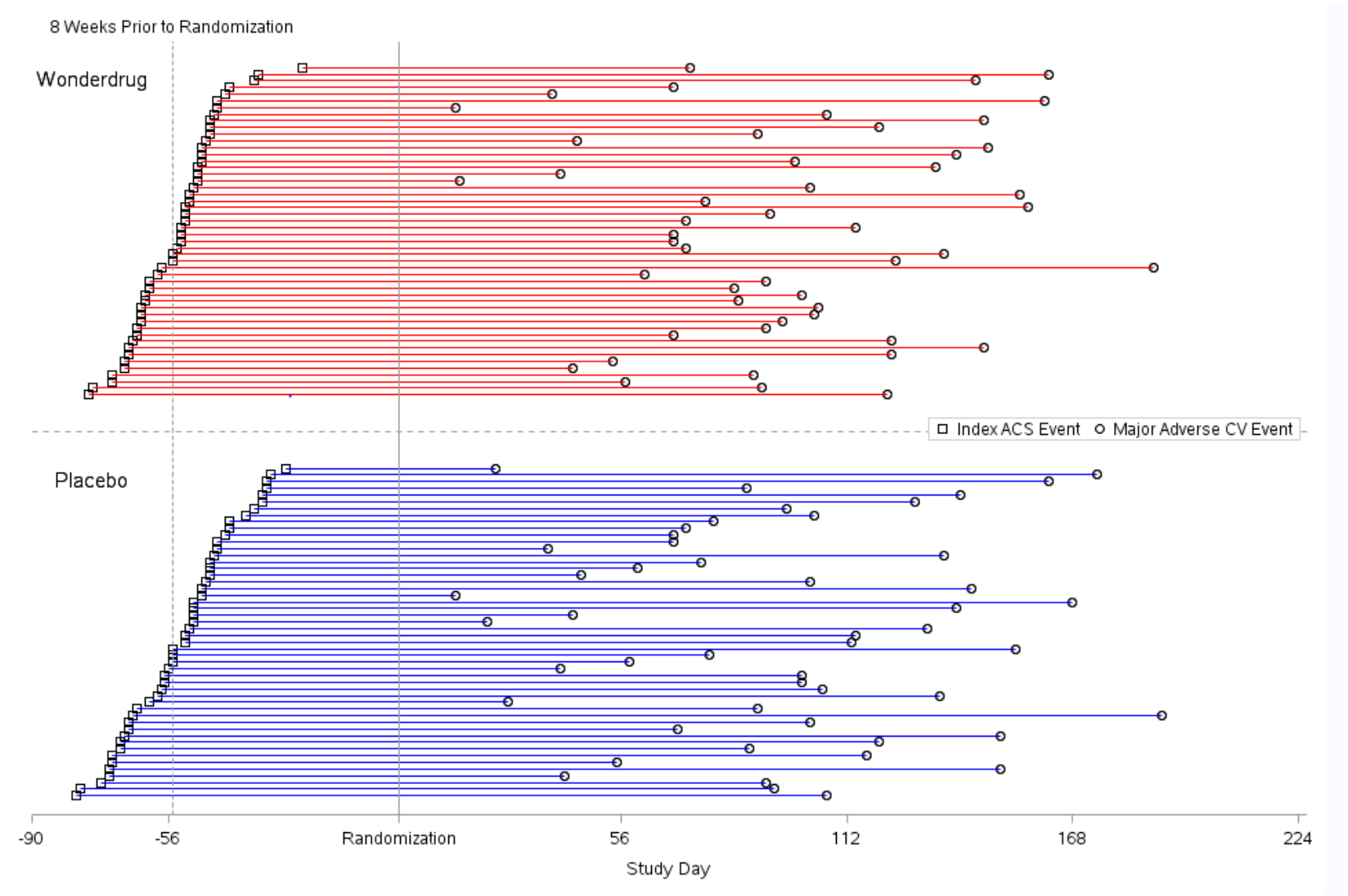
Explore event patterns by displaying all events for each subject on a single line

- Plot the entire population or relevant subgroups
- Shows timing/duration of events
- Can reveal temporal relationship of different events
- Proper sorting order can assist interpretation

