

REVIEW

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Drug safety assessment in clinical trials: methodological challenges and opportunities

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Abstract

Randomized controlled trials are the principal means of establishing the efficacy of drugs. However pre-marketing trials are limited in size and duration and exclude high-risk populations. They have limited statistical power to detect rare but potentially serious adverse events in real-world patients. We summarize the principal methodological challenges in the reporting, analysis and interpretation of safety data in clinical trials using recent examples from systematic reviews. These challenges include the lack of an evidentiary gold standard, the limited statistical power of randomized controlled trials and resulting type 2 error, the lack of adequate ascertainment of adverse events and limited generalizability of trials that exclude high risk patients. We discuss potential solutions to these challenges. Evaluation of drug safety requires careful examination of data from heterogeneous sources. Meta-analyses of drug safety should include appropriate statistical methods and assess the optimal information size to avoid type 2 errors. They should evaluate outcome reporting biases and missing data to ensure reliable and accurate interpretation of findings. Regulatory and academic partnerships should be fostered to provide an independent and transparent evaluation of drug safety.

Review

Background

Randomized controlled trials are primarily designed to provide reliable information on the efficacy of interventions [1]. They form the primary basis of regulatory approval for a drug in the US, which involves demonstrating evidence of efficacy and safety in two well-conducted studies. With rare exceptions, these are generally interpreted as statistically significant data from two randomized clinical trials. Several advances have been made in the approach to the conduct, analysis and interpretation of data from randomized controlled trials on efficacy outcomes [1].

Since trials are typically carried out to define therapeutic benefit for regulatory approval, safety receives less attention [2]. The role of drug safety regulation is to protect patients from rare, severe adverse reactions; most efforts are directed at early detection and prevention of serious events such as that seen with thalidomide. Post-marketing surveillance through spontaneous adverse event reporting systems are the mainstay of drug

safety evaluation. Methodological issues around the analysis of safety data from clinical trials have received less attention.

Systematic reviews and meta-analyses of clinical trials have recently raised concerns about an increase in the risk of serious adverse cardiovascular outcomes associated with varenicline [2-4], an increased risk of mortality associated with the tiotropium Respimat inhaler, and adverse cardiovascular outcomes associated with inhaled anticholinergics (including the ipratropium and tiotropium inhaler) [5,6]. Similarly, increased risks of myocardial infarction associated with rosiglitazone [7-9] and congestive heart failure and fractures associated with the thiazolidinediones (rosiglitazone and pioglitazone) in clinical trials have resulted in regulatory warnings [10,11]. These findings have been widely debated with conflicting interpretation by the academic community, regulators and industry sponsors [12-14]. Regulators have emphasized the limitations to defining and measuring adverse outcomes in randomized controlled trials and have called for caution in drawing any robust conclusions [12]. The lack of access to individual participant data, the heterogeneous nature of safety data, and the statistical challenges of analyzing rare events make safety data from such meta-analyses difficult to analyze and

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Drug Safety Assessment In Clinical Trials

Michael J. Klepper, Barton Cobert



Drug Safety Assessment In Clinical Trials:

Drug Safety Assessment in Clinical Trials Gene Sogliero-Gilbert,1993-07-14 Details the methods pharmaceutical companies employ to determine the safety profile of their drugs Statistical procedures currently used or developed to analyze display and compare the massive amounts of laboratory data collected from controlled clinical trials are surveyed

Quantitative Evaluation of Safety in Drug Development Qi Jiang,H. Amy Xia,2014-12-08 State of the Art Methods for Drug Safety Assessment Responding to the increased scrutiny of drug safety in recent years Quantitative Evaluation of Safety in Drug Development Design Analysis and Reporting explains design monitoring analysis and reporting issues for both clinical trials and observational studies in biopharmaceutical product deve

