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| | Sommario/riassunto | This book offers an overview of the statistical methods used in clinical and observational vaccine studies. Pursuing a practical rather than theoretical approach, it presents a range of real-world examples with SAS codes, making the application of the methods straightforward. This revised edition has been significantly expanded to reflect the current interest in this area. 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 analysis of immunogenicity data. Discussed are, amongst others, maximum likelihood estimation for censored antibody titers, ANCOVA for antibody values, analysis of data of equivalence, and non-inferiority |

immunogenicity studies. Other topics covered include fitting protection curves to data from vaccine efficacy studies, and the analysis of vaccine safety data. In addition, the book features four new chapters on vaccine field studies: an introductory one, one on randomized vaccine efficacy studies, one on observational vaccine effectiveness studies, and one on the meta-analysis of vaccine efficacy studies. The book offers useful insights for statisticians and epidemiologists working in the pharmaceutical industry or at vaccines institutes, as well as graduate students interested in pharmaceutical statistics.