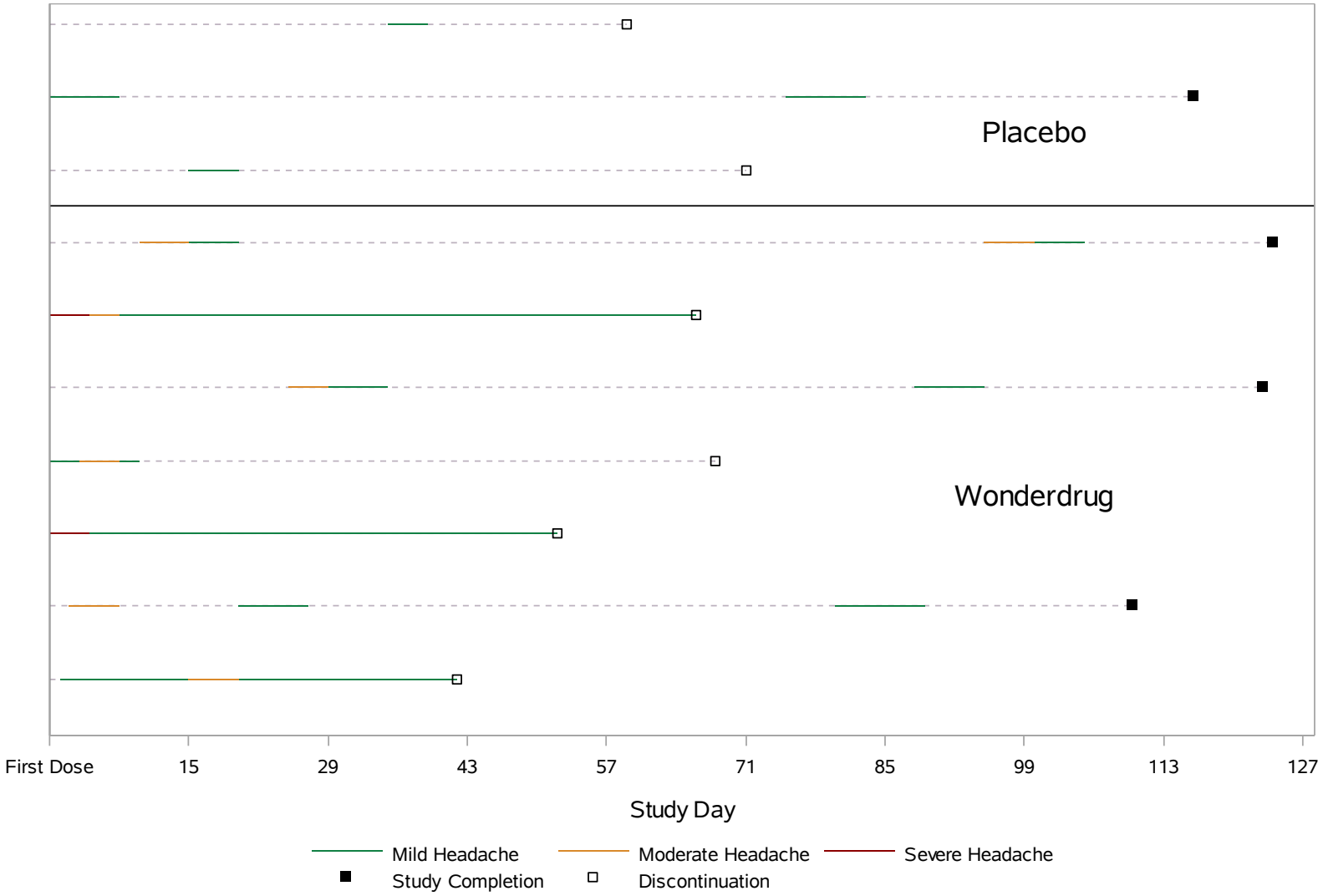
Event Chart to Show Relative Timing of Events

- Clinical question: Is time between index event and randomization correlated with time from randomization to first endpoint event?
- Each subject is depicted by a line from study day of index event to study day of first endpoint event
- Vertical reference lines depict randomization and 8 weeks pre-dose
- Sorting is critical to answer the clinical question – sort by time from index event to randomization and check for pattern in time from randomization to first endpoint event

