

Statistics In Clinical Vaccine Trials

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The Lancet
British Medical Journal
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Journal of the National Medical Association
BMJ
Vaccine Testing
The Vaccination Inquirer and Health Review
Yonsei Medical Journal
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Manmohan Singh
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Inquirer and Health Review Yonsei Medical Journal Jozef Nauta Manmohan Singh United States. Congress. House. Committee on Appropriations. Subcommittee on the Departments of Labor, Health and Human Services, Education, and Related Agencies United States. Congress. Senate. Committee on Appropriations United States. Congress. Senate. Committee on Appropriations. Subcommittee on Departments of Labor, Health and Human Services, Education, and Related Agencies United States. Congress. House. Committee on Appropriations. Subcommittee on the Departments of Labor, Health and Human Services, Education, and Related Agencies Jozef Nauta University of Michigan. Poliomyelitis Vaccine Evaluation Center European Commission. Directorate-General for Health and Consumer Protection Shein-Chung Chow European Commission. Directorate General for Research Victor Healey

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

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recoge basic vaccinology diseases specific vaccine research clinical research and capacity

building

presentation of principles and methodologies for various clinical trials and a well balanced summary of current regulatory requirements emphasizes real life examples and illustrations from clinical case studies as well as numerous references

vaccine testing explores the critical journey vaccines undertake emphasizing safety testing and efficacy trials it reveals the rigorous evaluations ensuring vaccines are both safe and effective in preventing infectious diseases which is vital given the dependence on immunization strategies for global health security one intriguing aspect discussed is the ethical considerations that have shaped testing protocols including informed consent and equitable access the book offers a complete picture of vaccine testing starting with immunology and regulatory frameworks it progresses through clinical trial phases from preclinical studies to large scale phase iii trials later chapters examine methods for monitoring adverse events strategies for improving trial design addressing vaccine hesitancy and preparing for future pandemics the book distinguishes itself by providing a holistic overview of the entire testing process from initial preclinical studies to post market surveillance addressing the ethical and regulatory dimensions

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