

Statistics In Clinical Vaccine Trials

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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

vaccinology and methods in vaccine research is a combination of cutting edge methodologies experimental approaches and literature reviews the book covers all aspects of vaccine development including basic immunology focusing on the stimulation of adaptive immunity which is required for vaccine efficacy approaches to vaccine design and target validation vaccine biomanufacturer and clinical development existing vaccinology resources are theoretical reference books whereas this book provides a practical handbook for use in the research lab and classroom by those working in vaccinology and training others in the field it is authored and edited by scientists actively engaged in vaccine research and development for day to day teaching methodological advice addresses how to design a vaccine for an emerging disease from a practical point of view with chapters written by scientists who are grappling with these questions provides new approaches to vaccine development including vaccine targeting and virus like particle vaccines gives up to date information and methodologies in use for vaccine adjuvants

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 objective of this volume is to give an overview of the present state of the art of pediatric clinical pharmacology including developmental physiology pediatric specific pathology special tools and methods for development of drugs for children assessment of efficacy toxicity long term safety etc as well as regulatory and ethical knowledge and skills in the future structural and educational changes have to lead back to a closer cooperation and interaction of pediatrics with clinical pharmacology and pharmacy

this book equips nurses and midwives with a role in providing vaccination services in the uk with the information they need to practice safely and effectively this includes ensuring they are equipped to answer questions as they arise starting with the importance of vaccination for public health the book takes a vaccination through the life course approach from pregnancy babies and childhood teenagers adults to older people discussing some of the key challenges and

issues with the different vaccine programmes the book provides readers with the best practice guidance to offer a safe effective and quality service to maximise the uptake of vaccination across the population it offers guidance on how to ensure vaccination is offered to and accessible to all those who are eligible information is offered on how to address parents and patients questions and concerns effectively to ensure they are provided with the evidence based information they need to make an informed decision about vaccination and be able to give informed consent this book also provides technical information on vaccine preparation injection techniques and how to minimise the pain and distress of vaccination it also provides clinical management support for patient observation after vaccination each chapter is written by nurses and midwives expert in immunisation and vaccine administration with contributions from physicians legal and pharmacy professionals where relevant

this book contains the proceedings of the international symposium on pertussis vaccine trials held in rome in october 1995 the meeting was organized following the almost simultaneous release of the results of five clinical trials and two other clinical studies of acellular pertussis vaccines these large multi center studies conducted independently and over several years explored the efficacy safety and immunogenicity of several acellular pertussis vaccines comparing them with whole cell vaccine and or placebo in addition the book covers other major topics concerning the use of acellular and whole cell pertussis vaccines including basic biological and epidemiological questions various considerations in interpreting the studies results regulatory issues and worldwide perspectives on the expanded use of acellular vaccines bringing together the world s leading experts in this field of research and summarizing all major aspects of pertussis prevention and control this book is a vital reference for pediatricians public health officials microbiologists immunologists epidemiologists and all biomedical scientists who produce or regulate the use of vaccines

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

recoge basic vaccinology diseases specific vaccine research clinical research and capacity building

cancer vaccine development has changed from a small scale academic enterprise in to an applied science requiring a large clinical research infrastructure in this book a team of expert contributors take a focused look at the hot emerging area of cancer vaccines and tumor immunity cancer vaccines and tumor immunity serves a unique role in that it presents as a continuum the basic science discoveries that have moved forward into clinical trials it is a one stop concise

reference for all those interested in cancer vaccines summarizing where we have come from demonstrating what we are curren

reviews current aspects of research providing a fascinating insight into papillomavirus molecular biology interactions with the host immunology and vaccine development

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