Drug Safety Data Michael J. Klepper,Barton Cobert,2011 Drug Safety Data How to Analyze Summarize and Interpret to Determine Risk provides pharmaceutical scientists researchers and technicians with an accessible practical framework for the analysis summary and interpretation of drug safety data The only guide of its kind Drug Safety Data How to Analyze Summarize and Interpret to Determine Risk is an invaluable reference for premarketing risk assessment This unique resource enhances the ability of pharmaceutical professionals those with and without clinical training to determine the risk of a drug or biologic ahead of its release thereby reducing unnecessary jeopardy to the patient Authors Dr Michael Klepper and Dr Barton Cobert who together bring decades of pharmaceutical research and drug safety expertise discuss how quality planning safety training and data standardization result in significant cost time and resource savings Through illustrative step by step instruction Drug Safety Data How to Analyze Summarize and Interpret to Determine Risk provides the definitive guide to drug safety data analysis and reporting Key features include Step by step instruction on how to analyze summarize and interpret safety data for mandatory governmental safety reports Pragmatic tips and mistakes to avoid Simple explanations of what safety data are collected and what the data mean Practical approaches to determining a drug effect and understanding its clinical significance Guidance for determining risk throughout the lifecycle of a drug biologic or nutraceutical Examples of user friendly data displays that enhance safety signal identification Ways to improve data quality and reduce the time resources and costs involved in mandatory safety reporting Relevant material for the required training of drug safety pharmacovigilance professionals SPECIAL FEATURE Actual examples of an Integrated Analysis of Safety IAS used in the preparation of the Integrated Summary of Safety ISS and the Summary of Clinical Safety SCS reports and the Periodic Safety Update Report PSUR

Quantitative Drug Safety and Benefit Risk Evaluation William Wang,Melvin Munsaka,James Buchanan,Judy Li,2021-12-30 Quantitative Methodologies and Process for Safety Monitoring and Ongoing Benefit Risk Evaluation provides a comprehensive coverage on safety monitoring methodologies covering both global trends and regional initiatives Pharmacovigilance has traditionally focused on the handling of individual adverse event reports however recently there had been a shift towards aggregate analysis to better understand the scope of product risks Written to be accessible not only to

statisticians but also to safety scientists with a quantitative interest this book aims to bridge the gap in knowledge between medical and statistical fields creating a truly multi disciplinary approach that is very much needed for 21st century safety evaluation

Drug Safety Evaluation Shayne Cox Gad,2003-09-05 Drug Safety Evaluation presents an all inclusive practical guide for those who are responsible for ensuring the safety of drugs and biologics for patients for health care providers for those involved in the manufacture of medicinal products and for all those who need to understand how the safety of these products is evaluated Individual chapters address specific approaches to evaluating hazards including problems that are encountered and their solutions Author Shayne Gad draws upon over twenty years of experience in toxicology drug development and risk assessment explaining the scientific and philosophical bases for evaluating specific concerns carcinogenicity development toxicity etc to provide both understanding and guidance for approaching new problems Containing information specifically relevant to the pharmaceutical and biotechnology industries Drug Safety Evaluation covers a wide variety of topics including Acute toxicity testing in pharmaceutical safety evaluation Genotoxicity Safety assessment of inhalant drugs Immunotoxicology in pharmaceutical development Large animal studies Evaluation of human tolerance and safety in clinical trials Drug Safety Evaluation provides a road map for safety assessment as an integral part of the development of new drugs and therapeutics

Drug Safety Evaluation Jean-Charles Gautier,2011-08-24 Non clinical drug safety evaluation the assessment of the safety profile of therapeutic agents through the conduct of laboratory studies in in vitro systems and in animals is an essential step in the progress of new pharmaceuticals heading toward the ultimate goal of clinical trials and eventually approval In Drug Safety Evaluation Methods and Protocols expert researchers detail a compendium of analytical technologies with a focus on clarity and applicability in real life laboratory practice These meticulous contributions feature key topics such as acute to chronic general toxicity studies histopathology studies reproductive toxicity studies genotoxicity studies safety pharmacology studies investigative toxicity studies and safety biomarker studies As a volume in the highly successful Methods in Molecular Biology™ series chapters include brief introductions to their respective subjects lists of the necessary materials step by step readily reproducible protocols and tips on troubleshooting and avoiding known pitfalls Comprehensive and authoritative Drug Safety Evaluation Methods and Protocols serves as an ideal guide to this field helpful to pharmaceutical scientists toxicologists biochemists and molecular biologists as well as scientists from all other disciplines who wish to translate these thorough methods into their own work