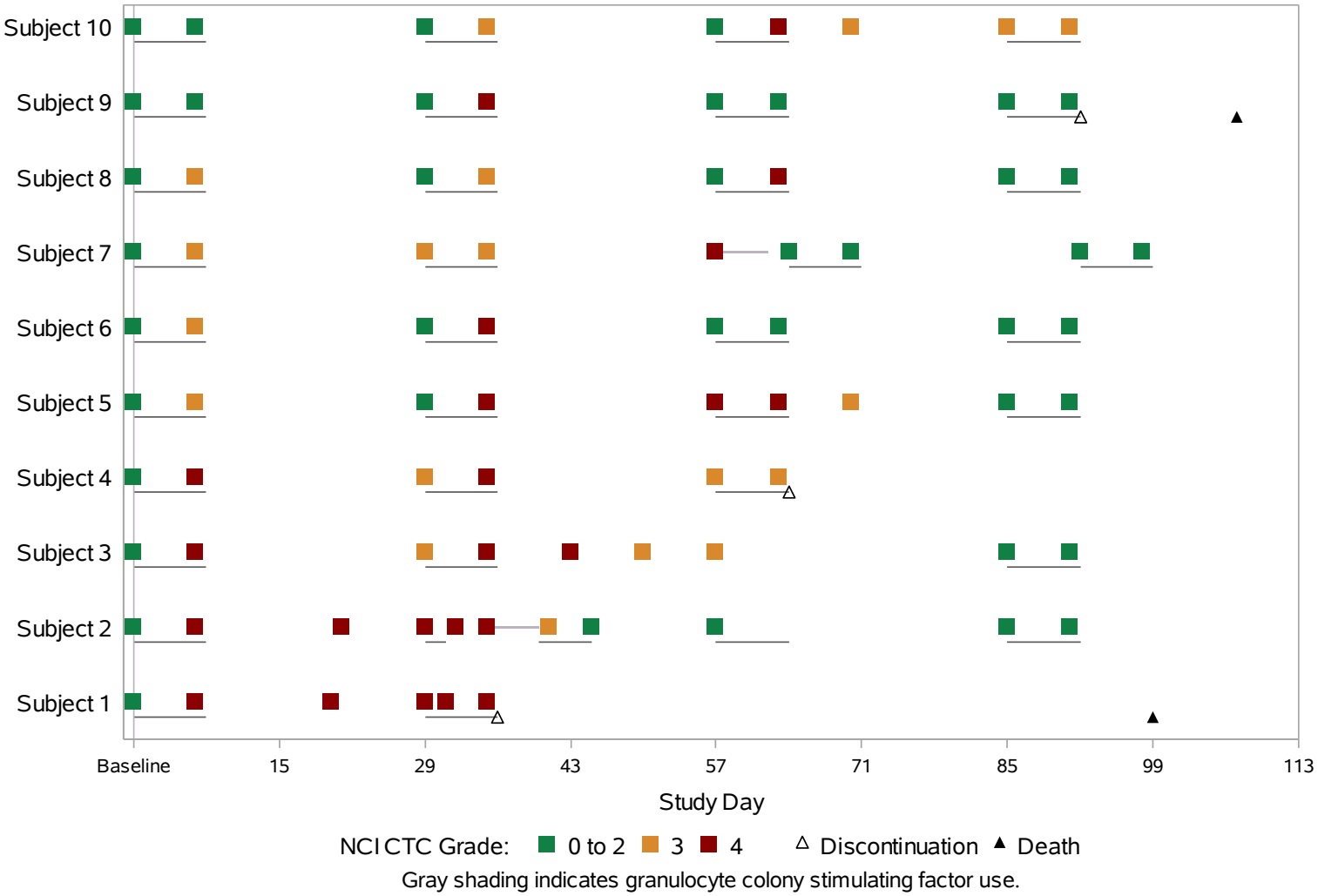
Event Chart to Show Relative Timing of Events



