

# The Relevance of **Ethnic Factors** in the Clinical Evaluation of Medicines

*Edited by Stuart Walker,  
Cyndy Lumley and Neil McAislane*



# Relevance Of Ethnic Factors In The Clinical Evaluation Of Medicines

**E. Nathaniel Gates**



## **Relevance Of Ethnic Factors In The Clinical Evaluation Of Medicines:**

**The Relevance of Ethnic Factors in the Clinical Evaluation of Medicines** S.R. Walker,C. Lumley,N. McAuslane,2012-12-06 For a research based pharmaceutical company to be successful in the 1990s it must have a strategic plan for the global development of new chemical entities Global development can be defined as an attempt to reach all major markets as rapidly as possible and for many companies these will include the United States Japan Germany France Italy UK and Canada which together represent approximately 85% of the pharmaceutical market in the developed world The mutual acceptance of foreign clinical data would reduce the time and resources required to develop a new medicine for the international market by eliminating the requirement for the routine repetition of clinical studies in local populations In Japan this has been largely based on the belief that genetic differences in responsiveness may result in a different benefit risk assessment for a new medicine while requests in Europe and the United States for local data relate mainly to methodological and cultural considerations The importance of this issue has been recognised internationally as it was one of the topics discussed at the International Conference on Harmonisation in Orlando October 1993 and it is currently on the programme for ICH3 which will be convened in Yokohama in Japan in November 1995 Responsibility for Drug-induced Injury Graham Dukes,Maurice Nelson Graham Dukes,Mark Mildred,Barbara Swartz,1998 This edition reflects the evolution of legal standards professional rules industrial codes of ethics and court experience in cases involving recompense for medical injury since the 1988 version While deriving from legal standards of the US British Commonwealth European Union and Nordic Council a chapter is devoted to issues particular to developing countries Following an introductory chapter on the emergence and recognition of problems relating to drug safety 20 chapters cover such areas as the legal framework types of proceedings evidence and proof the responsibility of everyone from the government and manufacturer to the prescriber and patient clinical investigation of drugs controlled drugs self medication alternative and complementary medicine and vaccines and biologicals Includes a table of cases and table of conventions statutes and regulations Annotation copyrighted by Book News Inc Portland OR Benefit-Risk Appraisal of Medicines Filip Mussen,Sam Salek,Stuart Walker,2009-08-04 Benefit risk assessment is at the centre of the approval process for every new medicine The ability to assess the risks of a new medicine accurately and to balance these against the benefits the medicine could bring is critical for every regulatory authority and pharmaceutical company Despite this there are very few tried and tested evaluative models currently available The authors of this book have developed a new pioneering tool for the assessment of benefits and risks for new medicines in development This model utilises a multi criteria decision analysis which involves selecting scoring and weighting key benefit and risk attributes and leads to an overall appraisal of benefits and risks of medicines Benefit Risk Appraisal of Medicines establishes the background and criteria required to assess benefit and risk in general and reviews the current practices by regulatory authorities and the pharmaceutical industry including those models currently available It outlines the development and

evaluation of the authors new model and analyses the implications of its implementation Describes an innovative systematic model which leads to transparent and responsible benefit risk decision making Contributes important ideas to the debate on benefit risk appraisal Provides a future framework for benefit risk appraisal of medicines Benefit Risk Appraisal of Medicines covers the entire process from the discovery of new medicines to their marketing and is ideal for all those who work in the pharmaceutical industry and regulatory authorities as well as post graduate students of pharmaceutical medicine and clinical pharmacology

**Ethnicity in Drug Development and Therapeutics** Edyta J. Frackiewicz, Thomas M. Shiovitz, Stanford S. Jhee, 2011-06-16 This book was first published in 2002 It presents an overview of ethnic and racial differences in response to medications and offers insight into the genetic and non genetic reasons for these differences The roles of pharmacogenomics and pharmacogenetics in drug development regulatory aspects of representing minorities in clinical trials as well as NIH ICH and FDA guidelines as they pertain to these issues are examined in detail Finally various strategies to increase recruitment and retention of minority populations in clinical trials are considered