Drug Safety Evaluation Shayne Cox Gad,Dexter W. Sullivan, Jr.,2023-01-12 Drug Safety Evaluation Comprehensive and practical guide presenting a roadmap for safety assessment as an integral part of the development of drugs and therapeutics This fourth edition of Drug Safety Evaluation maintains the central objective of presenting an all inclusive practical guide for those who are responsible for ensuring the safety of drugs and biologics to patients healthcare providers those involved in the manufacture of medicinal products and all those who need to understand how the safety of these products is evaluated

and shepherding valuable candidates to market Individual chapters address specific approaches to evaluation hazards including problems that are encountered and their solutions Also covered are the scientific and philosophical bases for evaluation of specific concerns e g carcinogenicity development toxicity etc to provide both understanding and guidance for approaching the new problems that have come to face both our society and the new challenges they brought The many changes in regulatory requirements pharmaceutical development technology and the effects of Covid on our society and science have required both extensive revision to every chapter and the addition of four new chapters Specific sample topics covered in Drug Safety Evaluation include The drug development process and the global pharmaceutical marketplace and regulation of human pharmaceutical safety Sources of information for consideration in study and program design and in safety evaluation Electronic records reporting and submission screens in safety and hazard assessment and formulations routes and dosage regimens Mechanisms and endpoints of drug toxicity pilot toxicity testing in drug safety evaluation and repeat dose toxicity Genotoxicity QSAR tools for drug safety toxicogenomics nonrodent animal studies and developmental and reproductive toxicity testing An appendix which provides an up to date guide to CROs for conducting studies Drug Safety Evaluation was written specifically for the pharmaceutical and biotechnology industries including scientists consultants and academics to show a utilitarian yet scientifically valid path to the everyday challenges of safety evaluation and the problem solving that is required in drug discovery and development

Design and Analysis of Clinical Trials Shein-Chung Chow, Jen-Pei Liu, 1998-06-23 A unique unifying treatment for statistics and science in clinical trials What sets this volume apart from the many books dealing with clinical trials is its integration of statistical and clinical disciplines Stressing communication between biostatisticians and clinical scientists this work clearly relates statistical interpretation to clinical issues arising in different stages of pharmaceutical research and development Plus the principles presented here are universal enough to be easily adapted in non biopharmaceutical settings *Design and Analysis of Clinical Trials* tackles concepts and methodologies It not only covers statistical basics such as uncertainty and bias design considerations such as patient selection randomization and the different types of clinical trials but also deals with various methods of data analysis group sequential procedures for interim analysis efficacy data evaluation analysis of safety data and more Throughout the book Surveys current and emerging clinical issues and newly developed statistical methods Presents a critical review of statistical methodologies in various therapeutic areas Features case studies from actual clinical trials Minimizes the mathematics involved making the material widely accessible Offers each chapter as a self contained entity Includes illustrations to highlight the text This monumental reference on all facets of clinical trials is important reading for physicians clinical and medical researchers pharmaceutical scientists clinical programmers biostatisticians and anyone involved in this burgeoning area of clinical research It can also be used as a textbook in graduate level courses in the field

Drug Safety Evaluation Shayne Cox Gad, 2016-11-18 This practical guide presents a road map for safety assessment as an integral part of

the development of new drugs and therapeutics Helps readers solve scientific technical and regulatory issues in preclinical safety assessment and early clinical drug development Explains scientific and philosophical bases for evaluation of specific concerns including local tissue tolerance target organ toxicity and carcinogenicity developmental toxicity immunogenicity and immunotoxicity Covers the development of new small and large molecules generics 505 b 2 route NDAs and biosimilars Revises material to reflect new drug products small synthetic large proteins and cells and tissues harmonized global and national regulations and new technologies for safety evaluation Adds almost 20% new and thoroughly updates existing content from the last edition

