

Brief Biosketch
Stephen J. Ruberg, PhD
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Steve was in the pharma industry for 38 years where he worked in all phases of drug development and commercialization – from R&D to Business Analytics. He retired from Lilly at the end of 2017 where he spent the last 10 years of his career there as a Distinguished Research Fellow and the Scientific Leader for Advanced Analytics. Since then, he has formed his own consulting company - Analytix Thinking.

Steve is a Fellow of the ASA since 1994 and an elected Fellow of ISI. He has published widely on a variety of topics relevant to pharmaceutical research. In particular, he has helped pioneer many areas of data and statistics, including:

- Publications on dose-response design/analysis, starting with a JASA paper in 1989
- Analysis of drug stability studies, which is the basis of ICH-Q1E "Evaluation for Stability Data"
- co-authored ICH-E9, Statistical Principles for Clinical Trials
- collaboration on understanding QTc intervals and designed the first thorough QTc study
- helped establish CDISC and was its first Chairman of the Board for 6 years
- creating strategies for electronic medical records (EMRs) where he served on an Advisory Board to the Secretary of Health and Human Services in the George W. Bush Administration
- research on personalized medicine and biomarker research through subgroup identification, Bayesian methods, and statistical analysis of SNPs
- and, most recently, ESTIMANDS