



# Statistics in Clinical Vaccine Trials

By Jozef Nauta

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This monograph offers well-founded training and expertise on the statistical analysis of data from clinical vaccine trials, i.e., immunogenicity and vaccine field efficacy studies. The book's scope is practical rather than theoretical. It opens with two introductory chapters on the immunology of vaccines to provide readers with the necessary background knowledge. It then continues with an in-depth exploration of the statistical methodology. Many real-life examples and SAS codes are presented, making application of the methods straightforward. Topics discussed include maximum likelihood estimation for censored antibody titers, ANCOVA for antibody values, analysis of equivalence and non-inferiority immunogenicity trial data, analysis of data from vaccine field efficacy trials (including data from studies with recurrent infection data), fitting protection curves to data of challenge or field efficacy studies, and the analysis of vaccine safety data.

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“The presentation of the book is lucid. The author is to be congratulated for mixing his vast practical experience with his knowledge to make this book readable and practically valuable.” (Subir Ghosh, *Technometrics*, Vol. 55 (3), August, 2013)

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