

Statistics In Clinical Vaccine Trials

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2023 Jozef Nauta Manmohan Singh Alan D.T. Barrett Myron M. Levine William H. Barker Joseph L. Melnick Charles Edmund Fisher Fred F. Ferri Mrs. Chandos Leigh Hunt Wallace Maxine A. Papadakis

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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

development of vaccines from discovery to clinical testing outlines the critical steps and analytical tools and techniques needed to take a vaccine from discovery through a successful clinical trial contributions from leading experts in the critical areas of vaccine expression purification formulation pre clinical testing and regulatory submissions make this book an authoritative collection of issues challenges and solutions for progressing a biologic drug formulation from its early stage of discovery into its final clinical testing a section with details and real life experiences of toxicology testing and regulatory filing for vaccines is also included

the last 20 years has seen a rapid increase in infectious diseases particularly those that are termed emerging diseases such as sars neglected diseases such as malaria and those that are deemed biothreats such as anthrax it is well recognized that the most effective modality for preventing infectious diseases is vaccination this book provides researchers with a better understanding of what is currently known about these diseases including whether there is a vaccine available or under development it also informs readers of the key issues in development of a vaccine for each disease provides a comprehensive treatise of the agents that are responsible for emerging and neglected diseases and those that can be used as biothreats includes the processes such as the vaccine development pathway vaccine manufacturing and regulatory issues that are critical to the generation of these vaccines to the marketplace each chapter will include a map of the world showing where that particular disease is naturally found

highlighting the latest activities and initiatives of prominent organizations working in the vaccine industry such as the bill and melinda gates foundation the global alliance for vaccines and immunization who unicef the world bank new generation vaccines fourth edition details steps developing countries have taken toward research development manufacture and regulation of several new vaccines for widespread use this text will cover the current state of the art techniques in vaccine development including the successes and the failures trace vaccine development from the bench to public health with regard to both fda and european union regulations investigate improved methods for immunizing large populations and the use of needless vaccinations discuss the advancements in the heavily government funded areas for developing vaccines against potential bioterror and infectious disease agents as well as the immunization of large population bases for diseases like anthrax smallpox ebola west nile sars and others updated throughout with new cutting edge information on recent breakthroughs and developments new to generation vaccines fourth edition highlights the latest activities of prominent organizations in the vaccine industry covers the current techniques in vaccine development investigates improved methods for immunizing large populations

ferri s clinical advisor 2003 is a fast efficient way to access important diagnostic and therapeutic information five distinct sections offer key information on patient and disease management differential diagnosis clinical algorithms laboratory evaluations and preventive guidelines covering nearly 1 100 current topics this resource is a must have all in one guide to

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consists of proceedings of symposia organized by the international association of biological standardization

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