Safety Evaluation of Biotechnologically-derived Pharmaceuticals Susan A. Griffiths, C. Lumley, 2012-12-06 Considerable investment has been made by both pharmaceutical and biotechnology companies in pharmaceutical products of biotechnology However because relatively few of these products have been marketed lack of relevant experience means that uncertainty still surrounds the most appropriate strategy for their safety evaluation The 13th CMR International Workshop held in February 1997 provided the opportunity for regulatory authority and industry experts from Europe Japan and the USA to share their experiences of designing safety evaluation programmes for specific product classes colony stimulating factors growth factors hormones interferons interleukins monoclonal antibodies for therapeutic use and gene therapy products Participants worked together to recommend those studies that should be considered for such safety evaluation and those that may be unnecessary These recommendations subsequently made a valuable contribution to the ICH guideline Safety Studies for Biotechnological Products which was finalised at ICH 4 in Brussels in July 1997 The Workshop proceedings not only describe the recommendations but also provide the reader with an appreciation of the science behind safety evaluation strategies used by experts the influence of different regulatory systems on these strategies and the type of data required by both toxicologists and clinicians before they have sufficient confidence to administer pharmaceutical products of biotechnology to humans

*Case Studies in Emergency Medicine and the Health of the Public* Edward Bernstein, 1996

Pharmacogenomics in Admixed Populations Dr. G. Suarez-Kurtz, 2007-08-03 Ethnic specificity has become an integral part of research in the overlapping sciences of pharmacogenetics and pharmacogenomics Pharmacogenomics in Admixed Populations was conceived to compile pharmacogenetic genomic PGx data from peoples of four continents Africa America Asia and Oceania where admixture and population stratification occurs

**The Concept of Race in Natural and Social Science** E. Nathaniel Gates, 2014-05-01 Explores the concept of race The term race which originally denoted genealogical or class identity has in the comparatively

brief span of 300 years taken on an entirely new meaning In the wake of the Enlightenment it came to be applied to social groups This ideological transformation coupled with a dogmatic insistence that the groups so designated were natural and not socially created gave birth to the modern notion of races as genetically distinct entities The results of this view were the encoding of race and racial hierarchies in law literature and culture How racial categories facilitate social control The articles in the series demonstrate that the classification of humans according to selected physical characteristics was an arbitrary decision that was not based on valid scientific method They also examine the impact of colonialism on the propagation of the concept and note that racial categorization is a powerful social force that is often used to promote the interests of dominant social groups Finally the collection surveys how laws based on race have been enacted around the world to deny power to minority groups A multidisciplinary resource This collection of outstanding articles brings multiple perspectives to bear on race theory and draws on a wider range of periodicals than even the largest library usually holds Even if all the articles were available on campus chances are that a student would have to track them down in several libraries and microfilm collections Providing of course that no journals were reserved for graduate students out for binding or simply missing This convenient set saves students substantial time and effort by making available all the key articles in one reliable source Authoritative commentary The series editor has put together a balanced selection of the most significant works accompanied by expert commentary A general introduction gives important background information and outlines fundamental issues current scholarship and scholarly controversies Introductions to individual volumes put the articles in context and draw attention to germinal ideas and major shifts in the field After reading the material even a beginning student will have an excellent grasp of the basics of the subject

*Principles and Practice of Pharmaceutical Medicine* Lionel D. Edwards, Andrew J. Fletcher, Anthony W. Fox, Peter D. Stonier, 2007-04-30 The long awaited second edition of *Principles and Practice of Pharmaceutical Medicine* provides an invaluable guide to all areas of drug development and medical aspects of marketing The title has been extensively revised and expanded to include the latest regulatory and scientific developments New chapters include European Regulations Ethics of Pharmaceutical Medicine Licensing and Due Diligence Pharmacogenomics Encompassing the entire spectrum of pharmaceutical medicine it is the most up to date international guide currently available Review of the first edition This book was a joy to read and a joy to review All pharmaceutical physicians should have a copy on their bookshelves all pharmaceutical companies should have copies in their libraries

BRITISH ASSOCIATION OF PHARMACEUTICAL PHYSICIANS **Stephens' Detection of New Adverse Drug Reactions** John Talbot, Patrick Waller, 2004-11-19 A key text for all those involved in pharmacovigilance Detection of new adverse drug reactions is fundamental to the protection of patients from harm that may occur as a result of medication This book explores the methods used to investigate new adverse drug reactions discussing all elements from the scientific background and animal toxicology through to worldwide regulatory and ethical issues *Stephens' Detection of New Adverse Drug Reactions*

