

## **Life History Event Charts and other Graphical Methods for the Analysis of Safety Data**

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The interplay between treatment efficacy, side effects, and participant dropout is an important issue in many clinical trials, including longitudinal substance abuse treatment studies. Because of the complexity of such data, particularly when covariates are also considered, presentation in tables can be cumbersome. More importantly, statistical modeling is not necessarily straightforward and graphical techniques are useful and usually necessary to explore important patterns and relationships.

Two graphical methods, the event chart (Lee et al.; *American Statistician*, 2000) and the event history graph (Dubin et al.; *Statistics in Medicine*, 2001), will be emphasized, with application to a dose-ranging smoking cessation trial of naltrexone. We will use the graphs to "tell a story" regarding the complex data from this trial, with particular attention paid to the analysis of the safety data. Also, we hope to convey the utility of these graphical methods for other longitudinal clinical trials and observational studies.