Haschek and Rousseaux's Handbook of Toxicologic Pathology, Volume 2: Safety Assessment and Toxicologic Pathology Wanda M. Haschek, Colin G. Rousseaux, Matthew A. Wallig, Brad Bolon, 2023-02-18 Haschek and Rousseaux's Handbook of Toxicologic Pathology recognized by many as the most authoritative single source of information in the field of toxicologic pathology has been extensively updated to continue its comprehensive and timely coverage The fourth edition has been expanded to five separate volumes due to an explosion of information in this field requiring new and updated chapters Completely revised with a number of new chapters Volume 2 Toxicologic Pathology in Safety Assessment is an essential part of the most authoritative reference on toxicologic pathology principles and techniques for assessing product safety and human risk Volume 2 describes the integration of product induced structural and functional changes in tissues and the interpretation of their biological implications Completely revised with many new chapters Volume 2 of the Fourth Edition covers product safety assessment from many angles including current and emerging issues in toxicologic pathology for many product classes Volume 2 of the Handbook of Toxicologic Pathology is a key resource for pathologists toxicologists research scientists and regulators who use toxicologic pathology methods to study and make decisions on product safety Previous chapters on such topics as drug discovery and development toxicity and carcinogenicity testing report preparation and risk assessment and communication have undergone extensive revision that includes in depth discussion of new developments in the field New chapters consider fundamental attributes for additional product classes including protein therapeutics nucleic acid pharmaceutical agents gene therapy and gene editing stem cell and other cell therapies vaccines agricultural and bulk chemicals and assigning adversity Chapters dealing with product specific practices address pathology and regulatory issues Chapters offer high quality and up to date content in a trusted work written by the collaborative efforts of many leading international subject matter experts Hundreds of full color images and diagrams are featured in both the print and electronic versions of this book to illustrate classic examples and highlight difficult concepts

Principles of Scientific Literature Evaluation Frank J. Ascione, 2001 This volume hinges on a structured question based approach to evaluating clinical drug trials the major type of scientific study that practising pharmacists review Growing out of the author's 20 years of teaching the subject to PharmD students the instructional method is well established and effective The book refines and expands upon the scientific literature evaluation section of Principles of Drug Information

and Scientific Literature Evaluation 1994 a textbook co authored by Frank J Ascoine Drug Safety Evaluation Shayne C. Gad,2002-04-18 Covers the scientific and philosophical bases for evaluation of specific concerns such as carcinogenicity and development toxicity *Nonclinical Safety Assessment* William J. Brock,Kenneth L. Hastings,Kathy M. McGown,2013-03-05 Nonclinical Safety Assessment Nonclinical Safety Assessment A Guide to International Pharmaceutical Regulations Bringing a new drug to market is a costly time consuming process Increased regional and international regulation over the last twenty years while necessary has only served to amplify these costs In response to this escalation developmental strategies have shifted towards a more global approach In order to create the most cost effective and safe processes it is critical for those bringing drugs to market to understand both the globally accepted regulations and the local variations Nonclinical Safety Assessment A Guide to International Pharmaceutical Regulations provides a practical description of nonclinical drug development regulations and requirements in the major market regions It includes ICH the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use National regulations including US FDA Canada Mercosur and Brazil South Africa China Japan India and Australia Repeated dose toxicity studies Carcinogenicity Genotoxicity Developmental and reproductive toxicology Immunotoxicology Biotechnology derived pharmaceuticals Vaccine development Phototoxicity and photocarcinogenicity Degradants impurities excipients and metabolites Primarily intended for those professionals actively involved in the nonclinical and clinical development of a pharmaceutical product including toxicologists pharmacologists clinicians and project managers this book provides a roadmap for successful new drug approval and marketing Challenges for the FDA Institute of Medicine,Board on Health Sciences Policy,Forum on Drug Discovery, Development, and Translation,2007-10-02 As the principal agency regulating food drugs medical devices and biological products used by Americans the U S Food and Drug Administration FDA serves one of the most critical consumer protection functions of the federal government The FDA s reach is enormous regulating products that represent roughly 25 percent of all consumer spending in the United States Since 1992 however federal funding for the agency has diminished and the FDA s Center for Drug Evaluation and Research CDER currently relies on the fees it receives from the industry it regulates to fund the majority of its drug regulation functions Prescription drug safety is receiving heightened press coverage and congressional scrutiny as a result of recent highly publicized events such as the recall of Vioxx because of its link to heart attacks and the link between certain antidepressants selective serotonin reuptake inhibitors or SSRIs and an increased risk of suicidal ideation in children To address these concerns the FDA in 2005 commissioned the Institute of Medicine IOM to conduct an independent assessment of the current U S drug safety system In September 2006 the IOM committee released its report The Future of Drug Safety Promoting and Protecting the Health of the Public which included 25 recommendations for improving the system for drug safety review The committee identified four major vulnerabilities in the U S drug safety system 1 chronic underfunding 2 organization problems particularly inadequate