provides comprehensive and up to date coverage of material fundamentally important to all those active in the field whether they work in the pharmaceutical industry drug regulatory authorities or in academia The fifth edition of this classic reference work includes new chapters on vaccine safety surveillance managing drug safety issues with marketed products operational aspects of drug safety function safety of biotechnology products future of pharmacovigilance Reviews of previous editions This book surpasses all its educational aims Not only is the subject matter covered comprehensively but the material is presented in a very user friendly manner The editors have succeeded in producing a highly specific definitive reference book which doubles as a most enjoyable read Commended by the 1999 BMA Medical Book Competition For anyone entering the field of adverse reaction monitoring one could not wish for a better primer International Journal of Risk and Safety in Medicine     The Law and Ethics of the Pharmaceutical Industry M.N.G. Dukes,2005-11-04 As one of the most massive and successful business sectors the pharmaceutical industry is a potent force for good in the community yet its behaviour is frequently questioned could it serve society at large better than it has done in the recent past Its own internal ethics both in business and science may need a careful reappraisal as may the extent to which the law administrative civil and criminal succeeds in guiding and where necessary constraining it The rules of behavior that may be considered to apply to today's pharmaceutical industry have emerged over a very long period and the process goes on Even the immensely detailed standards for quality safety and efficacy laid down in drug law and regulation during the second half of the twentieth century have their limitations as tools for ensuring that the public interest is well served In particular national and regional regulatory agencies are heavily dependent on industrial data for their decision making their standards and competence vary and even the existing network of agencies does not cover the entire world What is more there are many areas of law and regulation affecting the industry concerning for example the pricing of medicines the conduct of clinical studies the health protection of workers and concern for the environment In some fields it is indeed hardly possible to maintain standards through regulation Professor N M Graham Dukes a physician and lawyer with long term experience in industrial research management academic study and international drug policy provides here a powerfully documented analysis into the way this industry thinks acts and is viewed and examines the current trends pointing to change Provides a balanced picture of the current role of the pharmaceutical industry in society Includes indices of conventions laws and regulations as well as judicial and disciplinary cases This is the only book addressing the legal implications of big pharma activities and ethical standards

**Inclusion** Steven Epstein,2008-09-15 With Inclusion Steven Epstein argues that strategies to achieve diversity in medical research mask deeper problems ones that might require a different approach and different solutions Formal concern with this issue Epstein shows is a fairly recent phenomenon Until the mid 1980s scientists often studied groups of white middle aged men and assumed that conclusions drawn from studying them would apply to the rest of the population But struggles involving advocacy groups experts and Congress led to reforms that forced researchers to diversify the population

from which they drew for clinical research While the prominence of these inclusive practices has offered hope to traditionally underserved groups Epstein argues that it has drawn attention away from the tremendous inequalities in health that are rooted not in biology but in society Epstein's use of theory to demonstrate how public policies in the health profession are shaped makes this book relevant for many academic disciplines Highly recommended Choice A masterful comprehensive overview of a wide terrain Troy Duster Biosocieties

Trends in Drug Research II H. van der Goot, 1998-01-16 This volume of Pharmacochimistry Library comprises the text of invited lectures presented at the 11th Noordwijkerhout Camerino Symposium Trends in Drug Research held in Noordwijkerhout The Netherlands from 11-15 May 1997 In the programme attention has been given to the generation of new biological target systems and the generation of new lead molecules with presentations on e.g. combinatorial chemistry compound libraries database search high throughput screening and molecular biology Other topics discussed were the perspectives for new medicines for the gastro intestinal tract the major developments in the search for effective anti HIV drugs and new aspects in synthetic approaches In a special session three topics which currently draw much attention were discussed How to deal with the major problem of resistance against antimicrobial agents Can the apoptosis mechanism be used as a drug target Is the newly observed phenomenon of inverse agonism a general principle and has it consequences for drug development and use

*Proceedings of the Third International Conference on Harmonisation* Patrick Francis D'Arcy, 1996

**Drug-Drug Interactions: Scientific and Regulatory Perspectives**, 1997-11-06 Drug-Drug Interactions is a comprehensive review of the scientific and regulatory perspectives of drug-drug interactions from the point of view of academia industry and government regulatory agencies This book is intended for professionals in the pharmaceutical industry health care and governmental regulatory agencies Topics of interest include the mechanistic understanding of drug-drug interactions the prediction of drug-drug interaction potential of new drugs and the avoidance of clinically significant drug-drug interaction in patients Provides useful references on the science of drug-drug interactions Describes in a basic and comprehensive manner drug-drug interactions from the mechanistic viewpoint Contains original data from academic and industrial laboratories Presents an overview of regulatory agency positions