Event Chart (Swimmer Plot) to Show Event Severity by Time



Event Chart to Show Lab Toxicity Grades (NCI CTC) by Time



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THE FULL PICTURE

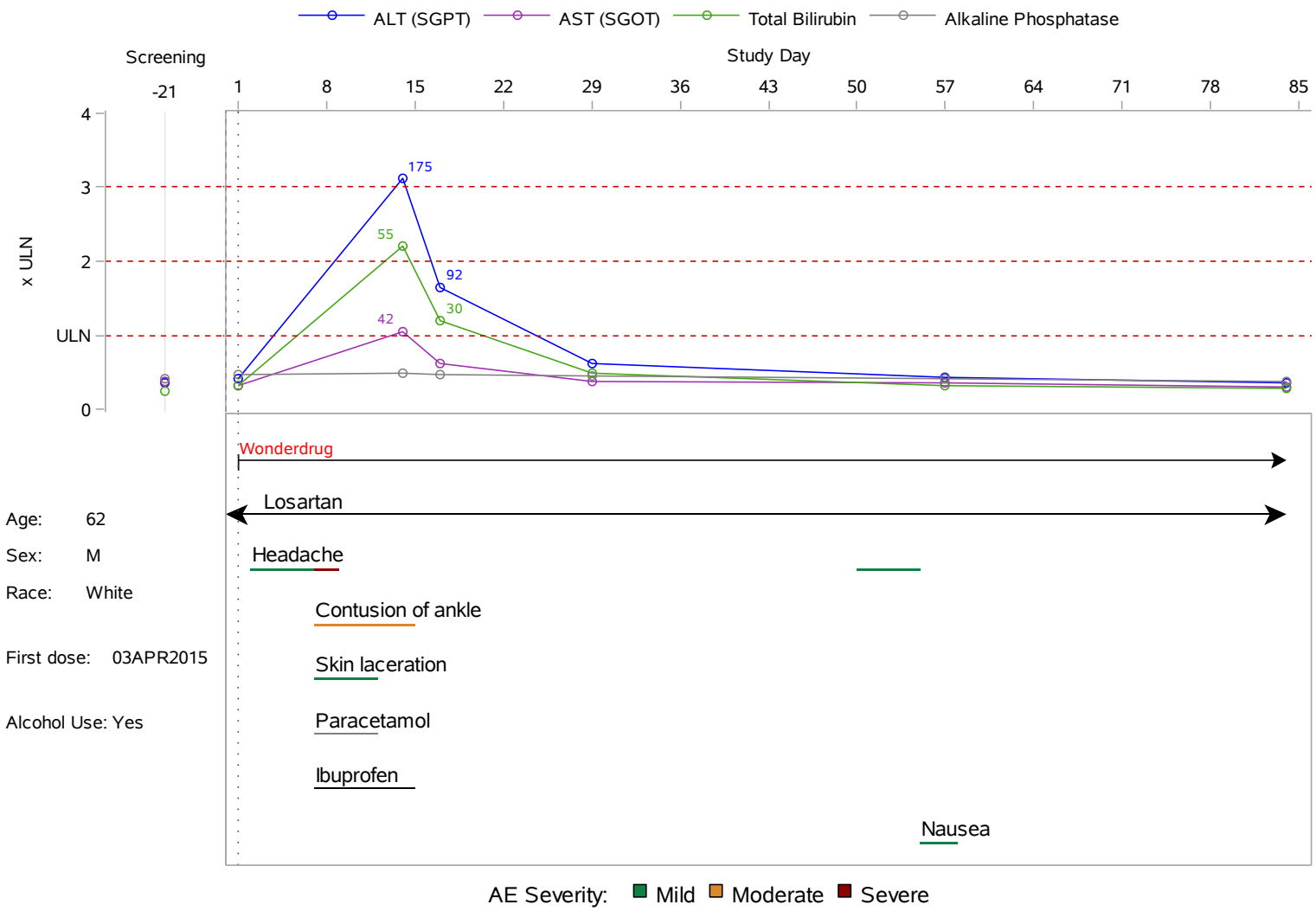
Patient profile plots to explore each case

Patient Profiles

Visually display multiple data types for a single subject

- Can include continuous data (labs, VS, ECGs) alongside AEs, medications, hospitalizations, etc.
- Assists in clinical understanding of an event
- Can be used to clinically adjudicate events
- Useful addition to narratives
- Design can be customized for data relevant to event of interest

Patient Profile Plot – Labs, AEs, Medications, Study Drug



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SUMMING UP

Conclusion

- Graphics facilitate the understanding of product safety in the clinical setting
- SAS and R programs are available (PhUSE, CTSPedia, etc)
- Start with The Basics
- Drill Down and get The Full Picture using customized presentations designed in consultation with clinical colleagues

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