integration of pre and postmarket data review 3 a range of technical problems related to the insufficient quantity and quality of postmarket data and inadequate capability to systematically monitor the risks and benefits of drugs after marketing and 4 unclear regulatory authority and insufficiently flexible regulatory tools Since the IOM report was issued the FDA has taken a number of steps toward implementing the recommended improvements Like many government agencies however the FDA is financially strained by its existing responsibilities and fully implementing the recommended improvements to the drug safety system would require significant financial commitments The IOM report addressed some of the costs associated with its recommendations but left many unanswered questions about the resources required to fully achieve the envisioned improvements To better understand the types and magnitude of resources required to achieve the goals of the IOM report the IOM's Forum on Drug Discovery Development and Translation convened a 1 day symposium in March 2007 Challenges for the FDA The Future of Drug Safety Workshop Summary explains the presentations and discussions in seven key areas addressing the FDA's resource challenges strengthening the scientific base of the agency integrating pre and postmarket review enhancing postmarket safety monitoring conducting confirmatory drug safety and efficacy studies enhancing the value of clinical trial registration and enhancing the FDA's postmarket regulation and enforcement

The Future of Drug Safety Institute of Medicine, Board on Population Health and Public Health Practice, Committee on the Assessment of the US Drug Safety System, 2007-03-27 In the wake of publicity and congressional attention to drug safety issues the Food and Drug Administration FDA requested the Institute of Medicine assess the drug safety system The committee reported that a lack of clear regulatory authority chronic underfunding organizational problems and a scarcity of post approval data about drugs risks and benefits have hampered the FDA's ability to evaluate and address the safety of prescription drugs after they have reached the market Noting that resources and therefore efforts to monitor medications risk benefit profiles taper off after approval The Future of Drug Safety offers a broad set of recommendations to ensure that consideration of safety extends from before product approval through the entire time the product is marketed and used

Proceedings of the Biometrics Section American Statistical Association. Biometrics Section, 1999

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

Drug Surveillance Zbigniew Bańkowski, John F. Dunne, 1994 Records the proceedings of an international conference convened to consider mechanisms for improving international cooperation in the surveillance of drug safety and the reporting of adverse reactions Attended by close to 200 representatives of regulatory authorities and the pharmaceutical industry as well as clinical pharmacologists the conference aimed to identify the strengths and weaknesses of existing mechanisms for international cooperation and to propose improvements for the future

Guide to Clinical Studies and Developing Protocols Bert Spilker, 1984

Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society IEEE Engineering in Medicine and Biology Society. Annual Conference, 1993

Drug Safety Assessment In Clinical Trials Book Review: Unveiling the Power of Words

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