**Cytochrome P450** Paul R. Ortiz de Montellano, 2007-02-05 Cytochrome P450 Structure Mechanism and Biochemistry third edition is a revision of a review that summarizes the current state of research in the field of drug metabolism The emphasis is on structure mechanism biochemistry and regulation Coverage is interdisciplinary ranging from bioinorganic chemistry of cytochrome P450 to its relevance in human medicine Each chapter provides an in depth review of a given topic but concentrates on advances of the last 10 years

**Improving the Regulatory Review Process: Assessing Performance and Setting Targets** N. McAuslane, S.R. Walker, 2012-12-06 At a time when it is becoming usual for medicines to be developed for a global market and pharmaceutical companies are endeavouring to expedite the drug development process Regulatory Authorities are concentrating on improving their efficiency and effectiveness Therefore it is

not surprising that questions are being asked as to how performance might be measured and compared between different authorities who are now often in receipt of dossiers that have been submitted to several agencies at the same time Issues such as what target should be set for the review of new medicines and how can quality be assured are now considered to be of critical importance The twelfth CMR International Workshop held in January 1997 provided the opportunity for Regulatory Authority and industry personnel from Europe North America Australia and Japan to openly discuss experiences and exchange views on how to improve the review process The proceedings of this meeting provide a comprehensive overview of the current review process in different countries and the need for performance measures and targets This volume summarises the many suggestions that were debated at the Workshop and includes chapters on measuring performance and on the integration of quality into the review process *Proceedings of the Second International Conference on Harmonisation* Patrick Francis D'Arcy, D. W. G. Harron, 1994

*Statistics In the Pharmaceutical Industry* C. Ralph Buncher, Jia-Yeong Tsay, 2019-03-07 The growth of the pharmaceutical industry over the past decade is astounding but the impact of this growth on statistics is somewhat confusing While software has made analysis easier and more efficient regulatory bodies now demand deeper and more complex analyses and pharmacogenetic genomic studies serve up an entirely new set of challenges For more than two decades *Statistics in the Pharmaceutical Industry* has been the definitive guide to sorting through the challenges in the industry and this Third Edition continues that tradition Updated and expanded to reflect the most recent trends and developments in the field *Statistics in the Pharmaceutical Industry Third Edition* presents chapters written by experts from both regulatory agencies and pharmaceutical companies who discuss everything from experimental design to post marketing studies This approach sheds light on what regulators consider acceptable methodologies and what methods have proven successful for industrial statisticians Both new and revised chapters reflect the increasingly global nature of the industry as represented by authors from Japan and Europe the increasing trend toward non inferiority equivalence testing adaptive design in clinical trials global harmonization of regulatory standards and multiple comparison studies The book also examines the latest considerations in anti cancer studies *Statistics in the Pharmaceutical Industry Third Edition* demystifies the approval process by combining regulatory and industrial points of view making it a must read for anyone performing statistical analysis at any point in the drug approval process *Design and Analysis of Clinical Trials* Shein-Chung Chow, Jen-Pei Liu, 2013-09-30 Praise for the Second Edition a grand feast for biostatisticians It stands ready to satisfy the appetite of any pharmaceutical scientist with a respectable statistical appetite *Journal of Clinical Research Best Practices* The Third Edition of *Design and Analysis of Clinical Trials* provides complete comprehensive and expanded coverage of recent health treatments and interventions Featuring a unified presentation the book provides a well balanced summary of current regulatory requirements and recently developed statistical methods as well as an overview of the various designs and analyses that are utilized at different stages of clinical research and development Additional features



of this Third Edition include New chapters on biomarker development and target clinical trials adaptive design trials for evaluating diagnostic devices statistical methods for translational medicine and traditional Chinese medicine A balanced overview of current and emerging clinical issues as well as newly developed statistical methodologies Practical examples of clinical trials that demonstrate everyday applicability with illustrations and examples to explain key concepts New sections on bridging studies and global trials QT studies multinational trials comparative effectiveness trials and the analysis of QT QTc prolongation A complete and balanced presentation of clinical and scientific issues statistical concepts and methodologies for bridging clinical and statistical disciplines An update of each chapter that reflects changes in regulatory requirements for the drug review and approval process and recent developments in statistical design and methodology for clinical research and development Design and Analysis of Clinical Trials Third Edition continues to be an ideal clinical research reference for academic pharmaceutical medical and regulatory scientists researchers statisticians and graduate level students

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